DRAFT
INTERNATIONAL
STANDARD

IEC 60601-1

THIRD EDITION

Medical electrical equipment

Part 1:
General requirements for safety and essential performance

Committee Draft for Vote (1CDV)[1]

62A/389/CDV

International Electrotechnical Commission 3, rue de Varembé Genève, Switzerland

INTRODUCTION TO THE COMMITTEE DRAFT FOR VOTE
(not a part of the CDV)

The first Committee Draft (1CD) of the third edition of IEC 60601-1 was circulated to national Committees as document 62A/281/CD on 28 May 1999. A second Committee Draft (2CD) was circulated as document 62A/321/CD on 24 November 2000. The working groups of Subcommittee 62A have now analysed and responded to a total 4 292 comments and this Committee Draft for Vote (CDV) reflects the range of important recommendations received.

As with the previous CDs, the working groups have included a number of editing notes to explain some of the changes between 2CD and this CDV. These editing notes will not form part of the published standard. National Committees are encouraged to refer to these notes when reviewing the document. In a few places, there are Box Notes intended to draw the reader's attention to the rationale or other information that should assist in reviewing the requirement. These Box Notes will not form part of the published standard.

National Committees that approve of this document should generally limit comments to recommendations for editorial improvements. National Committees making recommendations that would result in substantive changes to technical requirements could be expected to vote against adoption of this document.

The Chairman and Secretary again express their appreciation to the working group conveners and the expert members of these working groups for their diligence during the preparation of this document. We look forward to the response from National Committees.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

_____

Medical electrical equipment

Part 1: General requirements for safety and essential performance

FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, the IEC publishes International Standards. Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.

2) The formal decisions or agreements of the IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested National Committees.

3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical reports or guides and they are accepted by the National Committees in that sense.

4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.

5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.

6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 60601-1 has been prepared by subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this standard is based on the following documents:

FDIS	Report on voting
62A/xxx/FDIS	62A/XXX/RVD

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table.

This Standard follows the ISO/IEC Directives, Part 2 *Rules for the structure and drafting of International standards*. In addition the following editorial conventions have been used:

Requirements and definitions: in roman type.

Informative material appearing outside of tables, such as notes, explanations, advice, introduction to clauses and subclauses, general statements, exceptions and references: in smaller type. Normative text of tables is also in a smaller type.

Test specifications: in italic type.

TERMS USED THROUGHOUT THIS STANDARD THAT HAVE BEEN DEFINED IN CLAUSE 3 AND ALSO GIVEN IN THE INDEX: IN SMALL CAPITALS.

In referring to the structure of this standard, the term:

– “clause” means one of the eighteen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);

– “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this standard are by number only.

The verbal forms used in this standard conform to usage described in Annex G of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

“shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;

“should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

“may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph indicates that there is guidance or rationale related to that item in Annex A.

INTRODUCTION

In 1976, IEC sub-committee 62A published the first edition of IEC/TR 60513, *Basic aspects of the safety philosophy for electrical equipment used in medical practice*. The first edition of IEC/TR 60513 provided the basis for developing:

– the first edition of IEC 60601-1 (the parent safety standard for medical electrical equipment);

– the IEC 60601-1-xx series of collateral standards for medical electrical equipment;

– the IEC 60601-2-xx series of particular standards for particular types of medical electrical equipment; and

– the IEC 60601-3-xx series of performance standards for particular types of medical electrical equipment.

Aware of the need and the urgency for a standard covering electrical equipment used in medical practice, the majority of National Committees voted in 1977 in favour of the first edition of IEC 60601-1, based on a draft that at the time represented a first approach to the problem. The extent of the scope, the complexity of the equipment concerned, and the specific nature of some of the protective measures and the corresponding tests for verifying them, required years of effort in order to prepare this first standard, which can now be said to have served as a universal reference since its publication.

However, the frequent application of the first edition revealed room for improvement. These improvements were all the more desirable in view of the considerable success that this standard has enjoyed since its publication.

The careful work of revision subsequently undertaken and continued over a number of years resulted in the publication of the second edition in 1988. This edition incorporated all the improvements that could be reasonably expected up to that time. Further developments remained under constant study. The second edition was amended in 1991 and then again in 1995.

The original IEC approach was to prepare separate “safety” and “performance” standards for medical electrical equipment. This was a natural extension of the historical approach taken at the national and international level with other electrical equipment standards (e.g. those for domestic equipment), where basic physical safety is regulated through mandatory standards but other “performance” specifications are regulated by market pressure. In this context, it has been said that, “The ability of an electric kettle to boil water is not critical to its safe use!”

It is now recognized that this is not the situation with many items of medical electrical equipment, and responsible organizations have to depend on standards to ensure essential performance as well as basic safety. Such areas include the accuracy with which the equipment controls the delivery of energy or therapeutic substances to the patient, or processes and displays physiological data that will affect patient management. Medical authorities are equally concerned about the ability of the equipment to perform correctly and the prevention of other hazards.

This recognition means that separating “safety” and “performance” is somewhat inappropriate in addressing the hazards that result from inadequate design of medical electrical equipment. Many particular standards in the IEC 60601-2-xx series address a range of essential performance requirements that cannot be directly evaluated by the responsible organization without applying such standards. (However, the current IEC 60601 series includes fewer requirements for functional safety than for basic safety).

There is also a growing suggestion that all the safety and essential performance requirements for medical electrical equipment should be found within one set of international standards. The European Directive on medical devices also highlights the need for a single series of standards covering essential requirements for all such products.

In anticipation of a third edition of IEC 60601-1, IEC sub-committee 62A prepared a second edition of IEC/TR 60513 in 1994. It was intended that the second edition of IEC/TR 60513 would provide guidance for developing the third edition of IEC 60601-1, and for the further development of the IEC 60601-1-xx and IEC 60601-2-xx series.

In order to achieve consistency in international standards, address present expectations in the health care community and align with developments in IEC 60601-2-xx, the second edition of IEC/TR This standard contains requirements concerning safety and essential performance that are generally applicable to medical electrical equipment. For certain types of medical electrical equipment, these requirements are supplemented or modified by the special requirements of a particular or collateral standard. Where particular standards exist, this standard should not be used alone. In all cases, the risk management process will determine whether the requirements of this standard are appropriate and acceptable.

IEC/TR 60513 includes two major new principles:

– the first change is that the concept of “safety” has been broadened from the simple, basic safety considerations in the first and second editions of IEC 60601-1 to include essential performance matters, (e.g. the accuracy of physiological monitoring equipment). Application of this principle leads to the change of the title from “Medical electrical equipment, Part 1: General requirements for safety” in the second edition, to “Medical electrical equipment, Part 1: General requirements for safety and essential performance”,

– the second change is that in specifying minimum safety requirements, provision is made for assessing the adequacy of the design process where this provides an appropriate alternative to the application of laboratory testing with specific pass/fail criteria, (e.g. in assessing the safety of new technologies such as programmable electronic systems). Application of this principle leads to the introduction of a general requirement to carry out a risk management process as part of demonstrating compliance with this standard.

1. Scope, object and related standards

1.1 *Scope

This International Standard applies to the SAFETY and ESSENTIAL PERFORMANCE of ME EQUIPMENT (as defined in 3.63) and ME SYSTEMS (as defined in 3.64).

HAZARDS inherent in the intended physiological function of ME EQUIPMENT covered by this standard are not considered.

This standard does not apply to *in vitro* diagnostic equipment covered by the IEC 61010 series or to the implantable parts of active implantable medical devices covered by the ISO 14708 series.

1.2 Object

The object of this standard is to specify general requirements and to serve as the basis for particular standards.

1.3 *Particular standards

In the IEC 60601 series, particular standards may add, modify, replace or delete requirements contained in this standard as appropriate for the particular ME EQUIPMENT under consideration, and may add other SAFETY and ESSENTIAL PERFORMANCE requirements where these could reduce an otherwise unacceptable RISK.

A requirement of a particular standard takes priority over this standard.

1.4 Collateral standards

In the IEC 60601 series, collateral standards specify general requirements for SAFETY and ESSENTIAL PERFORMANCE applicable to:

– a group of ME EQUIPMENT (e.g. radiological equipment);

– a specific characteristic of all ME EQUIPMENT not fully addressed in this standard.

If a collateral standard applies to ME EQUIPMENT for which a particular standard exists, then the particular standard takes priority over the collateral standard.

2. Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of IEC and ISO maintain registers of currently valid International Standards.

Informative references are listed in the bibliography on page 327.

IEC 60065: 2001, *Audio, video and similar electronic apparatus – Safety requirements*

IEC 60068-2-2: 1974, *Environmental testing procedures – Part 2: Tests. Test B, Dry heat*, incorporating Amendment No. 1 (1993) and Amendment No. 2 (1994)

IEC 60079-0 – Consol. Ed. 3.1: 2000, *Electrical apparatus for explosive gas atmospheres – Part 0: General requirements*

IEC 60079-2: 2001, *Electrical apparatus for explosive gas atmospheres – Part 2: Pressurized enclosures "p"*

IEC 60079-5: 1997, *Electrical apparatus for explosive gas atmospheres – Part 5: Powder filling "q"*

IEC 60079-6: 1995, *Electrical apparatus for explosive gas atmospheres – Part 6: Oil-immersion "o"*

IEC/TR3 60083: 1997, *Plugs and socket-outlets for domestic and similar general use standardized in member countries of IEC*

IEC 60085: 1984, *Thermal evaluation and classification of electrical insulation*

IEC 60086-4: 2000, *Primary batteries – Part 4: Safety of lithium batteries*

IEC 60112: 1979, *Method for determining the comparative and the proof tracking indices of solid insulating materials under moist conditions*

IEC 60127-1: Consol. Ed. 1.1: 1999: *Miniature fuses - Part 1: Definitions for miniature fuses and general requirements for miniature fuse-links*

IEC 60227-1 – Consol. Ed. 2.2: 1998, *Polyvinyl chloride insulated cables of rated voltages up to and including 450/750 V – Part 1: General requirements*

IEC 60245-1 – Consol. Ed. 3.2: 1998, *Rubber insulated cables – Rated voltages up to and including 450/750 V – Part 1: General requirements*

IEC 60252-1: 2001, *AC motor capacitors – Part 1: General – Performance, testing and rating – Safety requirements – Guide for installation and operation*

IEC 60320-1: 2001, *Appliance couplers for household and similar general purposes – Part 1: General requirements*

IEC 60335-1: 2001, *Household and similar electrical appliances – Safety – Part 1: General requirements*

IEC 60364-4-41: 2001, *Electrical installations of buildings, Part 4-41: Protection for safety – Protection against electric shock*

IEC 60384-14: 1993, *Fixed capacitors for use in electronic equipment - Part 14: Sectional specification: Fixed capacitors for electromagnetic interference suppression and connection to the supply mains*, incorporating Amendment No. 1 (1995)

IEC 60417-1, *Graphical symbols for use on equipment – Part 1: Overview and application*

IEC 60417-2, *Graphical symbols for use on equipment – Part 2: Symbol originals*

IEC 60445: 1999, *Basic and safety principles for man-machine interface, marking and identification – Identification of equipment terminals and of terminations of certain designated conductors, including general rules for an alphanumeric system*

IEC 60447: 1993*, Man-machine-interface (MMI) - Actuating principles*

IEC 60529 – Consol. Ed. 2.1, *Degrees of protection provided by enclosures (IP Code)*

IEC 60601-1-2, *Medical electrical equipment – Part 1-2: General requirements for safety – Collateral Standard: Electromagnetic compatibility - Requirements and tests*

IEC 60601-1-3*, Medical electrical equipment – Part 1: General requirements for safety – 3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment*

IEC 60651, *Sound level meters*

IEC 60707: 1999, *Flammability of solid non-metallic materials when exposed to flame sources – List of test methods*

IEC 60730-1: 1999, *Automatic electrical controls for household and similar use – Part 1: General requirements*

IEC 60804: 2000, *Integrating-average sound level meters*

IEC 60825-1 – Consol. Ed. 1.2: 2001, *Safety of laser products – Part 1: Equipment classification, requirements and user's guide*

IEC 60825-2: 2000, *Safety of laser products - Part 2: Safety of optical fibre communication systems*

IEC 60884-1: 1994, *Plugs and socket-outlets for household and similar purposes - Part 1: General requirements,* incorporating Amendment No. 1 (1994) and Amendment No. 2 (1995)

IEC 60950-1: 2001, *Information technology equipment – Safety – Part 1: General requirements*

IEC 60989: 1991, *Separating transformers, autotransformers, variable transformers and reactors*

IEC 61058-1 – Consol. Ed. 3.1: 2001*, Switches for appliances - Part 1: General requirements*

IEC 61558-1 – Consol. Ed. 1.1: 1998, *Safety of power transformers, power supply units and similar – Part 1: General requirements and tests*

ISO 32: 1977, *Gas cylinders for medical use – Marking for identification of content*

ISO 407: 1991, *Small medical gas cylinders – Pin-index yoke-type valve connections*

ISO 471: 1995, *Rubber – Temperatures, humidities and times for conditioning and testing*

ISO 780: 1997, *Packaging – Pictorial marking for handling of goods*

ISO 1000: 1992, *SI units and recommendations for the use of their multiples and of certain other units* incorporating Amendment No. 1 (1998)

ISO 1853: 1998, *Conducting and dissipative rubbers, vulcanized or thermoplastic – Measurement of resistivity*

ISO 2878: 1987, *Rubber, vulcanized – Antistatic and conductive products – Determination of electrical resistance*

ISO 2882: 1979, *Rubber, vulcanized – Antistatic and conductive products for hospital use – Electrical resistance limits*

ISO 3746: 1995, *Acoustics – Determination of sound power levels of noise sources using sound pressure survey method using an enveloping measurement surface over a reflecting plane*

ISO\FDIS 3864-1: 200x, *Graphical symbols – Safety colours and safety signs – Part 1: Design principles for safely signs in work places and public areas*

ISO 5349-1: 2001, *Mechanical vibration – Measurement and evaluation of human exposure to hand-transmitted vibration – Part 1: General requirements*

ISO 7000, *Graphical symbols for use on equipment – Index and synopsis*

ISO/DIS 7010, *Graphical symbols – Safety signs in work places and public areas*

ISO 8185: 1997, *Humidifiers for medical use – General requirements for humidification systems*

ISO 9614-1: 1993, *Acoustics – Determination of sound power levels of noise sources using sound intensity – Measurement at discrete points*

ISO 10993-1: 1997*, Biological evaluation of medical devices – Part 1: Evaluation and testing*

ISO 11134: 1994, *Sterilization of health care products – Requirements for validation and routine control – Industrial moist heat sterilization*

ISO 11135: 1994, *Medical devices – Validation and routine control of ethylene oxide sterilization*

ISO 11137: 1995, *Sterilization of health care products – Requirements for validation and routine control – Radiation sterilization* including Amendment No. 1 (2001)

ISO 11469: 2000, *Plastics – Generic identification and marking of plastic products*

ISO 13852: 1996, *Safety of machinery – Safety distances to prevent danger zones being reached by the upper limbs*

ISO 14971: 2000, *Medical devices – Application of risk management to medical devices*

ISO 15223, *Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied*

3. Terminology and definitions[1)]

For the purpose of this standard, where the terms “voltage” and “current” are used, they mean the r.m.s. values of an alternating, direct or composite voltage or current unless stated otherwise.

This standard uses the term “equipment” to mean ME EQUIPMENT (see 3.63) or other non-ME EQUIPMENT in the context of an ME SYSTEM (see 3.64). The term “electrical equipment” is used to mean ME EQUIPMENT or other electrical equipment.

3.1
ACCESS COVER

Part of an ENCLOSURE or GUARD providing the possibility of access to electrical equipment parts for the purpose of adjustment, inspection, replacement or repair.

3.2
ACCESSIBLE PART

Part of electrical equipment that can be touched without the use of a TOOL. See also 5.9.

3.3
ACCESSORY

Additional component for use with equipment in order to:

– perform its INTENDED USE/INTENDED PURPOSE,

– adapt it to some special use,

– facilitate its use,

– enhance its performance,

– enable its functions to be integrated with those of other equipment.

NOTE Adapted from IEC 60788.

[1)] An index of the defined terms is found beginning on page 334.

3.4
ACCOMPANYING DOCUMENT

Document accompanying an ME SYSTEM, an equipment or an ACCESSORY and containing important information for the RESPONSIBLE ORGANIZATION, OPERATOR, or SERVICE PERSONNEL, particularly regarding SAFETY.

3.5
AIR CLEARANCE

Shortest path in air between two conductive parts.

3.6
APPLIANCE COUPLER

Means enabling the connection of a flexible cord to electrical equipment without the use of a TOOL, consisting of two parts: a MAINS CONNECTOR and an APPLIANCE INLET (see Figure 1).

3.7
APPLIANCE INLET

Part of an APPLIANCE COUPLER either integrated in or FIXED to equipment (see Figure 1 and Figure 2).

3.8
APPLIED PART

Part of ME EQUIPMENT that in NORMAL USE necessarily comes into physical contact with the PATIENT for the ME EQUIPMENT or an ME SYSTEM to perform its function (see Figure 3, Figure 4 and Figure A1 to Figure A5).

NOTE 1 See also 4.4 regarding the treatment of parts that do not fall within the definition of APPLIED PARTS but need to be treated as APPLIED PARTS as a result of applying the RISK MANAGEMENT PROCESS.

NOTE 2 See also 3.79 for the definition of the associated term PATIENT CONNECTION.[2]

3.9
***BASIC INSULATION**

Insulation providing basic protection against electric shock.

[IEV 826-03-17]

NOTE BASIC INSULATION provides one MEANS OF PROTECTION.

3.10
CATEGORY AP [3]

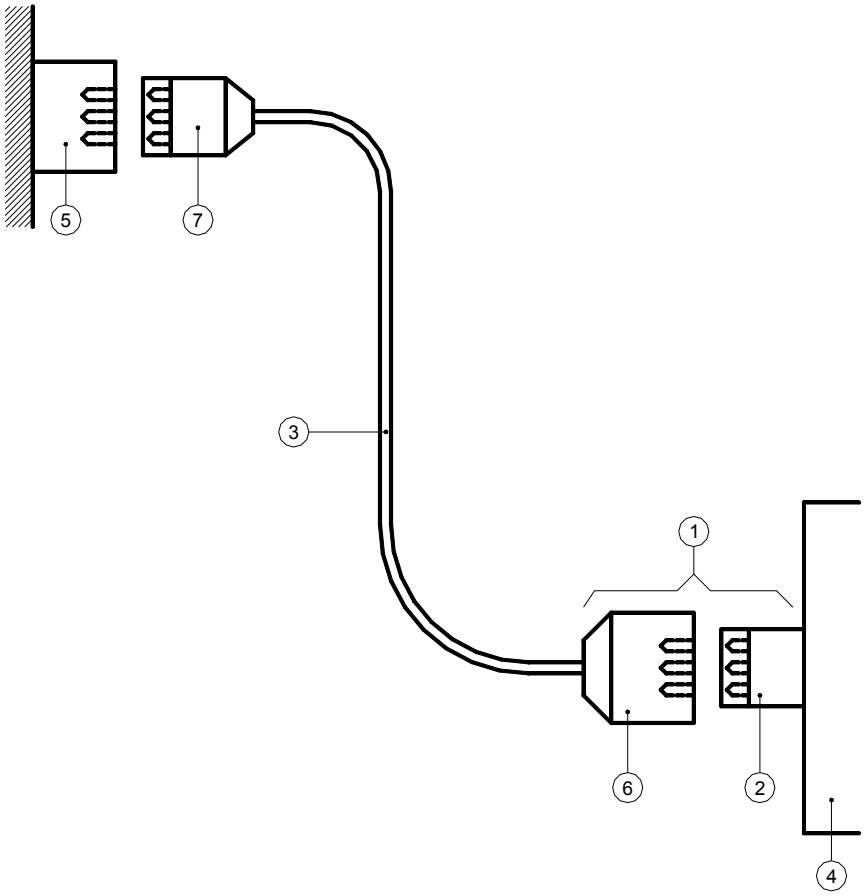
Rating for ME EQUIPMENT or ME EQUIPMENT part complying with specified requirements on construction, marking and documentation in order to avoid sources of ignition in a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR.

3.11
CATEGORY APG

Rating for ME EQUIPMENT or ME EQUIPMENT part complying with specified requirements on construction, marking and documentation in order to avoid sources of ignition in a FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE.

3.12
CLASS I

Adjective referring to electrical equipment in which protection against electric shock does not rely on BASIC INSULATION only, but which includes an additional safety precaution in that means are provided for ACCESSIBLE PARTS of metal or internal parts of metal to be PROTECTIVELY EARTHED (see Figure 3).



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1 APPLIANCE COUPLER

2 APPLIANCE INLET

3 DETACHABLE POWER SUPPLY CORD

4 ME EQUIPMENT

5 FIXED mains socket-outlet

6 MAINS CONNECTOR

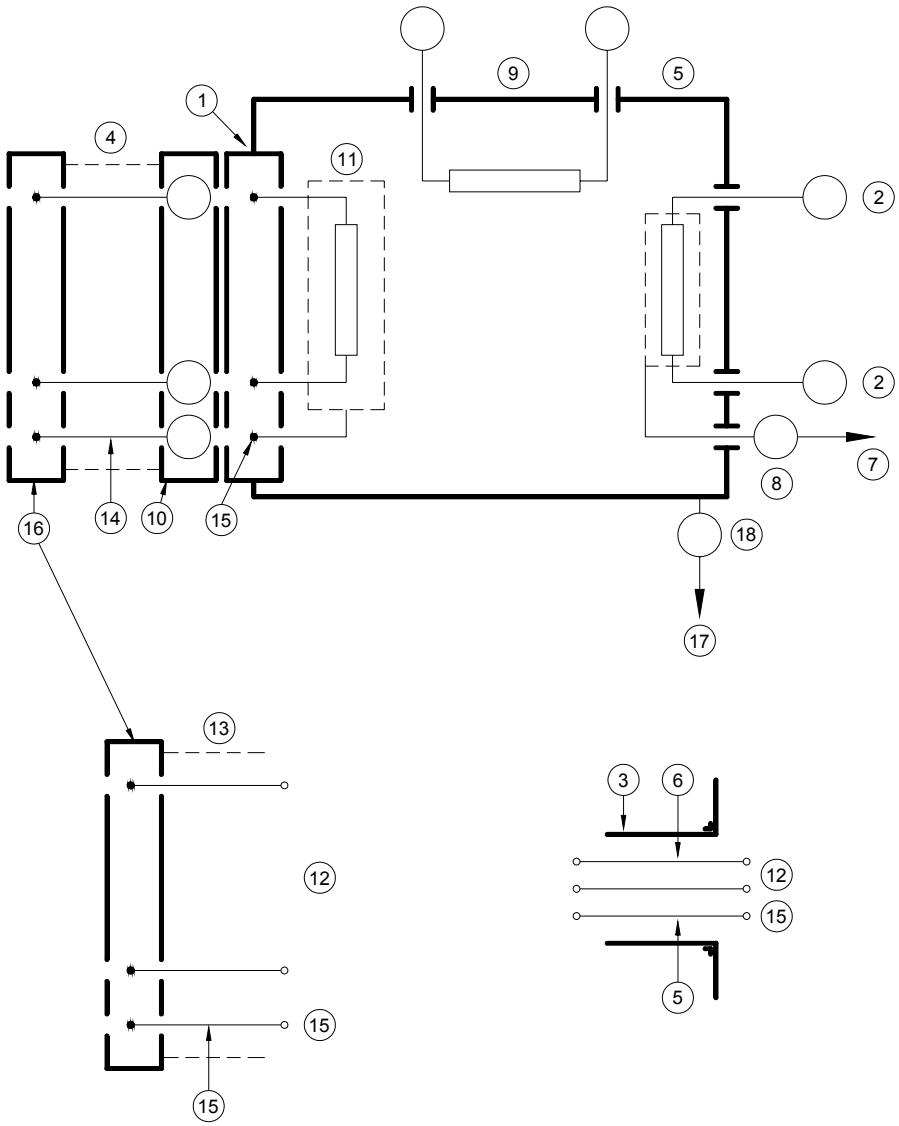
7 MAINS PLUG

344 **Figure 1 – Detachable mains connection**
345 **(see 3.6)**

346 **3.13**
347 **CLASS II**

348 Adjective referring to electrical equipment in which protection against electric shock does not
349 rely on BASIC INSULATION only, but in which additional safety precautions such as DOUBLE
350 INSULATION or REINFORCED INSULATION are provided, there being no provision for protective
351 earthing or reliance upon installation conditions (see Figure 4).

352 NOTE CLASS II equipment may be provided with a FUNCTIONAL EARTH TERMINAL or a FUNCTIONAL EARTH
353 CONDUCTOR. See also 8.6.8 and 8.6.9.



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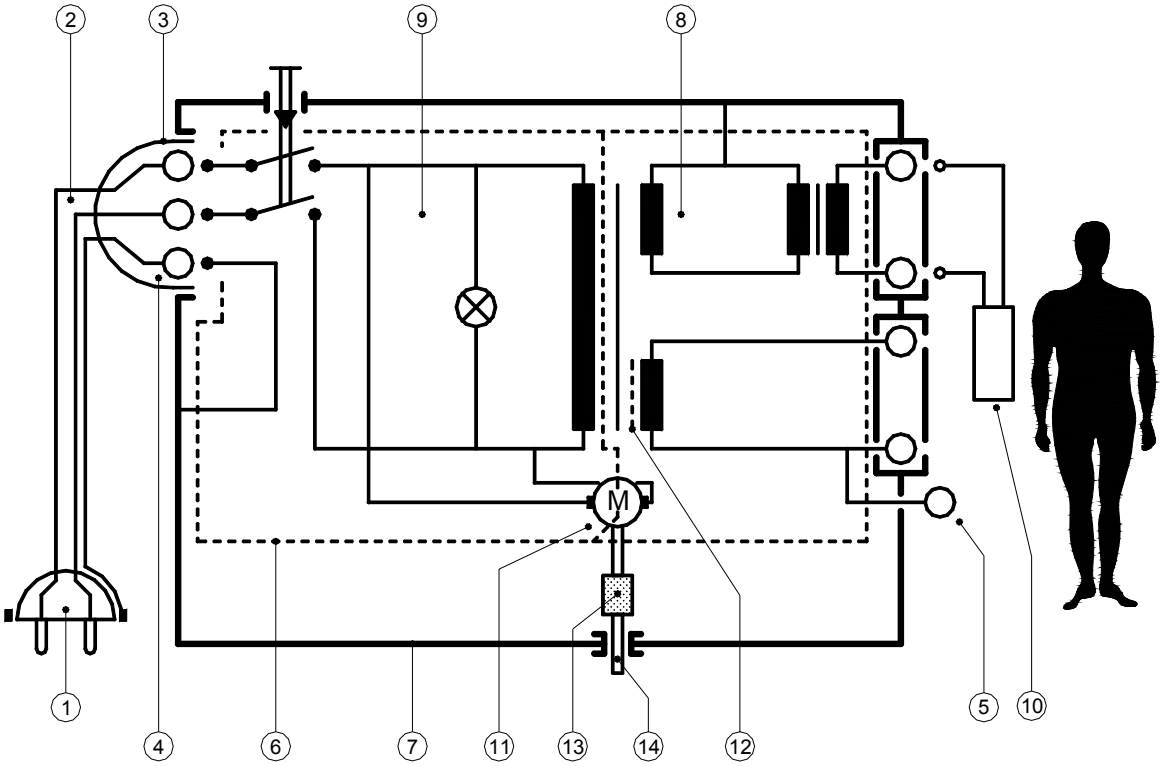
1	APPLIANCE INLET (see also Figure 1)	11	MAINS PART
2	PATIENT CONNECTION	12	MAINS TERMINAL DEVICE
3	Conduit	13	POWER SUPPLY CORD
4	DETACHABLE POWER SUPPLY CORD	14	PROTECTIVE EARTH CONDUCTOR
5	ENCLOSURE	15	PROTECTIVE EARTH TERMINAL
6	FIXED wiring	16	MAINS PLUG
7	FUNCTIONAL EARTH CONDUCTOR	17	POTENTIAL EQUALIZATION CONDUCTOR
8	FUNCTIONAL EARTH TERMINAL	18	Terminal for the connection of a POTENTIAL EQUALIZATION CONDUCTOR
9	SIGNAL INPUT/OUTPUT PART		
10	MAINS CONNECTOR		

355 **Figure 2 – Example of the defined terminals and conductors**
356 **(see 3.7)**



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1 Plug with protective earth contact

2 DETACHABLE POWER SUPPLY CORD

3 APPLIANCE COUPLER

4 Protective earth contact and pin

5 FUNCTIONAL EARTH TERMINAL

6 BASIC INSULATION

7 ENCLOSURE

8 Intermediate circuit

9 MAINS PART

10 APPLIED PART

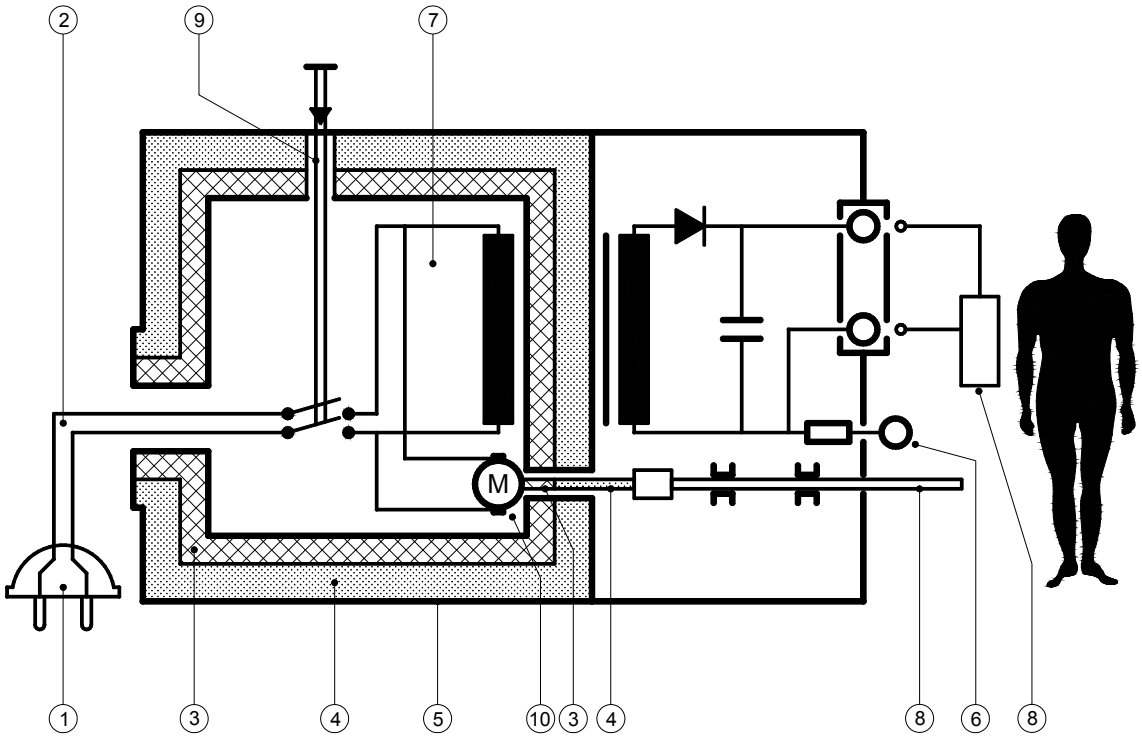
11 Motor

12 PROTECTIVELY EARTHED screen

13 SUPPLEMENTARY INSULATION

14 Shaft that is an ACCESSIBLE PART

358 **Figure 3 – Example of a CLASS I ME EQUIPMENT**
359 **(see 3.12)**



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1 MAINS PLUG
2 POWER SUPPLY CORD
3 BASIC INSULATION
4 SUPPLEMENTARY INSULATION
5 ENCLOSURE
6 FUNCTIONAL EARTH TERMINAL
7 MAINS PART
8 APPLIED PART
9 REINFORCED INSULATION
10 Motor

361 **Figure 4 – Example of a metal-enclosed CLASS II ME EQUIPMENT**
362 **(see 3.13)[4]**

363 **3.14**
364 **CLEARLY LEGIBLE**

365 Capable of being read by the OPERATOR or other relevant person with normal vision. See also
366 7.1.2.

3.15
COLD CONDITION

Condition obtained if electrical equipment is de-energized for a sufficiently long time to attain the ambient temperature.

3.16
***CONTINUOUS OPERATION**

Operation under normal load for an unlimited period without the specified limits of temperature being exceeded.

3.17
CREEPAGE DISTANCE

Shortest distance along the surface of the insulating material between two conductive parts.

[IEV 151-03-37]

3.18
***DEFIBRILLATION-PROOF APPLIED PART**

APPLIED PART having protection against the effects of a discharge of a cardiac defibrillator to the PATIENT.

3.19
***DETACHABLE POWER SUPPLY CORD**

Flexible cord intended to be connected to electrical equipment by means of a suitable APPLIANCE COUPLER for mains supply purposes (see Figure 1, Figure 2 and Figure 3).

3.20
DEVELOPMENT LIFE-CYCLE

Necessary activities occurring during a period of time that starts at the concept phase of a project and finishes when the PEMS VALIDATION is complete.

3.21
***DIRECT CARDIAC APPLICATION**

Use of APPLIED PART that may come in direct contact with the PATIENT'S heart.

3.22
DISPOSABLE

Any material, component, ACCESSORY or ME EQUIPMENT that is intended for one time operation.

3.23
***DOUBLE INSULATION**

Insulation comprising both BASIC INSULATION and SUPPLEMENTARY INSULATION.

[IEV 195-06-08]

NOTE DOUBLE INSULATION provides two MEANS OF PROTECTION.

3.24
DUTY CYCLE

Maximum activation (on) time followed by minimum deactivation (off) time necessary for the safe operation of the ME EQUIPMENT.[5]

3.25
EARTH LEAKAGE CURRENT

Current flowing from the MAINS PART through or across the insulation into the PROTECTIVE EARTH CONDUCTOR.[6]

3.26
***ENCLOSURE**

Exterior surface of electrical equipment or parts thereof.[7]

NOTE For the purpose of testing to this standard, metal foil, with specified dimensions, applied in contact with parts of the exterior surface made of material with low conductivity or made of insulating material is considered a part of the ENCLOSURE (see Figure 2, Figure 3 and Figure 4).

3.27
ENVIRONMENTAL IMPACT

Consequences for human health, for the well being of flora and fauna or for the future availability of natural resources, attributable to the input and output streams of a system.

[IEC Guide 109]

3.28
***ESSENTIAL PERFORMANCE**

Performance characteristics necessary to maintain the RESIDUAL RISK within acceptable limits.

3.29
F-TYPE ISOLATED (FLOATING) APPLIED PART (hereinafter referred to as F-TYPE APPLIED PART)

APPLIED PART in which the PATIENT CONNECTIONS are isolated from other parts of the ME EQUIPMENT to such a degree that no current higher than the allowable[8] PATIENT LEAKAGE CURRENT flows if an unintended voltage originating from an external source is connected to the PATIENT, and thereby applied between the PATIENT CONNECTION and earth.

F-TYPE APPLIED PARTS are either TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS.[9]

3.30
FIXED

Adjective meaning fastened or otherwise secured at a specific location either permanently or so it can only be detached by means of a TOOL.

EXAMPLE 1 PERMANENTLY AFFIXED by welding, etc.

EXAMPLE 2 Affixed by means of fasteners (screws, nuts, etc.) making removal/opening impossible without using a TOOL.[10] [11]

3.31
FLAMMABLE ANAESTHETIC MIXTURE WITH AIR [12]

Mixture of a flammable anaesthetic vapour with air in such a concentration that ignition may occur under specified conditions. A mixture of the vapour of a flammable disinfection or cleaning agent with air may be treated as a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR subject to national or local regulations.

3.32
FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE

Mixture of a flammable anaesthetic vapour with oxygen or with nitrous oxide in such a concentration that ignition may occur under specified conditions.

3.33
***FUNCTIONAL CONNECTION**

Connection, electrical or otherwise, including those intended to transfer signals, power or substances.

3.34
***FUNCTIONAL EARTH CONDUCTOR**

Conductor to be connected to a FUNCTIONAL EARTH TERMINAL (see Figure 2).

3.35
***FUNCTIONAL EARTH TERMINAL**

Terminal, directly connected to a circuit or to a screening part, that is intended to be earthed for functional purposes (see Figure 2, Figure 3 and Figure 4).

3.36
GUARD

Part of equipment specifically used to provide protection by means of a physical barrier. Depending on its construction, a GUARD may be called casing, cover, screen, door, enclosing guard, etc. A GUARD may act:

– alone; it is then only effective when it is in place;

– in conjunction with an interlocking device with or without guard locking; in this case, protection is ensured whatever the position of the GUARD.

3.37
HAND-HELD

Adjective referring to electrical equipment intended to be supported by the hand during NORMAL USE.

3.38
***HARM**[13]

Physical injury or damage to the health of people or animals, or damage to property or the NATURAL ENVIRONMENT.

NOTE Adapted from ISO 14971: 2000.

3.39
HAZARD

Potential source of HARM.

[ISO 14971: 2000]

3.40
HAZARDOUS SUBSTANCES AND MATERIALS

Substances or materials (solid, liquid or gas) used in quantities in ME EQUIPMENT that are HAZARDS to the health of human beings and animals. The effects can be toxic, carcinogenic, mutagenic, teratogenic, reproductive, hormonogenic and allergenic.

3.41
HIGH-INTEGRITY COMPONENT

A component that is regarded as fault-free in relation to the safety requirements of this standard during the useful life of the ME EQUIPMENT in NORMAL USE and REASONABLY FORESEEABLE MISUSE.

3.42
HIGH VOLTAGE

Any voltage over 1 000 V a.c. or over 1 500 V d.c. or over 1 500 V peak value.

3.43
HYDRAULIC TEST PRESSURE

PRESSURE applied to test a vessel or part of it for compliance with 9.7.3.

3.44
INTENDED USE/INTENDED PURPOSE

Use of a product, PROCESS or service in accordance with the specifications, instructions and information provided by the MANUFACTURER.

[ISO 14971: 2000]

3.45
INTERNAL ELECTRICAL POWER SOURCE

Electrical power source for operating equipment that is a part of the equipment and which produces electrical current from some other form of energy (such as chemical, mechanical, solar, or nuclear).

NOTE: An INTERNAL ELECTRICAL POWER SOURCE may be inside the principal part of equipment, attached to the outside, or contained in a separate ENCLOSURE.

3.46
INTERNALLY POWERED

Adjective referring to electrical equipment, which is able to operate from an INTERNAL ELECTRICAL POWER SOURCE.

3.47
LEAKAGE CURRENT

Current that is not functional. The following LEAKAGE CURRENTS are defined: EARTH LEAKAGE CURRENT, TOUCH CURRENT and PATIENT LEAKAGE CURRENT.[14]

3.48
MAINS CONNECTOR

Part of an APPLIANCE COUPLER integral with or intended to be attached to a flexible cord that is intended to be connected to the SUPPLY MAINS.

NOTE A MAINS CONNECTOR is intended to be inserted into the APPLIANCE INLET of equipment (see Figure 1 and Figure 2).

3.49
***MAINS PART**

Electrical circuit that is intended to be connected to the SUPPLY MAINS. The MAINS PART includes all conductive parts that are not separated from the SUPPLY MAINS by at least one MEANS OF PROTECTION.

NOTE For the purpose of this definition, the PROTECTIVE EARTH CONDUCTOR is not regarded as a part of the MAINS PART (see Figure 2, Figure 3 and Figure 4).

3.50
***MAINS PLUG**

Part, integral with or intended to be attached to a POWER SUPPLY CORD of ELECTRICAL EQUIPMENT, to be inserted into a mains socket-outlet installed in a FIXED wiring system in a building or a vehicle (see Figure 1).

3.51
MAINS SUPPLY TRANSFORMER

A static piece of apparatus with two or more windings which, by electro-magnetic induction, transforms a system of alternating voltage and current from a SUPPLY MAINS into another system of voltage and current usually of different values at the same frequency.

3.52
MAINS TERMINAL DEVICE

TERMINAL DEVICE by which the electrical connection to the SUPPLY MAINS is made (see Figure 2).

3.53
MAINS VOLTAGE

Voltage of a SUPPLY MAINS between two line conductors of a polyphase system or voltage between the line conductor and the neutral conductor of a single-phase system.

3.54
MANUFACTURER

Natural or legal person with responsibility for the design, manufacture, packaging, marking or ACCOMPANYING DOCUMENTS[15] of ME EQUIPMENT, assembling an ME SYSTEM, or adapting ME EQUIPMENT or an ME SYSTEM, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

NOTE 1 "Adapting" includes making substantial modifications to ME EQUIPMENT or an ME SYSTEM already in use.

NOTE 2 In some jurisdictions, the RESPONSIBLE ORGANIZATION may be considered a MANUFACTURER when involved in the activities described.

NOTE 3 Adapted from ISO 14971: 2000.

3.55
MATERIALS TO BE CONSUMED

Any material, component or ACCESSORY that needs to be consumed during the useful life to enable NORMAL USE of ME EQUIPMENT.

3.56
***MAXIMUM MAINS VOLTAGE**[16]

Voltage used for test purposes related to the voltage of the SUPPLY MAINS and connected to certain ME EQUIPMENT parts. The value for MAXIMUM MAINS VOLTAGE is determined according to 8.5.3.

3.57
***MAXIMUM PERMISSIBLE WORKING PRESSURE**

Maximum PRESSURE permitted on a component according to a declaration of the MANUFACTURER of such component if his instructions for installation and use are followed.

3.58
***MEANS OF PROTECTION (MOP)**

Means for reducing the RISK due to electric shock in accordance with the requirements of this standard.

NOTE MEANS OF PROTECTION include insulation, AIR CLEARANCES, CREEPAGE DISTANCES, impedances, and PROTECTIVE EARTH CONNECTIONS.

3.59
***MEANS OF PATIENT PROTECTION (MOOP)**

MEANS OF PROTECTION for reducing the RISK due to electric shock to the PATIENT.

3.60
***MEANS OF OPERATOR PROTECTION (MOOP)**

MEANS OF PROTECTION for reducing the RISK due to electric shock to persons other than the PATIENT.

3.61
MECHANICAL HAZARD

HAZARDS connected with or produced by physical force.[17]

3.62
MEDICAL DISPOSABLE

DISPOSABLE that is intended for a medical treatment of a PATIENT.[18]

3.63
MEDICAL ELECTRICAL EQUIPMENT (hereinafter ME EQUIPMENT)

Electrical equipment, provided with not more than one connection to a particular SUPPLY MAINS; and intended by its MANUFACTURER to be used in the diagnosis, treatment, or monitoring of a PATIENT; and that makes physical or electrical contact with the PATIENT or transfers energy to or from the PATIENT or detects such energy transfer to or from the PATIENT.

MEDICAL ELECTRICAL EQUIPMENT includes those ACCESSORIES as defined by the MANUFACTURER that are necessary to enable the NORMAL USE of the MEDICAL ELECTRICAL EQUIPMENT.[19]

NOTE 1 Not all electrical equipment used in medical practice falls within this definition (e.g. *in vitro* diagnostic equipment or the implantable parts of active implantable medical devices).

NOTE 2 This standard uses the term "electrical equipment" to mean ME EQUIPMENT or other electrical equipment.

NOTE 3 The assignment of a purpose including use in diagnosis, treatment or monitoring to equipment brings it under this definition and makes it subject to the relevant requirements of this standard.

3.64
***MEDICAL ELECTRICAL SYSTEM (**hereinafter ME SYSTEM)

Combination, as specified by its MANUFACTURER, of items of equipment, at least one of which must be ME EQUIPMENT to be inter-connected by FUNCTIONAL CONNECTION or by use of a MULTIPLE SOCKET-OUTLET.

NOTE Equipment, when mentioned in this standard, should be taken to include ME EQUIPMENT.

3.65
MOBILE

Adjective referring to TRANSPORTABLE equipment intended to be moved from one location to another between periods of use while supported by its own wheels or equivalent means.

3.66
***MODEL OR TYPE REFERENCE**

Combination of figures, letters or both used to identify a particular model of equipment or ACCESSORY.[20]

3.67
***MULTIPLE SOCKET-OUTLET (MSO)**

Socket-outlets intended to be connected to, or integral with, flexible cables or cords or ME EQUIPMENT for SUPPLY MAINS or equivalent voltage.

NOTE A MULTIPLE SOCKET-OUTLET may be a separate item or an integral part of equipment.

3.68
NATURAL ENVIRONMENT

Attributes which affect the quality of life, such as water, air, and soil quality, conservation of energy and materials and avoidance of waste.

[IEC Guide 109]

3.69
***NETWORK/DATA COUPLING**

Any means to transmit and/or receive information to or from other equipment in accordance with the MANUFACTURER'S specifications.[21]

3.70
NOMINAL (value)

Value quoted for reference purposes that is subject to agreed tolerances, for example, nominal MAINS VOLTAGE or nominal diameter of a screw.

3.71
NORMAL CONDITION

Condition in which all means provided for protection against HAZARDS are intact.

3.72
NORMAL USE

Operation, including routine inspection and adjustments by the OPERATOR, and stand-by, according to the instructions for use.

3.73
OBJECTIVE EVIDENCE

Information which can be proven true, based on facts obtained through observation, measurement, test or other means

[ISO 14971: 2000]

3.74
OPERATOR
USER[22]

Person handling equipment.[23] See also 3.105.

3.75
OVER-CURRENT RELEASE

Protective device that causes a circuit to open, with or without delay, when the current in the device exceeds a predetermined value.

3.76
***OXYGEN RICH ENVIRONMENT**

An environment in which the concentration of oxygen (within the pressure range specified in 5.3) is greater than 25 % or the partial pressure of oxygen is greater than 27,5 kPa.

3.77
PATIENT

Living being (person or animal) undergoing a medical, surgical or dental PROCEDURE.

3.78
***PATIENT AUXILIARY CURRENT**

Current flowing in the PATIENT in NORMAL USE between any PATIENT CONNECTION and all other PATIENT CONNECTIONS and not intended to produce a physiological effect.[24]

3.79
***PATIENT CONNECTION**

Every individual part of the APPLIED PART through which current can flow between the PATIENT and the ME EQUIPMENT in NORMAL CONDITION or SINGLE FAULT CONDITION.

3.80
***PATIENT ENVIRONMENT**

Any volume in which intentional or unintentional contact can occur between a PATIENT and parts of the ME EQUIPMENT or ME SYSTEM or between a PATIENT and other persons touching parts of the ME EQUIPMENT or ME SYSTEM.

3.81
PATIENT LEAKAGE CURRENT

Current flowing from the PATIENT CONNECTIONS via the PATIENT to earth or originating from the unintended appearance of a voltage from an external source on the PATIENT and flowing from the PATIENT via the PATIENT CONNECTIONS of an F-TYPE APPLIED PART to earth.

3.82
PEMS VALIDATION[25]

PROCESS of evaluating a PEMS or a component of a PEMS during or at the end of the development PROCESS, to determine whether it satisfies the requirements for its INTENDED USE/INTENDED PURPOSE.

3.83
PERMANENTLY AFFIXED

Removable only with a TOOL or by appreciable force.

3.84
PERMANENTLY INSTALLED

Adjective meaning electrically connected to the SUPPLY MAINS by means of a permanent connection that can only be detached by the use of a TOOL.

3.85
PORTABLE

Adjective referring to TRANSPORTABLE equipment intended to be moved from one location to another while in use or between periods of use while being carried by one or more persons.

3.86
POTENTIAL EQUALIZATION CONDUCTOR

Conductor other than a PROTECTIVE EARTH CONDUCTOR or a neutral conductor, providing a direct connection between electrical equipment and the potential equalization busbar of the electrical installation (see Figure 2).

3.87
POWER SUPPLY CORD

Flexible cord, FIXED to or assembled with electrical equipment for connection to SUPPLY MAINS (see Figure 1 to Figure 4 [inclusive]).

3.88
PRESSURE

Pressure above atmospheric (gauge pressure).

3.89
PROCEDURE

Specific way to perform an activity.

[ISO 14971: 2000]

3.90
PROCESS

Set of inter-related resources and activities which transform inputs into outputs.

[ISO 14971: 2000]

3.91
PROPERLY INSTALLED

Installed in accordance with the relevant instructions given by the MANUFACTURER in the ACCOMPANYING DOCUMENTS.

3.92
PROGRAMMABLE ELECTRICAL MEDICAL SYSTEM (PEMS)

ME EQUIPMENT or an ME SYSTEM containing one or more PROGRAMMABLE ELECTRONIC SUBSYSTEMS (PESS).

723 **3.93**
724 **PROGRAMMABLE ELECTRONIC SUBSYSTEM (PESS)**

725 System based on one or more central processing units, including their software and
726 interfaces.

727 **3.94**
728 **PROTECTIVE EARTH CONDUCTOR**

729 Conductor to be connected between the PROTECTIVE EARTH TERMINAL and an external
730 protective earthing system (see Figure 2).

731 **3.95**
732 **PROTECTIVE EARTH CONNECTION**

733 Connection to the PROTECTIVE EARTH TERMINAL provided for protective purposes and complying
734 with the requirements of this standard.

735 **3.96**
736 **PROTECTIVE EARTH TERMINAL**

737 Terminal connected to conductive parts of CLASS I equipment for safety purposes. This
738 terminal is intended to be connected to an external protective earthing system by a
739 PROTECTIVE EARTH CONDUCTOR (see Figure 2).

740 **3.97**
741 **PROTECTIVELY EARTHED**

742 Connected to the PROTECTIVE EARTH TERMINAL for protective purposes by means complying
743 with the requirements of this standard.

744 **3.98**
745 **RATED** (value)

746 Adjective referring to a value assigned by the MANUFACTURER for a specified operating
747 condition.

748 **3.99**
749 **REASONABLY FORESEEABLE MISUSE**
750 **UNINTENDED MISUSE**[26]

751 Use in a way not intended by the MANUFACTURER as defined by the ACCOMPANYING DOCUMENTS
752 but which may result from readily predictable human behaviour as defined through a human
753 factors engineering PROCESS.

754 **3.100**
755 **RECORD**

756 Document which furnishes OBJECTIVE EVIDENCE of activities performed or results achieved.

757 [ISO 14971: 2000]

758 **3.101**
759 **RECYCLING**

760 A set of PROCESSES for diverting materials, that would otherwise be disposed of as wastes,
761 into an economic system where they contribute to the production of useful material.

762 [IEC Guide 109]

763 **3.102**
764 ***REFERENCE VOLTAGE (*U*)**[27]

765 Peak or d.c. voltage to which a MEANS OF PROTECTION (other than a PROTECTIVE EARTH
766 CONNECTION) is subjected in NORMAL USE and at RATED supply voltage or a voltage as specified
767 by the MANUFACTURER, whichever is the greater.

3.103
***REINFORCED INSULATION**

Single insulation system that provides two MEANS OF PROTECTION.

3.104
RESIDUAL RISK

RISK remaining after protective measures have been taken.

[ISO 14971: 2000]

3.105
RESPONSIBLE ORGANIZATION

Entity accountable for the use and maintenance of an ME EQUIPMENT or an ME SYSTEM.

NOTE 1 The accountable entity can be a hospital, the OPERATOR, or a lay person. In home use applications, the PATIENT, OPERATOR and RESPONSIBLE ORGANIZATION may be one and the same person.

NOTE 2 Education and training is included in "use."

3.106
REUSE

Use of a previously used component or part for its original purpose as specified by the MANUFACTURER without any physical or chemical changes.

3.107
RISK

Combination of the probability of occurrence of HARM and the SEVERITY of that HARM

[ISO 14971:2000]

3.108
RISK ANALYSIS

Systematic use of available information to identify HAZARDS and to estimate the RISK.

[ISO 14971:2000]

3.109
RISK ASSESSMENT

Overall PROCESS comprising a RISK ANALYSIS and a RISK EVALUATION.

[ISO 14971:2000]

3.110
***RISK CONTROL**

PROCESS through which decisions are reached and protective measures are implemented for reducing RISKS to, or maintaining RISKS within, specified levels.

[ISO 14971:2000]

3.111
RISK EVALUATION

Judgement, on the basis of RISK ANALYSIS, of whether a RISK which is acceptable has been achieved in a given context based on the current values of society.

[ISO 14971:2000]

3.112
RISK MANAGEMENT

Systematic application of management policies, PROCEDURES and practices to the tasks of analyzing, evaluating and controlling RISK.

[ISO 14971:2000]

3.113
RISK MANAGEMENT FILE

Set of RECORDS and other documents, not necessarily contiguous, that are produced by a RISK MANAGEMENT PROCESS.

[ISO 14971: 2000]

3.114
SAFE WORKING LOAD

Maximum mechanical load on equipment or an equipment part that is permitted in NORMAL USE.

3.115
SAFETY

Freedom from unacceptable RISK.

[ISO 14971: 2000]

3.116
SAFETY DEVICE

Device that eliminates or reduces RISK and which operates in the case of SINGLE FAULT CONDITION.[28]

3.117
***SECONDARY CIRCUIT**

Circuit which is separated from the MAINS PART by at least one MEANS OF PROTECTION and derives its power from a transformer, converter or equivalent isolation device, or from an INTERNAL ELECTRICAL POWER SOURCE. See also 8.9.1.11.

3.118
SELF-RESETTING THERMAL CUT-OUT

THERMAL CUT-OUT that automatically restores the current after the relevant part of electrical equipment has cooled.

3.119
***SEPARATION DEVICE**

A component or arrangement of components with input parts and output parts that, for safety reasons, prevents a transfer of unwanted voltage or current between parts of an ME SYSTEM.

3.120
SERVICE PERSONNEL

Individuals or entity accountable to the RESPONSIBLE ORGANIZATION that install, assemble, maintain or repair ME EQUIPMENT, ME SYSTEMS or equipment.

3.121
SEVERITY

Measure of the possible consequences of a HAZARD.

[ISO 14971:2000][29]

3.122
***SIGNAL INPUT/OUTPUT PART**

Part of ME EQUIPMENT, not being an APPLIED PART, intended to deliver or receive input signals to or from other electrical equipment, for example, for display, recording or data processing (see Figure 2).

3.123
SINGLE FAULT CONDITION

Condition in which a single means for reducing the RISK resulting from a HAZARD is defective or a single abnormal condition is present (see 4.5 and 13.2).[30]

3.124
SINGLE FAULT SAFE[31]

Characteristic of ME EQUIPMENT or ME EQUIPMENT parts whereby SAFETY is maintained throughout their useful life under the following conditions:

a) The ME EQUIPMENT employs a single means for reducing a RISK who's probability of failure is negligible (e.g. REINFORCED INSULATION, suspended masses without SAFETY DEVICES employing a TENSILE SAFETY FACTOR of 8X, HIGH-INTEGRITY COMPONENTS), or

b) A SINGLE FAULT CONDITION occurs, but:

– the initial fault will be detected during the useful life of the ME EQUIPMENT and before a second means for reducing a RISK fails (e.g. suspended masses with SAFETY DEVICES); or

– the probability that the second MEANS OF PROTECTION will fail during the useful life of the ME EQUIPMENT is negligible.

3.125
STATIC LOAD

Maximum loading of a part excluding any loading caused by acceleration or deceleration of masses. Where a load is divided over several parallel supporting parts and the distribution over these parts is not determined unequivocally, the least favourable possibility shall be considered.

3.126
STATIONARY

Adjective referring to equipment that is not intended to be moved from one place to another.

3.127
SUPPLEMENTARY INSULATION

Independent insulation applied in addition to BASIC INSULATION in order to provide protection against electric shock in the event of a failure of BASIC INSULATION.

[IEV 826-03-18]

NOTE SUPPLEMENTARY INSULATION provides one MEANS OF PROTECTION.

3.128
***SUPPLY MAINS**

Power source not forming part of ME EQUIPMENT or ME SYSTEM.

NOTE This also includes battery systems and converter systems in ambulances and the like.

3.129
TENSILE SAFETY FACTOR[32]

Ratio between TENSILE STRENGTH and the stress corresponding to the TOTAL LOAD.

3.130
TENSILE STRENGTH

Maximum stress a test piece will withstand before rupturing.

3.131
TERMINAL DEVICE

Part of electrical equipment by which electrical connection is made; it may contain several individual contacts.

3.132
THERMAL CUT-OUT

Device that, during abnormal operation, limits the temperature of electrical equipment or of part of it, by automatically opening the circuit or by reducing the current, and that is so constructed that its setting cannot be altered by the OPERATOR.

3.133
THERMAL STABILITY

Condition under which the temperature of an object does not increase by more than 2 ºC over a period of 1 h.

3.134
THERMOSTAT

Temperature sensing control, that is intended to keep a temperature within a specific range or above/below a preset value under normal operating conditions and that may have provision for setting by the OPERATOR.

3.135
TOOL

Extra-corporeal object that may be used to secure or release fasteners or to make adjustments.

NOTE Coins and keys are considered TOOLS within the context of this standard.[33]

3.136
TOTAL LOAD

Sum of the STATIC LOAD and the forces caused by acceleration and deceleration occurring in NORMAL CONDITION.

3.137
TOUCH CURRENT

Current flowing from the ENCLOSURE or from parts thereof, excluding PATIENT CONNECTIONS, accessible to the OPERATOR or PATIENT in NORMAL USE, through an external path other than the PROTECTIVE EARTH CONDUCTOR, to earth or to another part of the ENCLOSURE.

NOTE The meaning of this term is the same as that of "ENCLOSURE LEAKAGE CURRENT" in the 1st and 2nd editions of this standard. The term has been changed to align with IEC 60990-1 and to reflect the fact that the measurement now applies also to parts that are normally PROTECTIVELY EARTHED.

3.138
TRANSPORTABLE

Adjective referring to equipment that is intended to be moved from one place to another whether or not connected to a supply and without an appreciable restriction of range.

EXAMPLES MOBILE equipment and PORTABLE equipment.

3.139
TRAPPING ZONE

Location on or within the ME EQUIPMENT or ME SYSTEM where a human body or a part of the human body is exposed to trapping, crushing, shearing, impact, cutting, entanglement, drawing in, stabbing or abrasion HAZARD.

3.140

***TYPE B APPLIED PART**

APPLIED PART complying with the specified requirements of this standard to provide protection against electric shock, particularly regarding allowable PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT.

NOTE 1 A TYPE B APPLIED PART is marked with Symbols IEC 60417-5840 (see Table D1, Symbol 18 or, when applicable, with Symbol IEC 60417-5841 (see Table D1, Symbol 24. See also 3.18.

NOTE 2 TYPE B APPLIED PARTS are not suitable for DIRECT CARDIAC APPLICATION.

NOTE 3 See also 4.4 regarding the treatment of parts that do not fall within the definition of APPLIED PARTS but need to be considered as APPLIED PARTS as a result of applying the RISK MANAGEMENT PROCESS.

3.141

***TYPE BF APPLIED PART**

F-TYPE APPLIED PART complying with the specified requirements of this standard to provide a higher degree of protection against electric shock than that provided by TYPE B APPLIED PARTS.

NOTE 1 A TYPE BF APPLIED PART is marked with Symbol IEC 60417-5333 (see Table D1, Symbol 19 or, when applicable, with Symbol 60417-5334 (see Table D1, Symbol 25. See also 3.18.

NOTE 2 TYPE BF APPLIED PARTS are not suitable for DIRECT CARDIAC APPLICATION.

NOTE 3 See also 4.4 regarding the treatment of parts that do not fall within the definition of APPLIED PARTS but need to be considered as APPLIED PARTS as a result of applying the RISK MANAGEMENT PROCESS.

3.142

***TYPE CF APPLIED PART**

F-TYPE APPLIED PART complying with the specified requirements of this standard to provide a higher degree of protection against electric shock than that provided by TYPE BF APPLIED PARTS.

NOTE 1 A TYPE CF APPLIED PART is marked with Symbol IEC 60417-5335 (see Table D1, Symbol 20) or, when applicable, with Symbol 60417-5336 (see Table D1, Symbol 26). See also 3.18.

NOTE 2 See also 4.4 regarding the treatment of parts that do not fall within the definition of APPLIED PARTS but need to be considered as APPLIED PARTS as a result of applying the RISK MANAGEMENT PROCESS.

3.143

VERIFICATION

Confirmation by examination and provision of OBJECTIVE EVIDENCE that specified requirements have been fulfilled.

NOTE In design and development, VERIFICATION concerns the PROCESS of examining the result of a given activity to determine conformity with the stated requirements for that activity.

[ISO 14971: 2000]

4. General requirements

4.1 Conditions for application to ME EQUIPMENT or ME SYSTEMS

Unless otherwise specified, the requirements of this standard shall apply in NORMAL USE and REASONABLY FORESEEABLE MISUSE.

4.2 *RISK MANAGEMENT PROCESS for ME EDUIPMENT or ME SYSTEMS

A RISK MANAGEMENT PROCESS shall be carried out, applying ISO 14971.

In applying ISO 14971:

– The term “medical device” shall assume the same meaning as ME EQUIPMENT or ME SYSTEM.[34]

– The term “fault conditions” referred to in ISO 14971 shall include, but shall not be limited to, SINGLE FAULT CONDITIONS discussed in this standard.

– All RISKS associated with the ME EQUIPMENT or ME SYSTEM shall be considered, not only the RISKS that are subject to specific requirements of this standard.

– Where this standard specifies requirements addressing particular RISKS, and these requirements are complied with, the RESIDUAL RISKS shall be presumed to be acceptable unless there is OBJECTIVE EVIDENCE to the contrary.[35]

NOTE 1 This standard specifies requirements that are generally applicable to RISKS associated with ME EQUIPMENT or ME SYSTEMS, and is intended to serve as a tool during the RISK MANAGEMENT PROCESS. The RISK MANAGEMENT PROCESS should identify not only those HAZARDS addressed by this standard, but all HAZARDS, their associated RISKS and RISK CONTROL measures.

NOTE 2 Conditions or faults, which may give rise to HAZARDS, are identified in the clauses of this standard. In these cases, it will often be necessary to carry out a RISK MANAGEMENT PROCESS to determine what the actual HAZARDS are and the tests that need to be done to show that the identified HAZARDS do not arise in the specified circumstance.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

4.3 *Equivalent SAFETY for to ME EQUIPMENT or ME SYSTEMS

Where this standard specifies requirements addressing particular RISKS, alternative means of addressing these RISKS are acceptable provided that the MANUFACTURER can justify that the RESIDUAL RISKS after applying the alternative means are equal to or less than the RESIDUAL RISKS after applying the requirements of this standard that address the particular RISKS.[36]

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

4.4 *ME EQUIPMENT or ME SYSTEMS parts that contact the PATIENT

The RISK MANAGEMENT PROCESS shall include an assessment of whether parts that may possibly come into contact with the PATIENT but fall outside of the definition of APPLIED PARTS shall be subject to the requirements for APPLIED PARTS. If the RISK MANAGEMENT PROCESS determines that such parts shall be subject to the requirements for APPLIED PARTS, then all the relevant requirements and tests of this standard shall apply, except that 7.2.8 does not apply to such parts.[37]

4.5 *NORMAL CONDITION and SINGLE FAULT CONDITION for ME EQUIPMENT

ME EQUIPMENT shall be so designed and manufactured that:

– in NORMAL CONDITION, no unacceptable RISK exists.

– it remains SINGLE FAULT SAFE.

A fault that cannot be detected by the maintenance PROCEDURES as specified in the ACCOMPANYING DOCUMENTS and that is unlikely to be noticed because it does not affect the function of the ME EQUIPMENT shall be considered a NORMAL CONDITION.

Where a SINGLE FAULT CONDITION results unavoidably in another SINGLE FAULT CONDITION, the two failures are considered as one SINGLE FAULT CONDITION.

During any test under SINGLE FAULT CONDITION, only one fault at a time shall be applied.

NOTE Faults identified in this standard are generally divided into 3 categories (based on probability):

a) So remote that they can be ignored. The RISKS arising from these faults are considered acceptable.

b) High enough that they need to be considered, but low enough that they need only be considered one at a time (single fault). Faults of this category include all those identified as SINGLE FAULT CONDITIONS in this standard, and any other faults identified in applying ISO 14971, which meet the SINGLE FAULT CONDITION criteria.

c) So likely, so unpredictable or undetectable that they are considered to be a NORMAL CONDITION and need to be considered individually and collectively.

The results of the RISK ANALYSIS shall be used to determine which failures shall be tested. The failure of any one component at a time, which could cause a HAZARD including those mentioned in 13.1, shall be simulated, physically or theoretically. The evaluation of whether a component is subject to failure simulation shall take into account the probability of failure of the component (as defined by the component manufacturer) during the useful life of the product. This evaluation shall be accomplished by applying the principles of RISK MANAGEMENT. The evaluation shall take into account issues such as reliability, TENSILE SAFETY FACTORS and derating of components. Additionally, during the simulation of SINGLE FAULT CONDITIONS, component failures that are highly probable or undetectable shall be simulated.

NOTE See also Note 2 in 4.2.

This requirement and relevant tests shall not be applied to failures of DOUBLE or REINFORCED INSULATION or HIGH-INTEGRITY COMPONENTS.

Compliance is determined by applying the specific requirements and tests associated with the SINGLE FAULT CONDITIONS identified in 13.2. Compliance is confirmed if the introduction of any of the SINGLE FAULT CONDITIONS described in 13.2, one at a time, does not lead directly to a HAZARD, including those described in 13.1, with an unacceptable RISK.[38]

4.6 Components of ME EQUIPMENT[39]

All components including wiring[40], the failure of which could cause a HAZARD, shall be used in accordance with their specified ratings unless a specific exception is made in this standard or through the RISK MANAGEMENT PROCESS. The reliability of components that are used as MEANS OF PROTECTION shall be assessed for the conditions of use in the ME EQUIPMENT. If the reliability is low, the component shall not be considered as a MEANS OF PROTECTION. They shall comply with one of the following:

a) the applicable safety requirements of a relevant IEC standard (see 4.3). Compliance with other requirements of the component standard is not required. Where necessary for the application, they shall be subjected to the tests of this standard, except that it is not necessary to carry out identical or equivalent tests already performed to check compliance with the component standard;

b) where there is no relevant IEC standard, the requirements of this standard.

See Figure 5 *for a schematic flow chart for* a) *and* b).

Compliance is checked by inspection and, where necessary, by test. The tests of this standard for motors (see 13.2.9 and 13.2.14.3) and transformers (see 15.5.3) are considered to be comprehensive and together with the evaluation of the motor or transformer insulation system according to Table 19 represent all testing required by this standard.[41] *ME SYSTEM components that provide isolation from non-ME EQUIPMENT shall comply with Clause 16.*[42]

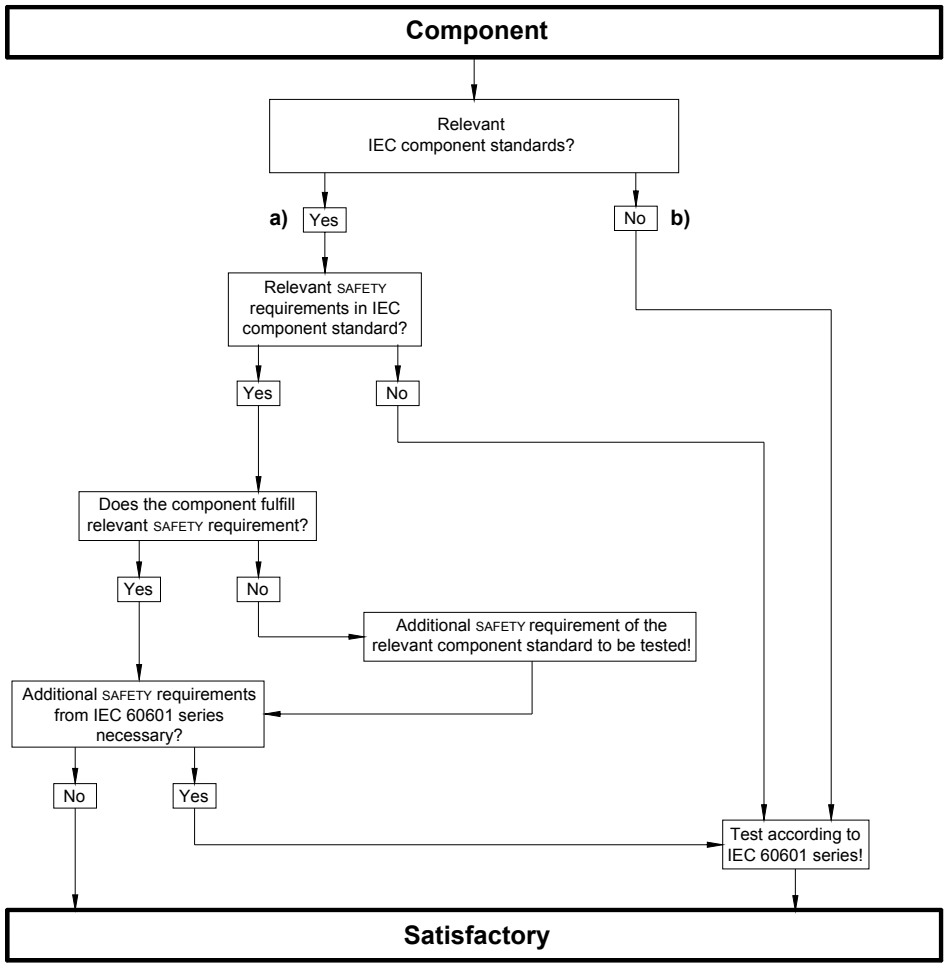


Figure 5 – Schematic flow chart for component qualification (see 4.6)

4.7 Use of HIGH-INTEGRITY COMPONENTS in ME EQUIPMENT

The SINGLE FAULT CONDITION does not apply to failure of HIGH-INTEGRITY COMPONENTS. HIGH-INTEGRITY COMPONENTS shall be selected and evaluated consistent with their conditions of use and REASONABLY FORESEEABLE MISUSE over the useful life of the ME EQUIPMENT.

EXAMPLE 1 REINFORCED INSULATION;

EXAMPLE 2 Securely installed PROTECTIVE EARTH CONDUCTOR.

Compliance is checked by inspection of the RISK MANAGEMENT FILE and the selection criteria for the HIGH-INTEGRITY COMPONENTS.

4.8 *Power supply

4.8.1 Source of power for ME EQUIPMENT

ME EQUIPMENT shall either be powered by an INTERNAL ELECTRICAL POWER SOURCE, be specified for connection to a separate power supply, or be suitable for connection to a SUPPLY MAINS.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

4.8.2 SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS

For ME EQUIPMENT intended to be connected to SUPPLY MAINS, the following RATED voltages shall not be exceeded:[43]

1088 – 250 V for HAND-HELD ME EQUIPMENT;

1089 – 250 V d.c. or single-phase a.c. or 500 V polyphase a.c. for ME EQUIPMENT and ME SYSTEMS
1090 with a RATED input ≤ 4 kVA;

1091 – 500 V for all other ME EQUIPMENT and ME SYSTEMS;

1092 SUPPLY MAINS in this standard shall be assumed to have the following characteristics:

1093 – voltage dips, short interruptions and voltage variations on the SUPPLY MAINS as described
1094 in IEC 60601-1-2;

1095 – no voltage in excess of 110 % or lower than 90 % of the NOMINAL value between any of the
1096 conductors of the system or between any of these conductors and earth;

1097 – voltages that are practically sinusoidal and forming a practically symmetrical supply
1098 system in case of polyphase supply;

1099 – a frequency of not more than 1 kHz;

1100 – a frequency deviation of ≤ 1 Hz from the NOMINAL value up to 100 Hz and ≤ 1 % from the
1101 NOMINAL value from 100 Hz to 1 kHz;

1102 – the protective measures as described in IEC 60364-4-41.

1103 NOTE If ME EQUIPMENT or an ME SYSTEM is intended to be operated from a SUPPLY MAINS with characteristics
1104 different from the SUPPLY MAINS described in this subclause, additional SAFETY measures may be necessary.

1105 – a d.c. voltage (as measured by a moving coil meter or equivalent method) having a peak-
1106 to-peak ripple not exceeding 10 % of the average value.[44]

1107 NOTE Where peak-to-peak ripple exceeds 10 % of the average value, the peak voltage has to be applied.

5. *General requirements for tests for ME EQUIPMENT

5.1 *Tests

The tests shall be determined taking into consideration the requirements of Clause 4, in particular 4.2. Tests described in this standard are type tests.

A test need not be carried out if analysis shows that the condition being tested has been adequately evaluated by other tests.

The results of the RISK ANALYSIS shall be used to determine which combination(s) of simultaneous faults shall be tested.

5.2 *Number of samples

Type tests are performed on a representative sample of the item being tested.

NOTE Multiple samples may be utilized simultaneously if the validity of the results are not significantly affected.

5.3 Ambient temperature, humidity, atmospheric pressure

a) *After the ME EQUIPMENT to be tested has been set up for NORMAL USE (according to 5.7), tests are carried out within the range of environmental conditions specified by the MANUFACTURER.*[45]

b) *ME EQUIPMENT shall be shielded from other influences (for example, draughts), that might affect the validity of the tests.*

c) *In cases where ambient temperatures cannot be maintained, the test conditions are to be consequently modified and results adjusted accordingly*.

5.4 Other conditions

a) *Unless otherwise specified in this standard, ME EQUIPMENT is to be tested under the least favourable working conditions as specified in the instructions for use.*

b) *ME EQUIPMENT having operating values that can be adjusted or controlled by the OPERATOR shall be adjusted as part of the tests to values least favourable for the relevant test, but in accordance with the instructions for use.*

c) *If the test results are influenced by the inlet pressure and flow or chemical composition of the cooling liquid, the test shall be carried out within the limits for these characteristics as prescribed in the technical description.*

d) *Where cooling water is required, potable water shall be used.*

5.5 Supply voltages, type of current, nature of supply, frequency

a) *Where test results are influenced by deviations of the supply voltage from its RATED value, the effect of such deviations shall be taken into account.*

The supply voltage during tests shall be according to 4.8 or according to that specified by the MANUFACTURER, whichever is least favourable.[46]

b) *ME EQUIPMENT for a.c. only shall be tested with a.c. at RATED frequency (if marked) ± 1 Hz between 0 and 100 Hz and ± 1 % above 100 Hz. ME EQUIPMENT marked with a RATED frequency range shall be tested at the least favourable frequency within that range.*

c) *ME EQUIPMENT designed for more than one RATED voltage, or for both a.c. and d.c., shall be tested in conditions (described in 5.4) related to the least favourable voltage and nature of supply, for example, number of phases (except for single-phase supply) and type of current. It may be necessary to perform some tests more than once in order to establish which supply configuration is least favourable*.

d) *ME EQUIPMENT for d.c. only shall be tested with d.c. When performing the tests, the possible influence of polarity on the operation of the ME EQUIPMENT shall be taken into consideration, according to the instructions for use.*

e) *Unless otherwise specified by this standard, ME EQUIPMENT shall be tested at the least favourable RATED voltage within the relevant range. It may be necessary to perform some of the tests more than once in order to establish the least favourable voltage.*

f) *ME EQUIPMENT for which alternative ACCESSORIES or components specified by the MANUFACTURER are available shall be tested with those ACCESSORIES or components that give the least favourable conditions.*

g) *If the instructions for use specify that ME EQUIPMENT is intended to receive its power from a separate power supply, it shall be connected to such a power supply. See also 7.2.4 and 8.2.1.*

NOTE What was referred to in the first and second editions of this standard as a "specified power supply" is now considered either as another part of the same ME EQUIPMENT or as another equipment in an ME SYSTEM.[47]

5.6 Repairs and modifications

In the event of the necessity for repairs or modifications after a failure or a likelihood of future failure during the sequence of tests, the testing laboratory and the supplier of the ME EQUIPMENT for the test may agree, either upon the presentation of a new sample on which all tests shall be carried out again or, preferably, upon making all the necessary repairs or modifications after which only relevant tests shall be repeated.

5.7 *Humidity preconditioning treatment

Prior to the tests of 8.7.4 and 8.8.3, all ME EQUIPMENT or its parts shall be subjected to a humidity preconditioning treatment.[48]

ME EQUIPMENT or its parts shall be set up complete (or where necessary partially). Covers used during transport and storage shall be detached.

This test shall be applied only to those ME EQUIPMENT parts likely to be influenced by the climatic conditions that are simulated by the test.

Parts that can be detached without the use of a TOOL shall be detached but shall be treated simultaneously with the major part.

ACCESS COVERS that can be opened or detached without the use of a TOOL shall be opened and detached.

The humidity preconditioning treatment shall be performed in a humidity cabinet containing air with a relative humidity of 93 % ± 3 %. The temperature of the air in the cabinet, at all places where ME EQUIPMENT can be located, shall be maintained within 2 °C of any convenient value T *in the range of +20 °C to +32 °C. Before being placed in the humidity cabinet, ME EQUIPMENT shall be brought to a temperature between* T *and* T + 4 *°C, and kept at this temperature for at least 4 h before the humidity treatment.*

ME EQUIPMENT and its parts shall be kept in the humidity cabinet for:

– *2 days (48 h) for ME EQUIPMENT.*

– *Where the RISK MANAGEMENT PROCESS suggests that the ME EQUIPMENT may be exposed to high humidity for extended periods (such as ME EQUIPMENT intended for out-door use), the period shall be extended appropriately.*

After the treatment, the ME EQUIPMENT is reassembled, if necessary.

5.8 Sequence of tests

Unless stated otherwise, the tests in this standard shall be sequenced in such a way so that the results of any test do not influence the results of other tests.[49]

NOTE It is recommended that all tests be performed in the sequence given in Annex B.

5.9 *Determination of ACCESSIBLE PARTS

5.9.1 APPLIED PARTS

APPLIED PARTS are identified by inspection and by reference to the ACCOMPANYING DOCUMENTS.

5.9.2 Other ACCESSIBLE PARTS

5.9.2.1 Test finger

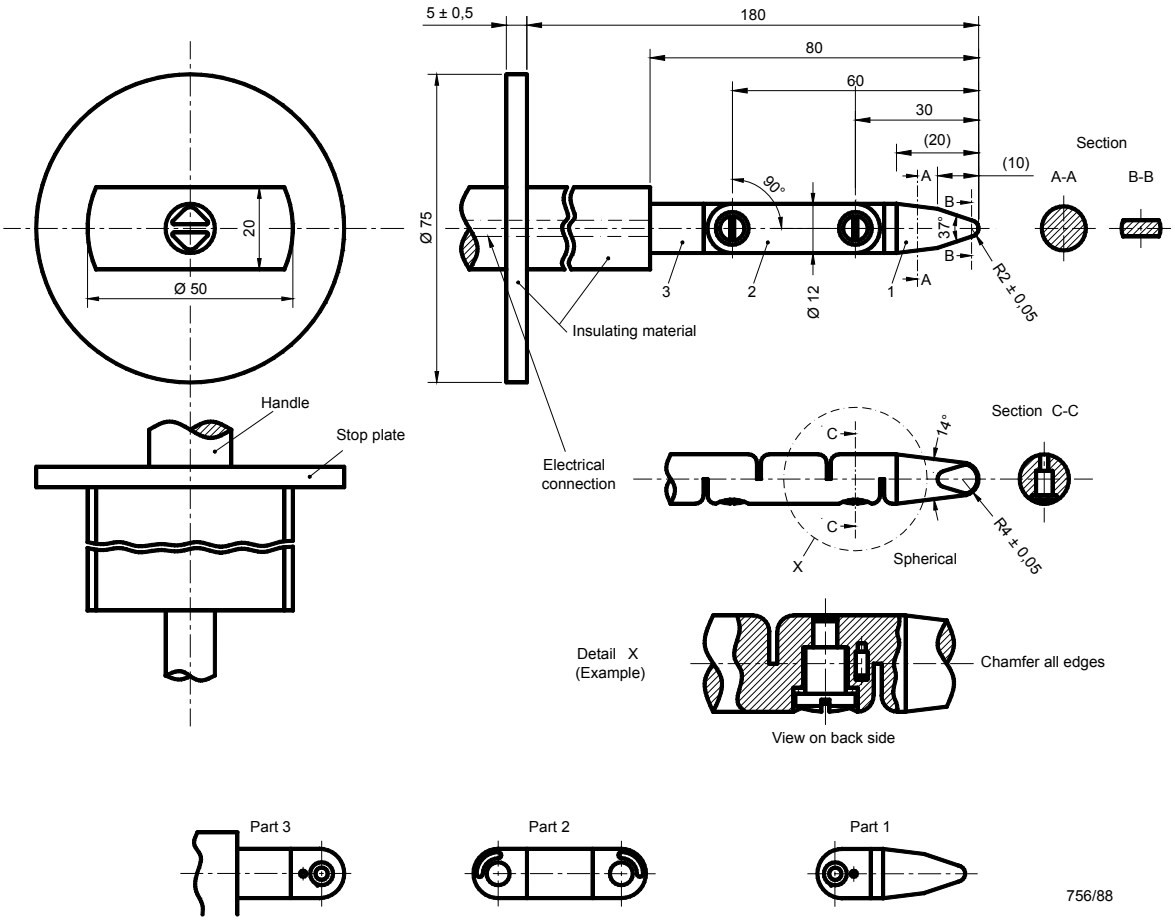
Parts of ME EQUIPMENT other than APPLIED PARTS that are to be regarded as ACCESSIBLE PARTS are identified by inspection and where necessary by test. In case of doubt, accessibility is determined by a test with the standard test finger shown in Figure 6, applied in a bent or straight position:

– *for all positions of ME EQUIPMENT when operated as in NORMAL USE,*

– *even after opening of ACCESS COVERS and removal of parts, including lamps, fuses and fuseholders, without the use of a TOOL or according to the instructions for use.*

The standard test finger is applied without appreciable force in every possible position, except that ME EQUIPMENT intended to be used on the floor and having a mass in any operational condition exceeding 40 kg shall not be tilted. ME EQUIPMENT which, according to the technical description, is intended for mounting into a cabinet, is tested in its final mounting position.

Openings preventing the entry of the standard test finger of Figure 6 are mechanically tested by means of a straight unjointed test finger of the same dimensions, which is applied with a force of 30 N. If this finger enters, the test with the standard test finger of Figure 6 is repeated, the finger being pushed through the opening if necessary.



1217

Linear dimensions in millimetres

Tolerances on dimensions without specific tolerances:

on angles: $^{0°}_{-10°}$

on linear dimensions: up to 25 mm $^{0}_{-0,05}$ mm

over 25 mm: ± 0,2 mm

Material of parts 1, 2 and 3: metal (e.g. heat-treated steel)

Both joints of this finger may be bent through an angle of $90\ ^{+10°}_{0°}$ but in one and the same direction only.

Using the pin and groove solution is only one of the possible approaches in order to limit the bending angle to 90º. For this reason, dimensions and tolerances of these details are not given in the drawing. The actual design must ensure a 90º bending angle with a 0º to +10º tolerance.

1218

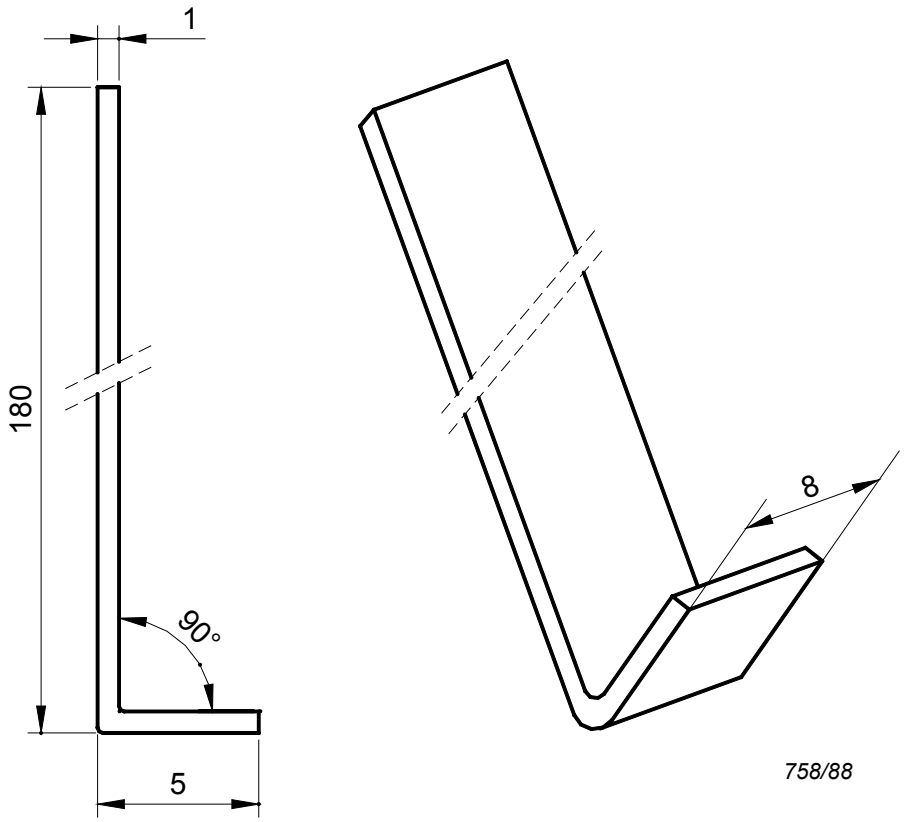
1219 **Figure 6 – Standard test finger**
1220 **(see 5.9.2.1)**

1221 **5.9.2.2 Test hook**

1222 *ME EQUIPMENT openings are mechanically tested by means of the test-hook (see Figure 7), if*
1223 *the hook can be inserted.*

1224 *The test-hook is inserted in all openings in question and is subsequently pulled with a force of*
1225 *20 N for 10 s and in a direction substantially perpendicular to the surface in which the relevant*

opening is present. Any additional parts that have become accessible are identified by using the standard test finger and by inspection.



Dimensions in millimetres, material: steel

Figure 7 – Test hook
(see 5.9.2.2)

5.9.2.3 Actuating mechanisms

Conductive parts of actuating mechanisms of electrical controls that are accessible after the removal of handles, knobs, levers and the like are regarded as ACCESSIBLE PARTS, unless removal requires the use of a TOOL and inspection of the MANUFACTURER'S RISK MANAGEMENT FILE demonstrates that the relevant part is unlikely to become detached unintentionally during the useful life of the ME EQUIPMENT. See also 15.4.6.1.

6. *Classification of ME EQUIPMENT and ME SYSTEMS

6.1 General

For purposes of this standard, ME EQUIPMENT, or parts thereof, including APPLIED PARTS, shall be classified as follows.

6.2 *Protection against electric shock

ME EQUIPMENT energized from an external electrical power source shall be classified as CLASS I ME EQUIPMENT or CLASS II ME EQUIPMENT (see 7.2.5). Other ME EQUIPMENT shall be classified as INTERNALLY POWERED ME EQUIPMENT.

APPLIED PARTS shall be classified as either TYPE B APPLIED PARTS, TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS (see 7.2.8 and 8.3).

6.3 Protection against harmful ingress of water or particulate matter

ENCLOSURES shall be classified according to the degree of protection against harmful ingress of water or particulate matter as detailed in IEC 60529 (see 7.2.7 and 11.6.5*)*.

NOTE: This classification is IPXY where:

– X is an integer indicating degree of protection against particulate matter.

– Y is an integer indicating the degree of protection against ingress of water.

6.4 Method(s) of sterilization

ME EQUIPMENT or its parts intended to be sterilized shall be classified according to the method(s) of sterilization recommended by the MANUFACTURER (see 7.10.2.12 and 11.6.7).

EXAMPLE 1 By ethylene oxide;

EXAMPLE 2 By irradiation;

EXAMPLE 3 By moist heat;

EXAMPLE 4 By other methods validated and described by the MANUFACTURER.

6.5 Suitability for use in an OXYGEN RICH ENVIRONMENT

ME EQUIPMENT and ME SYSTEMS shall be classified according to the degree of SAFETY when used in the presence of an OXYGEN RICH ENVIRONMENT (see 11.2.2).

6.6 *Mode of operation

ME EQUIPMENT shall be classified for either CONTINUOUS OPERATION or non-CONTINUOUS OPERATION (see 7.2.9).

7. ME EQUIPMENT identification, marking and documents

7.1 General

7.1.1 Human factors

The MANUFACTURER shall address the RISK of use error(s) associated with the design of identification, marking and documents in the RISK MANAGEMENT PROCESS.[50]

NOTE 1 The RISKS associated with the design of the identification, marking and documents connected with ME EQUIPMENT can be controlled through the application of a human factors engineering PROCESS. Such a PROCESS is detailed in a collateral standard, which is under development. IEC 60601-1-6 describes a PROCESS for the analysis, test and validation of human factors compatibility.

NOTE 2 Annex C contains a guide to assist the reader in locating the marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS contained in this standard.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.[51]

7.1.2 Legibility of markings

The markings required by 7.2, 7.3 and 7.4 shall be CLEARLY LEGIBLE.

Warning statements, symbols and drawings on the outside of ME EQUIPMENT shall be CLEARLY LEGIBLE when the ME EQUIPMENT is in the position of NORMAL USE.

Other markings shall be:

– For FIXED ME EQUIPMENT: CLEARLY LEGIBLE when the equipment is mounted in its position of NORMAL USE.

– For TRANSPORTABLE ME EQUIPMENT and for STATIONARY ME EQUIPMENT that is not FIXED ME EQUIPMENT: CLEARLY LEGIBLE in NORMAL USE or after dislodging the equipment from a wall against which it has been positioned, or after turning the equipment from its position of NORMAL USE and, in the case of dismountable rack units, after their removal from the rack.

– For internal markings: CLEARLY LEGIBLE when viewed from the intended OPERATORS position for the function be performed.

Compliance is checked by following test:

The ME EQUIPMENT or its part is positioned so that the viewpoint is the intended OPERATORS position; or the viewpoint is at any point within the base of a cone subtended by an angle of 30° to the axis normal to the centre of the plane of the marking and at a distance of 1 m. The ambient illuminance is in the range of 100 lx to 1 500 lx. The observer has a visual acuity of 0 on the log Mean Angle Resolvable (log MAR) scale or 6/6 (20/20), corrected if necessary.

The observer correctly perceives the marking from the viewpoint.

7.1.3 *Durability of markings

The markings required by 7.2, 7.3 and 7.4 shall be PERMANENTLY AFFIXED and sufficiently durable to remain CLEARLY LEGIBLE for the useful life of the ME EQUIPMENT.

Compliance is checked by inspection and the following tests:

a) *Markings shall be CLEARLY LEGIBLE after all the tests of this standard have been performed (see the recommended sequence of tests in Annex B). Adhesive labels shall not have worked loose or become curled at the edges.*

b) *For markings required by 7.2 and 7.4, an additional test for durability is to be performed. Markings are rubbed by hand, without undue pressure, first for 15 s with a cloth rag soaked with distilled water, then for 15 s with a cloth rag soaked with methylated spirit and then for 15 s with a cloth rag soaked with isopropyl alcohol.*

c) *When evaluating durability, the effect of* NORMAL USE *on markings is also to be taken into account.*

7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts (see also Table C1)

7.2.1 Minimum requirements for marking on ME EQUIPMENT and on interchangeable parts

If the size of the ME EQUIPMENT, an ME EQUIPMENT part or an ACCESSORY, or the nature of its ENCLOSURE, does not allow affixation of all markings specified in 7.2.2 to 7.2.18, then at least the markings as indicated in 7.2.2, 7.2.4 (not for PERMANENTLY INSTALLED ME EQUIPMENT), 7.2.8 and 7.2.11 (if applicable) shall be affixed and the remaining markings shall be recorded in full in the ACCOMPANYING DOCUMENTS. Where no marking is practicable, all information shall be included in the ACCOMPANYING DOCUMENTS or on the relevant end-USER packaging.[52]

Compliance is checked by inspection.

7.2.2 *Identification

ME EQUIPMENT and its detachable components shall be marked with the name or trade-mark of the MANUFACTURER, and with a MODEL OR TYPE REFERENCE.[53]

Compliance is checked by inspection

7.2.3 *ACCESSORIES and MEDICAL DISPOSABLES

ACCESSORIES and MEDICAL DISPOSABLES shall be marked with the name or trade-mark of their MANUFACTURER or supplier, and with a MODEL OR TYPE REFERENCE. Where no marking is practicable, all information shall be included in the ACCOMPANYING DOCUMENTS or on the relevant end-USER packaging.[54]

MEDICAL DISPOSABLES or their packaging shall be marked “Do Not Reuse” or with symbol 3.2 from ISO 15223.

Compliance is checked by inspection

7.2.4 ME EQUIPMENT intended to receive power from other equipment

If ME EQUIPMENT is intended to receive its power from other equipment in an ME SYSTEM and SAFETY is involved, the MODEL OR TYPE REFERENCE of the specified other equipment shall be permanently marked adjacent to the relevant connection point. See also 16.3.

NOTE What was formerly referred to, in the first and second editions of this standard, as a “specified power supply” is now considered either as another part of the same ME EQUIPMENT or as another equipment in an ME SYSTEM.

Compliance is checked by inspection

7.2.5 Connection to the supply

Mains operated ME EQUIPMENT shall be marked with the following information:

– The RATED supply voltage(s) or voltage range(s) to which it may be connected. A RATED supply voltage range shall have a hyphen (-) between the minimum and maximum voltages. Where multiple RATED supply voltages or RATED supply voltage ranges are given, they shall be separated by a solidus (/).

EXAMPLE 1 RATED supply voltage range: 220-240 V. This means that the MEDICAL ELECTRICAL EQUIPMENT is designed to be connected to a SUPPLY MAINS having a NOMINAL voltage between 220 V and 240 V.

EXAMPLE 2 Multiple RATED supply voltage: 120/220/240 V. This means that the MEDICAL ELECTRICAL EQUIPMENT is designed to be connected to a SUPPLY MAINS having a NOMINAL voltage of 120 V or 220 V or 240 V.

Nature of supply, for example, number of phases (except for single-phase supply) and type of current. Symbols IEC 60417-5032, 5032-1, 5032-2, 5031, and 5033 may be used for this purpose (see Table D1, Symbols 1, 2, 3, 4 and 5).

NOTE For alternating current, the RATED frequency in hertz is sufficient to identify the type of current.

– The RATED supply frequency or RATED frequency range in hertz.

– The electrical input power or input current (see 18.2.4.3)

– Symbol IEC 60417-5172 for CLASS II equipment, if relevant (see Table D1, Symbol 9).

Except for PERMANENTLY INSTALLED ME EQUIPMENT, these marking shall appear on the outside of the part that contains the SUPPLY MAINS connection and preferably adjacent to the connection point. For PERMANENTLY INSTALLED ME EQUIPMENT, the NOMINAL supply voltage or voltage range to which it can be connected may be marked on the inside or the outside of the ME EQUIPMENT, preferably adjacent to the supply connection terminals.

Compliance is checked by inspection.

7.2.6 Output connectors

7.2.6.1 Mains power output

For MULTIPLE SOCKET-OUTLETS that are integral with ME EQUIPMENT, see 16.9.2.1.

7.2.6.2 Other power sources

With the exception of MULTIPLE SOCKET-OUTLETS or connectors intended only for specified equipment, equipment parts or ACCESSORIES, output connectors of ME EQUIPMENT intended to deliver power shall be marked with the following information:

– RATED output voltage.

– RATED current or power (where applicable).

– Output frequency (where applicable).

Compliance is checked by inspection.

7.2.7 IP classification

ME EQUIPMENT or ME EQUIPMENT parts shall be marked with a symbol, using the letters IP followed by the designations described in IEC 60529, according to the degree of protection provided by the ENCLOSURE with respect to harmful ingress of particulate matter or water (see Table D3, Code 2).

ME EQUIPMENT classified IPX0 need not be marked as such.

Compliance is checked by inspection.

7.2.8 *APPLIED PARTS

APPLIED PARTS or their connection points shall be marked with a symbol indicating the degree of protection against electric shock, i.e., TYPE B APPLIED PARTS with Symbol IEC 60417-5840, TYPE BF APPLIED PARTS with Symbol IEC 60417-5333 or TYPE CF APPLIED PARTS with Symbol IEC 60417-5335 (see Table D1, Symbols 18, 19 and 20).

This requirement does not apply to parts that have been identified according to 4.4.

The relevant symbol shall be marked adjacent to the connection point of the APPLIED PART, unless either:

– there is no such connection point, in which case the marking shall be on the APPLIED PART; or

– the connection point is used for more than one APPLIED PART(s) and the different APPLIED PARTS have different classifications, in which case each APPLIED PART shall be marked with the relevant symbol.

For clear differentiation with Symbol IEC 60417-5333, Symbol IEC 60417-5840 shall not be applied in such a way as to give the impression of being inscribed within a square.

For DEFIBRILLATION-PROOF APPLIED PARTS, Symbols IEC 60417-5841, IEC 60417-5334, or IEC 60417-5336 shall be used as applicable (see Table D1, symbols 24, 25 and 26).

If the protection against the effect of the discharge of a cardiac defibrillator is partly in the PATIENT cable, Symbol ISO 7000-0434, shall be placed near the relevant outlet (see Table D1, Symbol 10). The instructions for use shall explain that protection of the ME EQUIPMENT against the effects of the discharge of a cardiac defibrillator is dependent upon the use of appropriate cables.

Compliance is checked by inspection.

7.2.9 Mode of operation

If no marking is provided, ME EQUIPMENT is assumed to be suitable for CONTINUOUS OPERATION. For ME EQUIPMENT intended for non-CONTINUOUS OPERATION, the DUTY CYCLE shall be indicated using an appropriate marking giving the maximum activation (on) time and the minimum deactivation (off) time.

Compliance is checked by inspection.

7.2.10 *Fuses

Where the fuse-holder is an ACCESSIBLE PART, the type and full rating of the fuse shall be marked adjacent to the fuse-holder.

NOTE The rupturing speed may be marked by the letter or colour codes of IEC 60127, which are as follows:

- very quick acting: FF, or black;
- quick acting: F, or red;
- medium time lag: M, or yellow;
- time lag: T, or blue;
- long time lag: TT, or grey

Compliance is checked by inspection.

7.2.11 Physiological effects (safety signs and warning statements)

ME EQUIPMENT producing physiological effects that are not obvious to the OPERATOR and may cause danger to the PATIENT or OPERATOR shall bear a suitable safety sign concerning the relevant HAZARD. The safety sign shall appear in a prominent location so that it will be clearly visible in NORMAL USE after the ME EQUIPMENT has been PROPERLY INSTALLED.[55]

For other HAZARDS, where no specific safety sign is available, Symbol ISO 7000-0434 shall be used (see Table D1, Symbol 10).

Compliance is checked by inspection.

7.2.12 HIGH VOLTAGE TERMINAL DEVICES

HIGH VOLTAGE TERMINAL DEVICES on the outside of ME EQUIPMENT that are accessible without the use of a TOOL shall be marked with the Symbol IEC 60417-5036 (see Table D1, Symbol 23).

Compliance is checked by inspection.

7.2.13 Cooling conditions

Requirements for cooling provisions for ME EQUIPMENT (for example, supply of water or air) shall be marked.

Compliance is checked by inspection.

7.2.14 Mechanical stability

For requirements on ME EQUIPMENT with a limited stability, see 9.4.

7.2.15 Protective packaging

If special handling measures have to be taken during transport or storage, the packaging shall be marked accordingly (see ISO 780).

The permissible environmental conditions for transport and storage shall be marked on the outside of the packaging (see 7.10.3.1 and ISO 15223).

Where premature unpacking of ME EQUIPMENT or its parts may result in a HAZARD, the packaging shall be marked with an appropriate safety sign (see 7.5).

EXAMPLE 1 Humidity sensitive ME EQUIPMENT.

EXAMPLE 2 ME EQUIPMENT containing HAZARDOUS SUBSTANCES AND MATERIALS.

The packaging of ME EQUIPMENT or ACCESSORIES supplied sterile shall be marked as sterile (see ISO 15223).

Compliance is checked by inspection.

7.2.16 External PRESSURE source

The RATED maximum supply PRESSURE from an external source shall be marked on the ME EQUIPMENT adjacent to each input connector.[56]

Compliance is checked by inspection.

7.2.17 FUNCTIONAL EARTH TERMINALS[57]

A FUNCTIONAL EARTH TERMINAL shall be marked with Symbol IEC 60417-5017 (see Table D1, Symbol 7).

[58]*Compliance is checked by inspection.*

7.2.18 Removable protective means

If ME EQUIPMENT has alternative applications that require the removal of a protective means to utilize a particular function, the protective means shall be marked to indicate the necessity for replacement when the relevant function is no longer needed. No marking is required when an interlock is provided.

Compliance is checked by inspection.

7.3 Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts (see also Table C2)

7.3.1 Heating elements or lampholders

The maximum power loading of heating elements or lampholders designed for use with heating lamps shall be CLEARLY LEGIBLE and PERMANENTLY AFFIXED near the heater or in the heater itself.

For heating elements or lampholders designed for use with heating lamps not intended to be changed by the OPERATOR and that can be changed only with the use of a TOOL, an identifying marking referring to information stated in the ACCOMPANYING DOCUMENTS is sufficient.

7.3.2 HIGH VOLTAGE parts

The presence of HIGH VOLTAGE parts shall be marked with Symbol IEC 60417-5036 (see Table D1, Symbol 23).

7.3.3 Batteries

The type of battery and the mode of insertion (if applicable) shall be marked (see 15.4.3.2).

For batteries not intended to be changed by the OPERATOR and that can be changed only with the use of a TOOL, an identifying marking referring to information stated in the ACCOMPANYING DOCUMENTS is sufficient.

Where lithium batteries[59] or fuel cells are incorporated, a warning indicating that replacement by inadequately trained personnel could result in explosion shall be given in addition to the identifying marking referring to information stated in the ACCOMPANYING DOCUMENTS.

7.3.4 *Fuses, THERMAL CUT-OUTS and OVER-CURRENT RELEASES

Fuses and replaceable THERMAL CUT-OUTS and OVER-CURRENT RELEASES that are accessible only by the use of a TOOL shall be identified either by type and full rating next to the component, or by a reference to information in the ACCOMPANYING DOCUMENTS.[60]

NOTE The rupturing speed may be marked by the letter or colour codes of IEC 60127, which are as follows:

- very quick acting: FF, or black;
- quick acting: F, or red;
- medium time lag: M, or yellow;
- time lag: T, or blue;
- long time lag: TT, or grey

7.3.5 PROTECTIVE EARTH TERMINALS

PROTECTIVE EARTH TERMINALS shall be marked with Symbol IEC 60417-5019 (see Table D1, Symbol 6) unless the PROTECTIVE EARTH TERMINAL is in an APPLIANCE INLET according to IEC 60320-1.

7.3.6 FUNCTIONAL EARTH TERMINALS

FUNCTIONAL EARTH TERMINALS shall be marked with Symbol IEC 60417-5017 (see Table D1, Symbol 7).

7.3.7 Supply terminals[61]

Terminals that are provided exclusively for the connection of the neutral supply conductor in PERMANENTLY INSTALLED ME EQUIPMENT shall be marked with the appropriate code from IEC 60445 (see Table D3, Code 1).

The correct method of connection of the supply conductors shall be marked clearly with terminal marking that should be affixed adjacent to the terminals, unless no HAZARD can develop if connections are interchanged.

If ME EQUIPMENT is so small that the terminal marking cannot be affixed, it shall be included in the ACCOMPANYING DOCUMENTS. If marking for connection to a three-phase supply is necessary, it shall be according to IEC 60445.

Markings required in this subclause and in 7.3.5, 7.3.7 and 7.3.8 that are on or near electrical connection points shall not be affixed to parts that have to be removed to make the connection. They shall remain visible after the connection has been made.

Markings on or near terminals shall comply with IEC 60445.

7.3.8 Temperature of supply terminals

If any point within a terminal box or wiring compartment intended for connection of the power supply conductors for PERMANENTLY INSTALLED ME EQUIPMENT (including such conductors themselves), attains a temperature of more than 75 °C during NORMAL USE and NORMAL CONDITION at the maximum ambient operating temperature as specified by the MANUFACTURER, the ME EQUIPMENT shall be marked with the following or an equivalent statement:

"For supply connections, use wiring materials suitable for at least...°C".

This statement shall be located at or near the point where the supply connections are to be made and shall be CLEARLY LEGIBLE after the connections have been made.

7.3.9 Hazardous Energies

Capacitors or the connected circuit parts shall be marked as required in 8.4.4.

7.3.10 HAZARDOUS SUBSTANCES AND MATERIALS

HAZARDOUS SUBSTANCES AND MATERIALS shall be marked with Symbol IEC 60417-xxx1Pr (see Table D1, Symbol 27). Where marking is not practical, the location of HAZARDOUS SUBSTANCES AND MATERIALS in the ME EQUIPMENT shall be described in the required list of HAZARDOUS SUBSTANCES AND MATERIALS (see 7.10.3.7).[62]

Compliance with the requirements of 7.3 is checked by inspection and by application of the tests and criteria in 7.1.2 and 7.1.3.

7.4 Marking of controls and instruments (see also Table C3)

7.4.1 Power switches

Switches used to control power to ME EQUIPMENT or its parts, including mains switches, shall have their “on” and “off” positions marked with Symbols IEC 60417-5007 and IEC 60417-5008 (see Table D1, Symbols 11 and 12), or indicated by an adjacent indicator light or by other unambiguous means. If a push button with stable positions is used, it shall be marked with either Symbol IEC 60417-5010 or Symbol 60417-5011 as appropriate (see Table D1, Symbols 13 and 14) together with the symbols for “on” and “off” positions.

7.4.2 Control devices

Different positions of control devices and different positions of switches on ME EQUIPMENT shall be indicated by figures, letters or other visual means, e.g. by use of Symbols IEC 60417-5264 and IEC 60417-5265 (see Table D1, Symbols 15 and 16).

If in NORMAL USE the change of setting of a control could cause an unacceptable RISK to the PATIENT, such controls shall be provided with either:

– an associated indicating device, e.g. instruments or scale, or

– an indication of the direction in which the magnitude of the function changes. See also 15.4.6.2.

7.4.3 Units of measure

Numeric indications of parameters shall be in SI units according to ISO 1000 with the addition of the following units outside the SI units system that can be used on ME EQUIPMENT:

Plane angle units:

revolution,

grade,

degree,

minute of angle,

second of angle;

Time units:

minute,

hour,

day;

Energy unit:

electron volt;

Pressure of blood and other body fluids:

millimetre of mercury (mm Hg),

centimetres of water (cm H_2O);

Pressure of gasses:[63]

Bar,

milli-Bar.

Compliance with the requirements of 7.4 is checked by inspection and by application of the tests and criteria in 7.1.2 and 7.1.3.

7.5 Safely signs

For the purpose of this clause, markings used to convey warnings (There is certain danger), prohibitions (You must not…) or mandatory actions (You must…) that mitigate RISK that are not obvious to the OPERATOR shall be safety signs selected from ISO 7010. Where a safety sign is not available to indicate a particular desired meaning, the meaning may be obtained by using the warning sign from Clause 5, Table 1 of ISO 3864-1 together with a supplementary symbol or together with text (see Table D2, Safely sign 1).

NOTE The colours for safety signs are specified in ISO 3864-1.

These safety signs shall be explained in the ACCOMPANYING DOCUMENTS (see 7.10.1).

The safety sign shall be followed by an affirmative statement (i.e., a safety notice) describing the principal RISK(S) foreseen (e.g. “Causes burns”, “Risk of explosion”, etc.). If there is insufficient space to place the affirmative statement on the ME EQUIPMENT, it may be placed in the instructions for use.

NOTE A safety notice should include the appropriate precautions or include instructions on how to reduce the RISK (e.g. “Do not use for . . . ”, “Keep away from . . .”, etc.).[64]

7.6 Symbols

7.6.1 Explanation of symbols

The meaning of the symbols used for marking shall be explained in the instructions for use.

Compliance is checked by inspection.

7.6.2 Symbols from Annex D

Symbols required by this standard shall conform to the requirements in the referenced IEC or ISO publication. Annex D provides the symbol graphic and description for these symbols as a quick reference.

NOTE The colour of symbols is not specified.

7.6.3 Symbols for controls and performance

Symbols used for controls and performance shall conform to the requirements of the IEC or ISO publication where the symbol is defined, where applicable. See also 7.2.11.

NOTE 1 The colour of symbols is not specified.

NOTE 2 IEC/TR 60878 provides a survey of titles, descriptions and graphical representations of symbols for electrical equipment used in medical practice.

Compliance is checked by application of the tests and criteria in 7.1.2 and 7.1.3.

7.7 Colours of the insulation of conductors

7.7.1 PROTECTIVE EARTH CONDUCTOR

A PROTECTIVE EARTH CONDUCTOR shall be identified throughout its length by green and yellow coloured insulation.

7.7.2 PROTECTIVE EARTH CONNECTIONS

Any insulation on conductors inside ME EQUIPMENT that form PROTECTIVE EARTH CONNECTIONS shall be identified by the colours green and yellow at least at the termination of the conductors.

EXAMPLE Conductors of a multi-conductor cord that are connected in parallel, where the maximum allowed resistance of the PROTECTIVE EARTH CONNECTIONS would be exceeded if only the green and yellow coloured conductor were used.

7.7.3 Green and yellow insulation

Identification by green and yellow insulation shall only be used for:

– PROTECTIVE EARTH CONDUCTORS (see 8.6.2);

– Conductors as specified in 7.7.2;

– POTENTIAL EQUALIZATION CONDUCTORS (see 8.6.7);

– FUNCTIONAL EARTH CONDUCTORS (see 8.6.9).

7.7.4 Neutral conductor

Conductors in POWER SUPPLY CORDS intended to be connected to the neutral conductor of the supply system shall be coloured “light blue” as specified in IEC 60227-1 or in IEC 60245-1.

7.7.5 POWER SUPPLY CORDS conductors

Colours of conductors in POWER SUPPLY CORDS shall be in accordance with IEC 60227-1 or with IEC 60245-1.

Compliance with the requirements of 7.7 is checked by inspection.

7.8 Identification of medical gas cylinders and connections

7.8.1 Gas cylinders colours

Identification of the content of gas cylinders used in medical practice as a part of ME EQUIPMENT shall be in accordance with ISO 32. See also 15.4.1.

7.8.2 Gas cylinders connections

The point of connection of gas cylinders shall be so identified on ME EQUIPMENT that errors are avoided when a replacement is made.

Compliance with the requirements of 7.8 is checked by inspection of the identification of the content, and the point of connection of gas cylinders.

7.9 *Indicator lights and controls[65]

7.9.1 Colours of indicator lights

The colours of indicator lights and their meanings shall comply with Table 1.

Dot-matrix and other alphanumeric displays are not considered to be indicator lights.

7.9.2 Colours of controls

The colour red shall be used only for a control by which a function is interrupted in case of emergency.

Compliance with the requirements of 7.9 is checked by inspection. See also 15.4.4.

Table 1 – Colours of indicator lights and their meaning for ME EQUIPMENT

Colour	Meaning
Red	Warning – immediate OPERATOR response is required
Yellow	Caution – prompt OPERATOR response or OPERATOR awareness is required
Green	Ready for use
Any other colour	Meaning other than that of red, yellow or green.

7.10 ACCOMPANYING DOCUMENTS

7.10.1 *General (see also Table C4)

ME EQUIPMENT shall be accompanied by documents containing at least the instructions for use and a technical description. The ACCOMPANYING DOCUMENTS shall be regarded as a part of the ME EQUIPMENT.

NOTE The purpose of the ACCOMPANYING DOCUMENTS is to promote the safe use of the ME EQUIPMENT during its useful life.

The ACCOMPANYING DOCUMENTS shall identify the ME EQUIPMENT by including, as applicable, the following:

– Name or trade-name of the MANUFACTURER, and an address to which the RESPONSIBLE ORGANIZATION can refer

– MODEL OR TYPE REFERENCE (see 7.2.2)

A PROGRAMMABLE ELECTRICAL MEDICAL SYSTEM (PEMS) shall be identified with a unique identifier, such as, revision level or date of release/issue.[66]

ACCOMPANYING DOCUMENTS may be provided electronically, e.g. electronic file format or CD-ROM, for ME EQUIPMENT capable of displaying or printing those documents. If the ACCOMPANYING DOCUMENTS are provided electronically, the RISK MANAGEMENT PROCESS shall include consideration of which information also needs to be provided as hard copy or as markings on the ME EQUIPMENT, e.g. to cover emergency operation.

The ACCOMPANYING DOCUMENTS shall specify the required skills, training and knowledge of the intended USER and any restrictions on locations or environments in which the ME EQUIPMENT can be used.

NOTE The intended USER is any person that the MANUFACTURER intends to interact with the ME EQUIPMENT e.g. the OPERATOR, SERVICE PERSONNEL, and the RESPONSIBLE ORGANIZATION.

The ACCOMPANYING DOCUMENTS shall be written at a level consistent with the education, training and any special needs of the intended USER.

Additional requirements for the ACCOMPANYING DOCUMENTS for ME SYSTEMS are specified in 16.2.

Additional requirements for the ACCOMPANYING DOCUMENTS relating to electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS are found in IEC 60601-1-2.

NOTE Guidance on the preparation of instructions for use is found in IEC 62079.

Compliance is checked by inspection.

7.10.2 **Instructions for use** (see also Table C5)

7.10.2.1 *General

The MANUFACTURER shall document the INTENDED USE/INTENDED PURPOSE and the functions frequently used or related to the basic SAFETY or ESSENTIAL PERFORMANCE of the ME EQUIPMENT and any known contraindication(s) to the use of the ME EQUIPMENT in the instructions for use.

All applicable classifications specified in Clause 6, all markings specified in 7.2, and warning statements and the explanation of safety signs (marked on the ME EQUIPMENT) shall be included in the instructions for use.

A brief description of the ME EQUIPMENT, how the ME EQUIPMENT functions, and its significant physical and performance characteristics shall be included in the instructions for use.

NOTE The instructions for use are intended for the OPERATOR or RESPONSIBLE ORGANIZATION.

The instructions for use shall be in a language that is acceptable to the intended OPERATOR.[67]

7.10.2.2 *Warning and safety notices

All warning and safety notices shall be listed in the instructions for use.

NOTE General warnings and safety notices should be placed in a specifically identified section of the instructions for use. A warning or safety notice that applies only to a specific instruction or action should precede the instruction to which it applies.

For CLASS I ME EQUIPMENT, a warning statement shall be included in the instructions for use to the effect: “WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.”

The instructions for use shall provide the OPERATOR or RESPONSIBLE ORGANIZATION with warnings regarding any significant RISKS of reciprocal interference posed by the presence of the ME EQUIPMENTduring specific investigations or treatments.

The instructions for use shall state the maximum surface temperature of any APPLIED PART if the surface temperature of that APPLIED PART exceeds 41 °C (see 11.1.2).

7.10.2.3 ME EQUIPMENT specified for connection to a separate power supply

If ME EQUIPMENT is intended for connection to a separate power supply, either the power supply shall be specified as part of the ME EQUIPMENT or the combination shall be specified as an ME SYSTEM. This specification shall be disclosed in the instructions for use.

7.10.2.4 Alternative electrical power source

For mains operated ME EQUIPMENT with an additional power source not automatically maintained in a fully usable condition, the instructions for use shall contain a warning statement referring to the necessity for periodic checking or replacement of such an additional power source.

If leakage from a battery would cause an unacceptable RISK, the instructions for use shall contain a warning to remove the battery if the ME EQUIPMENT is not likely to be used for some time.

An INTERNAL ELECTRICAL POWER SOURCE, if replaceable, shall be specified by the MANUFACTURER.

If the safe use of ME EQUIPMENT requires the continuity of the power source, the instruction for use shall contain a warning that the ME EQUIPMENT must be connected to an appropriate power source.

EXAMPLE Internal or external battery, uninterruptible power supply (UPS) or institutional stand-by generator.

7.10.2.5 ME EQUIPMENT description

The instructions for use shall include the physical and performance characteristics of the ME EQUIPMENT. In applicable, this description shall include the expected positions of the OPERATOR, PATIENT and other persons near the ME EQUIPMENT in NORMAL USE (see 9.2.2.3).

The instructions for use shall include information on the materials or ingredients to which the PATIENT or OPERATOR is exposed if such exposure may constitute an unacceptable RISK[68] (see 11.7).

NOTE The instructions for use should contain only the information most likely to be useful to the OPERATOR or RESPONSIBLE ORGANIZATION. Additional details may be contained in the technical description. See also 7.10.3.

The instructions for use shall specify any restrictions on other equipment or NETWORK/DATA COUPLINGS, other than those forming part of an ME SYSTEM, to which a SIGNAL INPUT/OUTPUT PART may be connected.

If applicable, the instructions for use shall include information on the energy saving modes mentioned in 18.2.4.2.

If applicable, the instructions for use shall include information on water consumption mentioned in 18.2.4.4.

If applicable, the instruction for use shall include information on the intended mode of operation (e.g. single use, single PATIENT, single session) of DISPOSABLES or MEDICAL DISPOSABLES mentioned in 18.2.7.[69]

7.10.2.6 *Installation

If installation of the ME EQUIPMENT or its parts is required, the instructions for use shall contain a reference to where these installation instructions are to be found (e.g. the technical description), or contact information for SERVICE PERSONNEL qualified to perform the installation[70].

7.10.2.7 *Isolation from the SUPPLY MAINS[71]

If an APPLIANCE COUPLER or separable plug is used as the isolation means to satisfy 8.11.1 *a)*, the instructions for use shall contain an instruction not to position the ME EQUIPMENT so that it is difficult to operate the disconnection device.

7.10.2.8 Start-up PROCEDURE

The instructions for use shall contain the necessary information for the OPERATOR to bring the equipment into operation including such items as any initial control settings, connection to or positioning of the PATIENT, etc.

The instructions for use shall detail any treatment or handling needed before the ME EQUIPMENT, its parts, or ACCESSORIES can be used.

EXAMPLE A pre-use checklist

7.10.2.9 Operating instructions

The instructions for use shall contain all information necessary to operate the ME EQUIPMENT in accordance with its specification. This shall include explanation of the function of controls, displays and signals, the sequence of operation, connection and disconnection of detachable parts and ACCESSORIES, and replacement of MATERIAL TO BE CONSUMED during use.

The meaning of figures, symbols, warning statements, abbreviations and indicator lights on ME EQUIPMENT shall be explained in the instructions for use.

7.10.2.10 Information signals and alarm conditions

The instructions for use shall list all system messages, error messages, fault messages, information signals and alarm conditions that annunciate.

NOTE These lists may be identified in groups.

The instructions for use shall explain the meanings of messages and alarm conditions including important causes, and possible OPERATOR action, if any, to resolve the message or alarm condition.

7.10.2.11 Shutdown PROCEDURE

The instructions for use shall contain the necessary information for the OPERATOR to safely terminate the operation of the ME EQUIPMENT.

7.10.2.12 Cleaning, disinfection and sterilization

For ME EQUIPMENT with parts or ACCESSORIES that may become contaminated through contact with the PATIENT during NORMAL USE except for MEDICAL DISPOSABLES sterilized by the MANUFACTURER, the instructions for use shall contain details about cleaning, disinfection or sterilization methods that may be used and list the temperature, pressure, humidity and time limits that such ME EQUIPMENT parts or ACCESSORIES can tolerate. See also 11.6.6 and 11.6.7.

7.10.2.13 Maintenance

The instructions for use shall instruct the OPERATOR or RESPONSIBLE ORGANIZATION in sufficient detail concerning preventive inspection and maintenance to be performed by them, including the frequency of such maintenance.

The instructions shall provide information for the safe performance of such routine maintenance necessary to ensure the continued safe use of the ME EQUIPMENT.

Additionally, instructions for use shall identify the parts on which preventive inspection and maintenance shall be performed by SERVICE PERSONNEL, including the periods to be applied, but not necessarily including details about the actual performance of such maintenance.

For ME EQUIPMENT containing rechargeable batteries, the instructions for use shall contain instructions to ensure adequate maintenance.

7.10.2.14 ACCESSORIES, supplementary equipment, used material

The instructions for use shall include a list of ACCESSORIES, detachable parts and materials that the MANUFACTURER has determined are intended for use with the ME EQUIPMENT.

If ME EQUIPMENT is intended to receive its power from other equipment in an ME SYSTEM, the instructions for use shall sufficiently specify such other equipment to ensure compliance with the requirements of this standard (e.g. part number, RATED voltage, maximum or minimum power, protection class, intermittent or continuous service).

NOTE What was referred to in the first and second editions of this standard as a “specified power supply” is considered either as another part of the same ME EQUIPMENT or as other equipment in an ME SYSTEM. Similarly, a battery charger is considered either as part of the ME EQUIPMENT or as other equipment in an ME SYSTEM.

7.10.2.15 Reference to the technical description

The instructions for use shall contain the information specified in 7.10.3 or a reference to where the material specified in 7.10.3 is to be found (e.g. in a service manual).

Compliance with the requirements of 7.10.2 is checked by inspection of the instructions for use.

7.10.3 Technical description (see also Table C6)

7.10.3.1 *General

The technical description shall provide all data that is essential for safe operation, storage and transport, and measures or conditions necessary for installing the ME EQUIPMENT, and preparing it for use. This shall include:

– The information required in 7.2.

– The permissible environmental conditions of use including conditions for transport and storage. See also 7.2.15.[72]

– All characteristics of the ME EQUIPMENT, including range(s), accuracy, and precision of the displayed values or an indication where they can be found.

– If liquid is used for cooling, the permissible range of values of inlet pressure and flow, and the chemical composition of the cooling liquid.

– A description of the means of isolating the ME EQUIPMENT from the SUPPLY MAINS, if such means is not incorporated in the ME EQUIPMENT (see 8.11.1 *b)*).[73]

– If applicable, a description of the means for checking the oil level in partially sealed oil-filled ME EQUIPMENT or its parts (see 15.4.9).[74]

– A warning statement to the effect: "WARNING: If the ME EQUIPMENT is modified, appropriate inspection and test must be conducted to ensure continued safe use of the ME EQUIPMENT."

– The data mentioned in 18.2.6 where applicable.[75]

If the technical description is separable from the instructions for use, it shall contain:

– All applicable classifications specified in Clause 6 and warning statements and the explanation of warning symbols (marked on the ME EQUIPMENT).

– A brief description of the ME EQUIPMENT, how the ME EQUIPMENT functions, and its significant physical and performance characteristics.

NOTE The technical description is intended for the RESPONSIBLE ORGANIZATION and SERVICE PERSONNEL.

The MANUFACTURER may designate the minimum qualifications for SERVICE PERSONNEL. If present, these requirements shall be documented in the technical description.

NOTE Some authorities with jurisdiction impose additional requirements for qualification of SERVICE PERSONNEL.[76]

7.10.3.2 Replacement of fuses, POWER SUPPLY CORDS and other parts

The technical description shall contain, as applicable, the following:

– If the type and rating of fuses utilized in the mains supply circuit external to PERMANENTLY INSTALLED ME EQUIPMENT is not apparent from the information concerning RATED current and mode of operation of ME EQUIPMENT, the required type and full rating of fuses.

– For ME EQUIPMENT having a non-DETACHABLE POWER SUPPLY CORD, a statement as to whether the POWER SUPPLY CORD is replaceable by SERVICE PERSONNEL, and, if so, instructions for correct connection and anchoring to ensure that the requirements of 8.11.3 will continue to be met.

– Instructions for correct replacement of interchangeable or detachable parts that the MANUFACTURER specifies as replaceable by SERVICE PERSONNEL.

– Where replacement of a component could result in an unacceptable RISK,[77] appropriate warnings that identify the nature of the HAZARD and provide all information necessary to safely replace the component.

7.10.3.3 Circuit diagrams, component part lists, etc.

The technical description shall contain a statement that the MANUFACTURER will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist SERVICE PERSONNEL to repair those parts of ME EQUIPMENT that are designated by the MANUFACTURER as repairable by SERVICE PERSONNEL.

7.10.3.4 Energy consumption

The technical description shall include the data mentioned in 18.2.4.2.

7.10.3.5 NETWORK/DATA COUPLING

The technical description shall include the data mentioned in 14.13.[78]

7.10.3.6 Mains isolation switch

The technical description shall clearly identify any mains isolation switch used to comply with the requirements of 8.11.1.[79]

7.10.3.7 HAZARDOUS SUBSTANCES AND MATERIALS

The technical description shall include the list of HAZARDOUS SUBSTANCES AND MATERIALS used for or by ME EQUIPMENT and their quantities. See also 18.2.2.[80]

Compliance with the requirements of 7.10.3 is checked by inspection of the technical description.

8. *Protection against electrical HAZARDS FROM ME EQUIPMENT

8.1 Fundamental rule of protection against electric shock

ACCESSIBLE PARTS of ME EQUIPMENT including PATIENT CONNECTIONS shall not exceed the limits specified in 8.4, in NORMAL CONDITION or SINGLE FAULT CONDITION.

a) *NORMAL CONDITION includes all of the following simultaneously:

– the presence on any SIGNAL INPUT/OUTPUT PART of any voltage or current from other electrical equipment that is permitted to be connected according to the ACCOMPANYING DOCUMENTS or, if the ACCOMPANYING DOCUMENTS place no restrictions on such other electrical equipment, the presence of the MAXIMUM MAINS VOLTAGE;

– transposition of supply connections, for ME EQUIPMENT intended for connection to a SUPPLY MAINS by means of a MAINS PLUG;

– short-circuit of any or all insulation that does not comply with the requirements of 8.8;

– short-circuit of any or all CREEPAGE DISTANCES or AIR CLEARANCES that do not comply with the requirements of 8.9;

– open-circuit of any or all earth connections that do not comply with the requirements of 8.6, including any functional earth connection.

b) *SINGLE FAULT CONDITIONS include:

– short-circuit of any one insulation that complies with the requirements for one MEANS OF PROTECTION as specified in 8.8;

– short-circuit of any one CREEPAGE DISTANCE or AIR CLEARANCE that complies with the requirements for one MEANS OF PROTECTION as specified in 8.9;

– short-circuit of any component other than a HIGH-INTEGRITY COMPONENT that is connected in parallel with insulation, with an AIR CLEARANCE or with a CREEPAGE DISTANCE unless shorting can be shown not to be a failure mode for the component (see also 4.6);

– open-circuit of any one PROTECTIVE EARTH CONDUCTOR or internal PROTECTIVE EARTH CONNECTION that complies with the requirements of 8.6: this does not apply to a PROTECTIVE EARTH CONDUCTOR of PERMANENTLY INSTALLED ME EQUIPMENT, which is considered unlikely to become disconnected;

– interruption of any one supply conductor, except for the neutral conductor of polyphase ME EQUIPMENT or PERMANENTLY INSTALLED ME EQUIPMENT;

– interruption of any one power-carrying conductor between ME EQUIPMENT parts in separate ENCLOSURES, if the RISK ANALYSIS indicates that this condition might cause permitted limits to be exceeded;

– unintended movement of a component; but only if the component is not mounted securely enough to ensure that such movement will be very unlikely to occur during the useful life of the ME EQUIPMENT, as determined by the RISK MANAGEMENT PROCESS (See also 8.10.1.);

– accidental detachment of conductors and connectors where breaking free could lead to a HAZARD. See also 8.10.2.

Determination of which parts are ACCESSIBLE PARTS is carried out in accordance with 5.9.

LEAKAGE CURRENTS are measured in accordance with 8.7.

8.2 Requirements related to power sources

8.2.1 Connection to a separate power source

If ME EQUIPMENT is specified for connection to a separate power source, other than the SUPPLY MAINS, either the separate power source shall be considered as part of the ME EQUIPMENT and all relevant requirements of this standard shall apply, or the combination shall be considered as an ME SYSTEM. See also 7.2.4, 7.10.2.14, 5.5 *g)* and Clause 16.

NOTE What was formerly referred to, in the first and second editions of this standard, as a "specified power supply" is now considered either as another part of the same ME EQUIPMENT or as another electrical equipment in an ME SYSTEM.

Compliance is checked by inspection and by testing as specified in 5.5 g). *If a particular separate power supply is specified then the relevant tests are performed with the ME EQUIPMENT connected to it. If a generic separate power supply is specified, then the specification in the ACCOMPANYING DOCUMENTS is inspected.*

8.2.2 Connection to an external d.c. power source

If ME EQUIPMENT is specified for power supplied from an external d.c. power source, no HAZARD, other than absence of function, shall develop when a connection with the wrong polarity is made and the ME EQUIPMENT shall provide ESSENTIAL PERFORMANCE as described in the ACCOMPANYING DOCUMENTS when connection is subsequently made with the correct polarity.

NOTE The external d.c. power source can be a SUPPLY MAINS or another item of electrical equipment. In the latter case, the combination is considered to be an ME SYSTEM as specified in 8.2.1.

Compliance is checked by inspection and, if necessary, by functional tests.[81]

8.3 Classification of APPLIED PARTS

a) *An APPLIED PART that is specified in the ACCOMPANYING DOCUMENTS as suitable for DIRECT CARDIAC APPLICATION shall be a TYPE CF APPLIED PART.

NOTE Other restrictions may apply for cardiac applications.

Compliance is checked by inspection.

b) *An APPLIED PART that includes a PATIENT CONNECTION that is intended to deliver electrical energy or an electrophysiological signal to or from the PATIENT shall be a TYPE BF APPLIED PART or TYPE CF APPLIED PART.

Compliance is checked by inspection.

c) An APPLIED PART not covered by *a)* or *b)* shall be a TYPE B APPLIED PART, TYPE BF APPLIED PART or TYPE CF APPLIED PART.

Compliance is checked by inspection.

d) *For a part that is identified according to 4.4 as needing to be subject to the requirements for an APPLIED PART (except for marking), the requirements for a TYPE B APPLIED PART shall apply unless the RISK MANAGEMENT PROCESS identifies a need for the requirements for a TYPE BF APPLIED PART or TYPE CF APPLIED PART to apply.

8.4 Limitation of voltage, current or energy

8.4.1 *PATIENT CONNECTIONS intended to deliver current

The limits specified in 8.4.2 do not apply to an electrode intended to deliver current to the body of the PATIENT to produce a physiological effect during NORMAL USE.

8.4.2 ACCESSIBLE PARTS including APPLIED PARTS

a) The currents from, to or between PATIENT CONNECTIONS shall not exceed the limits for PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT specified in Table 2 when measured as specified in 8.7.

Compliance is checked by measurement according to 8.7.

b) *The LEAKAGE CURRENTS from, to or between ACCESSIBLE PARTS other than PATIENT CONNECTIONS shall not exceed the limits for TOUCH CURRENT specified in Table 2 when measured as specified in 8.7.

Compliance is checked by measurement according to 8.7.

c) *The limits specified in *b)* above do not apply to the following parts if the probability of a connection to a PATIENT, either directly or through the body of the OPERATOR, through which a current exceeding the allowable TOUCH CURRENT could flow, is negligible in NORMAL USE, and the instructions for use instruct the OPERATOR not to touch the relevant part and the PATIENT simultaneously:

– accessible contacts of connectors,

– contacts of fuseholders that are accessible during replacement of the fuse,

– contacts of lampholders that are accessible after removal of the lamp,

– parts inside an ACCESS COVER that can be opened without the use of a TOOL, or where a TOOL is needed but the instructions for use instruct the OPERATOR to open the relevant ACCESS COVER.

EXAMPLE 1 illuminated push-buttons;

EXAMPLE 2 indicator lamps;

EXAMPLE 3 recorder pens;

EXAMPLE 4 parts of plug-in modules;

EXAMPLE 5 batteries.

For such parts, the voltage to earth or to other ACCESSIBLE PARTS shall not exceed 42,4 V peak a.c. or 60 V d.c. in NORMAL CONDITION or in SINGLE FAULT CONDITION. The d.c. limit of 60 V applies to d.c. with not more than 10 % peak-to-peak ripple. If the ripple exceeds that amount, the 42,4 V peak limit applies.

Compliance is checked by inspection of the RISK MANAGEMENT FILE, by reference to the instructions for use and by measurement.

d) *The voltage limits specified in *c)* above also apply to:

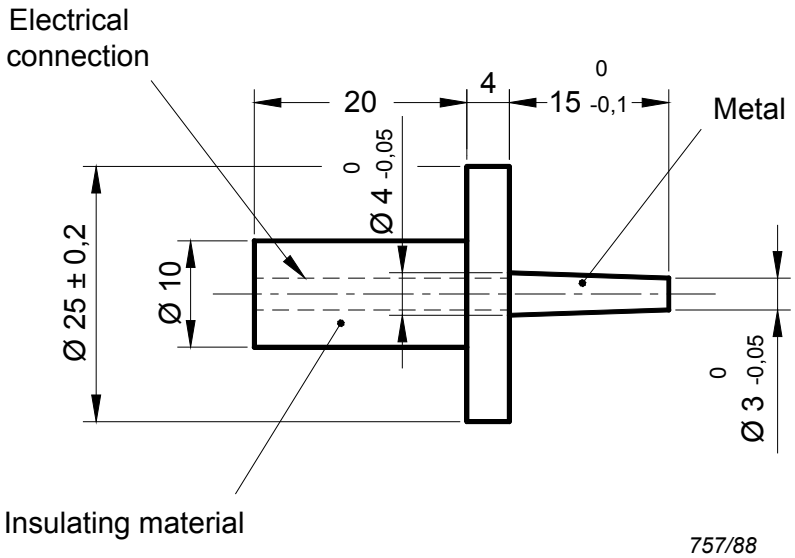
– internal parts, other than contacts of plugs, connectors and socket-outlets, that can be touched by the test pin shown in Figure 8 inserted through an opening in an ENCLOSURE; and

– internal parts that can be touched by a metal test rod with a diameter of 4 mm and a length of 100 mm, inserted through any opening in the top of an ENCLOSURE or through any opening provided for the adjustment of pre-set controls that may be adjusted by the RESPONSIBLE ORGANIZATION in NORMAL USE by using a TOOL. See also 8.9.4 concerning the measurement of CREEPAGE DISTANCES and AIR CLEARANCES through slots or openings in external parts to the standard test finger.

Compliance is checked by inserting the test pin or the test rod through relevant openings. The test pin is inserted in every possible position with minimal force (not more than 1 N).

The test rod is inserted in every possible position through openings provided for the adjustment of pre-set controls that may be adjusted by the RESPONSIBLE ORGANIZATION in NORMAL USE), in case of doubt with a force of 10 N. If the instructions for use specify that a particular TOOL is to be used, the test is repeated with that TOOL.

The test rod is also freely and vertically suspended through any opening in the top of an ENCLOSURE



Dimensions in millimetres, material: steel

Figure 8 – Test pin
(see 8.4.2 *d)*)

e) Where an ACCESS COVER that can be opened without the use of a TOOL gives access to parts that are normally at voltages above the levels permitted by this subclause, but these parts are automatically de-energized when the ACCESS COVER is opened, the device(s) used to de-energize the parts shall meet the requirements specified in 8.11.1 for mains isolating switches and shall remain effective in SINGLE FAULT CONDITION. If it is possible to prevent these devices from operating, a TOOL shall be required.

Compliance is checked by inspection

8.4.3 *ME EQUIPMENT intended to be connected to a power source by a plug

ME EQUIPMENT or its parts intended to be connected to a power source by means of a plug shall be so designed that 1 s after disconnection of the plug the voltage between the supply pins of the plug and between either supply pin and the ENCLOSURE does not exceed 60 V or, if this value is exceeded, the stored charge does not exceed 45 µC.

Compliance is checked by the following test:

ME EQUIPMENT is operated at RATED voltage or at the upper limit of the RATED voltage range.

ME EQUIPMENT is disconnected from the power source with any relevant switch in the "On" and "Off" positions.

Either the ME EQUIPMENT is disconnected from the power source by means of the plug, in which case the test is performed as many times as necessary to allow the worst case to be measured, or a triggering circuit is used to ensure that disconnection occurs at the peak of the supply voltage waveform.

The voltage between the pins of the plug and between any pin and the ENCLOSURE is measured 1 s after disconnection with an instrument the internal impedance of which does not affect the test.

The stored charge can be measured or calculated by any convenient method.

8.4.4 *Internal capacitive circuits

Conductive parts of capacitive circuits that become accessible after ME EQUIPMENT has been de-energized and ACCESS COVERS as present in NORMAL USE have been removed immediately

thereafter, shall not have a residual voltage exceeding 60 V, or, if this value is exceeded, shall not have a stored charge exceeding 45 µC.

If automatic discharging is not reasonably possible and ACCESS COVERS can be removed only with the aid of a TOOL, a device that is included and which permits manual discharging is acceptable. The capacitor(s) or the connected circuitry shall then be marked with Symbol IEC 60417-5036 (see Table D1, Symbol 23).

Compliance is checked by the following test:

ME EQUIPMENT is operated at RATED voltage and then de-energized. Any ACCESS COVERS present in NORMAL USE are removed as quickly as normally possible. Immediately thereafter, the residual voltage on any accessible capacitors or circuit parts is measured and the retained energy calculated. If a non-automatic discharging device is specified by the MANUFACTURER, its inclusion and marking are ascertained by inspection.[82]

8.5 Separation of parts

8.5.1 *MEANS OF PROTECTION

8.5.1.1 General

ME EQUIPMENT shall have two MEANS OF PROTECTION to prevent PATIENT CONNECTIONS and other ACCESSIBLE PARTS from exceeding the limits specified in 8.4.

Varnishing, enamelling, oxidation and similar protective finishes, as well as covering with sealing compounds that may replasticize at temperatures to be expected during operation (including sterilization), shall not be regarded as MEANS OF PROTECTION.

Components and wiring forming MEANS OF PROTECTION shall comply with the relevant requirements of 8.10.

Any insulation, CREEPAGE DISTANCE, AIR CLEARANCES, component or earth connection that does not comply with the requirements of 8.5.1 shall not be considered as a MEANS OF PROTECTION. Failure of any or all of such parts shall be regarded as NORMAL CONDITION.

8.5.1.2 MEANS OF PATIENT PROTECTION

Solid insulation forming a MEANS OF PATIENT PROTECTION shall comply with the dielectric strength test according to 8.8 at the test voltage specified in Table 3.

CREEPAGE DISTANCES and AIR CLEARANCES forming a MEANS OF PATIENT PROTECTION shall comply with the limits specified in Table 8.

PROTECTIVE EARTH CONNECTIONS forming a MEANS OF PATIENT PROTECTION shall comply with the requirements and tests of 8.6.

8.5.1.3 MEANS OF OPERATOR PROTECTION

Solid insulation forming a MEANS OF OPERATOR PROTECTION shall:

– comply with the dielectric strength test according to 8.8 at the test voltage specified in Table 3; or

– comply with the requirements of IEC 60950-1 for insulation co-ordination; or

– comply with the requirements for solid insulation forming a MEANS OF PATIENT PROTECTION.

CREEPAGE DISTANCES and AIR CLEARANCES forming a MEANS OF OPERATOR PROTECTION shall:

– comply with the limits specified in Table 9 to Table 12 (inclusive); or

– comply with the requirements of IEC 60950-1 for insulation co-ordination; or

– comply with the requirements for CREEPAGE DISTANCES and AIR CLEARANCES forming a MEANS OF PATIENT PROTECTION.

PROTECTIVE EARTH CONNECTIONS forming a MEANS OF OPERATOR PROTECTION shall either:

– comply with the requirements of 8.6; or

– comply with the requirements and tests of IEC 60950-1 for protective earthing.

Compliance with 8.5.1.1 to 8.5.1.3 (inclusive) is checked by examination of the physical and electrical configuration of the ME EQUIPMENT to identify points at which insulation, CREEPAGE DISTANCES, AIR CLEARANCES, impedances of components or PROTECTIVE EARTH CONNECTIONS prevent ACCESSIBLE PARTS from exceeding the limits specified in 8.4.

NOTE Such points typically include insulation between parts different from earth potential and ACCESSIBLE PARTS but may also include, for example, insulation between a floating circuit and earth or other circuits.

The REFERENCE VOLTAGE (U) is determined by inspection, calculation or measurement, according to 8.5.3.

For each such point, it is determined whether:

– *solid insulation complies with the dielectric strength test according to 8.8 or, for MEANS OF OPERATOR PROTECTION, with the requirements of IEC 60950-1 for insulation co-ordination;*

– *CREEPAGE DISTANCES and AIR CLEARANCES are as specified in 8.9 or, for MEANS OF OPERATOR PROTECTION, with the requirements of IEC 60950-1 for insulation co-ordination;*

– *components that are connected in parallel with an insulation, with an AIR CLEARANCE or with a CREEPAGE DISTANCE comply with 4.6 and 8.10.1;*

– *PROTECTIVE EARTH CONNECTIONS comply with the requirements of 8.6 or, for MEANS OF OPERATOR PROTECTION, with the requirements of IEC 60950-1 for protective earthing;*

and hence whether a failure at that point is to be regarded as a NORMAL CONDITION or as a SINGLE FAULT CONDITION.

Each MEANS OF PROTECTION is categorized in relation to the ME EQUIPMENT part(s) which it protects from exceeding permitted limits. It is a MEANS OF PATIENT PROTECTION if it protects APPLIED PARTS as defined in 3.8 or parts that are identified according to 4.4 as needing to be subject to the same requirements as APPLIED PARTS. Otherwise it is a MEANS OF OPERATOR PROTECTION.[83]

The REFERENCE VOLTAGE (U) is determined by inspection, calculation or measurement, according to 8.5.3.

The voltage, current, or energy that can appear between any ACCESSIBLE PART and any other ACCESSIBLE PART or earth in NORMAL CONDITION and in SINGLE FAULT CONDITION shall be determined by inspection or calculation or, where necessary, by measurement in the relevant conditions.

8.5.2 Separation of PATIENT CONNECTIONS

8.5.2.1 *F-TYPE APPLIED PARTS

The PATIENT CONNECTION(S) of any F-TYPE APPLIED PART shall be separated from all other parts, including the PATIENT CONNECTION(S) of other APPLIED PARTS, by means equivalent to one MEANS OF PATIENT PROTECTION for a REFERENCE VOLTAGE (*U*) equal to the MAXIMUM MAINS VOLTAGE and shall comply with the specified limit for PATIENT LEAKAGE CURRENT with 110 % of the MAXIMUM MAINS VOLTAGE applied.

NOTE A single F-TYPE APPLIED PART may include multiple functions, in which case separation between such functions is not required. Whether multiple functions are to be considered as all within one APPLIED PART or as multiple APPLIED PARTS is as defined by the MANUFACTURER. The classification TYPE BF, TYPE CF or DEFIBRILLATION-PROOF applies to the whole of one APPLIED PART.

Compliance is checked by inspection, by the LEAKAGE CURRENT tests of 8.7.3, by the dielectric strength test of 8.8.3 and by measurement of relevant CREEPAGE DISTANCES and AIR CLEARANCES.

NOTE The separation means between an F-TYPE APPLIED PART and other parts are subject both to these tests, related to the MAXIMUM MAINS VOLTAGE, and to tests related to the voltages present within the respective circuits as specified in 8.5.4. Depending on the magnitude of the latter voltages, one set of tests or the other may be more stringent.

Any protective device connected between PATIENT CONNECTIONS of an F-TYPE APPLIED PART and the ENCLOSURE for the purpose of providing protection against excessive voltages shall not operate below 500 V r.m.s.

Compliance is checked by testing the operating voltage of the protective device.

8.5.2.2 *TYPE B APPLIED PARTS

The PATIENT CONNECTION(S) of a TYPE B APPLIED PART that is not PROTECTIVELY EARTHED shall be separated by one MEANS OF PATIENT PROTECTION from metal ACCESSIBLE PARTS that are not PROTECTIVELY EARTHED, unless:

– the metal ACCESSIBLE PART is physically contiguous with the APPLIED PART and can be regarded as a part of the APPLIED PART; and

– the RISK that the metal ACCESSIBLE PART will make contact with a source of voltage or LEAKAGE CURRENT above permitted limits is acceptably low.

Compliance is checked by inspection, by the LEAKAGE CURRENT tests of 8.7.4, by the dielectric strength test of 8.8.3, by measurement of relevant CREEPAGE DISTANCES and AIR CLEARANCES, and by reference to the RISK MANAGEMENT FILE.

8.5.2.3 *PATIENT leads

Any connector on a PATIENT lead containing a conductive part that is not separated from all PATIENT CONNECTION(S) by one MEANS OF PATIENT PROTECTION for a REFERENCE VOLTAGE (U) equal to the MAXIMUM MAINS VOLTAGE shall be constructed so that the said part cannot become connected to earth or possible hazardous voltage while the PATIENT CONNECTION(S) contact the PATIENT. In particular:[84]

– the said part shall not come into contact with a flat conductive plate of not less than 100 mm diameter;

– the AIR CLEARANCE between connector pins and a flat surface shall be at least 0,5 mm;

– the straight unjointed test finger with the same dimensions as the standard test finger of Figure 6 shall not make electrical contact with the said part if applied in the least favourable position against the access openings with a force of 10 N ± 2 N, unless the RISK MANAGEMENT PROCESS demonstrates that no unacceptable RISK exists from contact with objects other than a mains socket or a flat surface (e.g. corners or edges);

– if able to be plugged into a mains socket, the said part shall be protected from making contact with parts at MAINS VOLTAGE by insulating means providing a CREEPAGE DISTANCE of at least 1,0 mm and a dielectric strength of 1 500 V and complying with 8.8.4.1.

Compliance is checked by inspection and test as required.

8.5.3 *MAXIMUM MAINS VOLTAGE

The MAXIMUM MAINS VOLTAGE shall be determined as follows:

– for single-phase or d.c. SUPPLY MAINS powered ME EQUIPMENT, including INTERNALLY POWERED ME EQUIPMENT that also has a means of connection to a SUPPLY MAINS, the MAXIMUM MAINS VOLTAGE is the highest RATED supply voltage; unless this is less than 100 V, in which case the MAXIMUM MAINS VOLTAGE is 250 V;

– for polyphase ME EQUIPMENT, the MAXIMUM MAINS VOLTAGE is the highest RATED phase to neutral supply voltage;

– for other INTERNALLY POWERED ME EQUIPMENT, the MAXIMUM MAINS VOLTAGE is 250 V.

8.5.4 *REFERENCE VOLTAGE

The REFERENCE VOLTAGE (*U*) for each MEANS OF PROTECTION shall be determined as follows:

For d.c. voltages with superimposed ripple, the REFERENCE VOLTAGE is the average value if the peak-to-peak ripple does not exceed 10 % of the average value or the peak voltage if the peak-to-peak ripple exceeds 10 % of the average value.

The REFERENCE VOLTAGE (*U*) for each part of insulation providing two MEANS OF PROTECTION is equal to the voltage to which that insulation providing two MEANS OF PROTECTION is subjected in NORMAL USE, NORMAL CONDITION and RATED supply voltage, the ME EQUIPMENT being energized at the voltage defined in *a)* above.

For REFERENCE VOLTAGES (*U*) involving a PATIENT CONNECTION not connected to earth, the situation in which the PATIENT is earthed (intentionally or accidentally) is regarded as a NORMAL CONDITION.[85] [86]

The REFERENCE VOLTAGE (*U*) between the PATIENT CONNECTION(S) of an F-TYPE APPLIED PART and the ENCLOSURE is taken as the highest voltage appearing across the insulation in NORMAL USE including earthing of any part of the APPLIED PART. See also 8.5.2.1.

For DEFIBRILLATION-PROOF APPLIED PARTS, the REFERENCE VOLTAGE (*U*) is determined without regard to the possible presence of defibrillation voltages. See also 8.5.5 and 8.9.1.14*)*.

In the case of motors provided with capacitors where a resonance voltage U_c may occur between the point where a winding and a capacitor are connected together on the one hand and any terminal for external conductors on the other hand, the REFERENCE VOLTAGE (*U*) shall be equal to U_c.

8.5.5 *DEFIBRILLATION-PROOF APPLIED PARTS

The classification DEFIBRILLATION-PROOF shall apply to the whole of one APPLIED PART.

See 8.9.1.14 for the requirements for CREEPAGE DISTANCES and AIR CLEARANCES associated with a DEFIBRILLATION-PROOF APPLIED PART.

Arrangements used to isolate the PATIENT CONNECTION(S) of a DEFIBRILLATION-PROOF APPLIED PART from other parts of ME EQUIPMENT shall be so designed that:

a) During a discharge of a cardiac defibrillator to a PATIENT connected to a DEFIBRILLATION-PROOF APPLIED PART, hazardous electrical energies, as determined by the peak voltage measured between the points Y_1 and Y_2 of Figure 9 and Figure 10 exceeding 1 V, do not appear on:

- the ENCLOSURE, including connectors in PATIENT leads and cables when connected to the ME EQUIPMENT;

  NOTE This requirement does not apply to a connecting lead from a DEFIBRILLATION-PROOF APPLIED PART or its connector when it is disconnected from the ME EQUIPMENT.

- any SIGNAL INPUT/OUTPUT PART;
- metal foil for test on which the ME EQUIPMENT is placed and which has an area at least equal to the base of the ME EQUIPMENT.
- PATIENT CONNECTIONS of any other APPLIED PART (whether or not classified as a DEFIBRILLATION-PROOF APPLIED PART).

b) Following exposure to the defibrillation voltage, and any necessary recovery time stated in the ACCOMPANYING DOCUMENTS, the ME EQUIPMENT shall comply with relevant requirements of this standard and shall continue to provide ESSENTIAL PERFORMANCE as described in the ACCOMPANYING DOCUMENTS.

Compliance is checked by the following tests, for each DEFIBRILLATION-PROOF APPLIED PART in turn:

Common-mode test

The ME EQUIPMENT is connected to the test circuit as shown in Figure 9. The test voltage is applied to all the PATIENT CONNECTIONS of the DEFIBRILLATION-PROOF APPLIED PART connected together, excluding any that are PROTECTIVELY EARTHED or functionally earthed.

Differential-mode test

The ME EQUIPMENT is connected to the test circuit as shown in Figure 10. The test voltage is applied to each PATIENT CONNECTION of the DEFIBRILLATION-PROOF APPLIED PART in turn with all the remaining PATIENT CONNECTIONS of the same DEFIBRILLATION-PROOF APPLIED PART being connected to earth.

NOTE The differential-mode test is not used when the APPLIED PART consists of a single PATIENT CONNECTION.

During each test:

– *the PROTECTIVE EARTH CONDUCTOR of CLASS I ME EQUIPMENT is connected to earth. CLASS I ME EQUIPMENT that is capable of operation without a SUPPLY MAINS, e.g. having an internal battery, is tested again without the PROTECTIVE EARTH CONNECTION;*

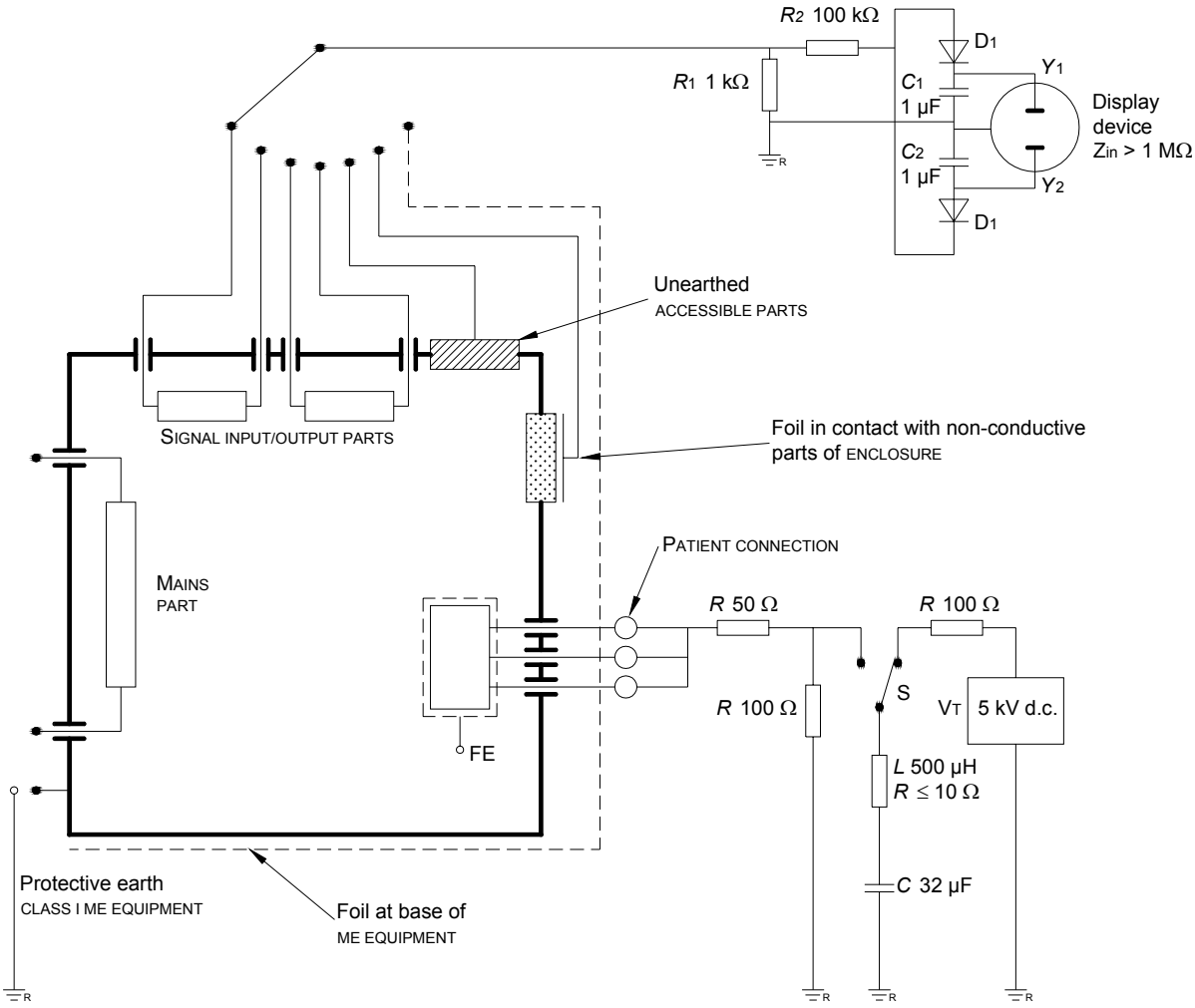
[87] – *insulating surfaces of APPLIED PARTS are covered with metal foil or immersed in a 0,9 % saline solution;*

– *any external connection to a FUNCTIONAL EARTH TERMINAL is removed;*

– *parts specified 8.5.5* a) *that are not PROTECTIVELY EARTHED are connected to a display device.*

After the operation of S*, the peak voltage between the points* Y_1 *and* Y_2 *is measured. Each test is repeated with* V_T *reversed.*

After any recovery time stated in the ACCOMPANYING DOCUMENTS, determine that the ME EQUIPMENT continues to provide ESSENTIAL PERFORMANCE as described in the ACCOMPANYING DOCUMENTS and complies with relevant requirements of this standard.



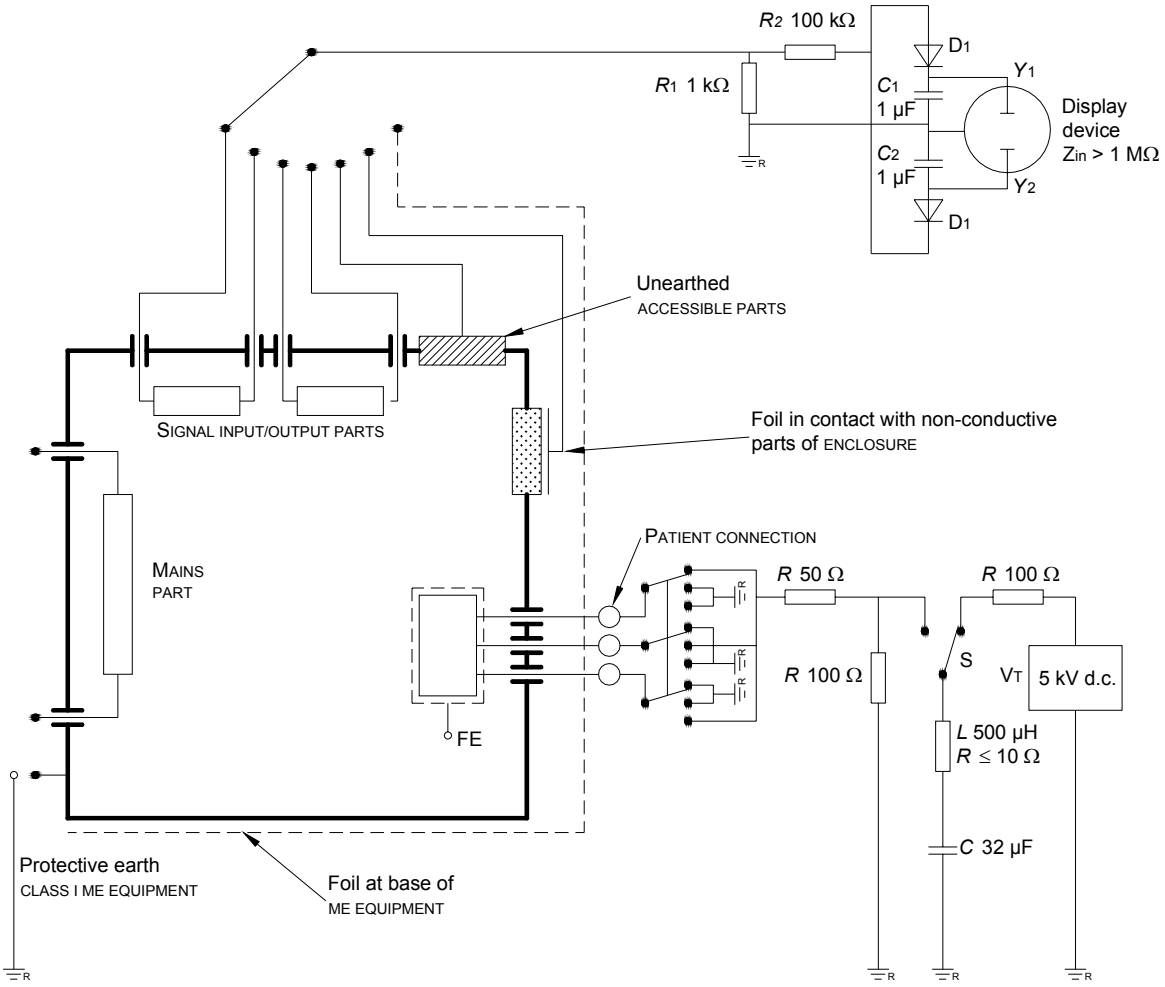
2237

See legends page 87.

V_T	Test voltage
S	Switch for applying the test voltage
R_1, R_2	Tolerance at ± 2 %, not less than 2 kV
D_1, D_2	Small signal silicon diodes

Other components toleranced at ± 5 %

2238 **Figure 9 – Application of test voltage to bridged PATIENT CONNECTIONS for DEFIBRILLATION-PROOF**
2239 **APPLIED PARTS**
2240 **(see 8.5.5)**



2241

See legends page 87.

V_T	Test voltage
S	Switch for applying the test voltage
R_1, R_2	Tolerance at ± 2 %, not less than 2 kV
D_1, D_2	Small signal silicon diodes

Other components toleranced at ± 5 %

2242 **Figure 10 – Application of test voltage to individual PATIENT CONNECTIONS for DEFIBRILLATION-PROOF**
2243 **APPLIED PARTS**
2244 **(see 8.5.5)**

2245 ## 8.6 *Protective earthing, functional earthing and potential equalization of
2246 ME EQUIPMENT

2247 ### 8.6.1 *Applicability of requirements

2248 The requirements of 8.6.2 to 8.6.8 (inclusive) apply unless the parts concerned comply with
2249 the requirements and tests of IEC 60950-1 for protective earthing and serve as MEANS OF
2250 OPERATOR PROTECTION but not as MEANS OF PATIENT PROTECTION.

2251 ### 8.6.2 *PROTECTIVE EARTH TERMINAL

2252 The PROTECTIVE EARTH TERMINAL of ME EQUIPMENT shall be suitable for connection to the
2253 protective conductor in the installation either by a PROTECTIVE EARTH CONDUCTOR in a POWER

SUPPLY CORD and, where appropriate, by a suitable plug, or by a FIXED PROTECTIVE EARTH CONDUCTOR.

The clamping means of the PROTECTIVE EARTH TERMINAL of ME EQUIPMENT for FIXED supply conductors or POWER SUPPLY CORDS shall comply with the requirements of 8.11.4.3. It shall not be possible to loosen the clamping means without the aid of a TOOL. Screws for internal PROTECTIVE EARTH CONNECTIONS shall be completely covered or protected against inadvertent loosening from the outside of ME EQUIPMENT.

Where an APPLIANCE INLET forms the supply connection to ME EQUIPMENT, the earth pin of the APPLIANCE INLET shall be regarded as the PROTECTIVE EARTH TERMINAL.

The PROTECTIVE EARTH TERMINAL shall not be used for the mechanical connection between different parts of the ME EQUIPMENT or the fixing of any component not related to protective earthing or functional earthing.

Compliance is checked by inspection of materials and construction, by manual tests, and by the test of 8.11.4.

8.6.3 Protective earthing of moving parts

Any PROTECTIVE EARTH CONNECTION shall not be used for a moving part unless the MANUFACTURER demonstrates that the connection will remain reliable for the useful life of the ME EQUIPMENT.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

8.6.4 *Impedance and current-carrying capability

a) *PROTECTIVE EARTH CONNECTIONS shall be able to carry fault currents reliably and without excessive voltage drop.

For PERMANENTLY INSTALLED ME EQUIPMENT, the impedance between the PROTECTIVE EARTH TERMINAL and any part that is PROTECTIVELY EARTHED shall not exceed 100 mΩ, except as allowed by 8.6.4 *b)*.

For ME EQUIPMENT with an APPLIANCE INLET the impedance between the earth pin in the APPLIANCE INLET and any part that is PROTECTIVELY EARTHED shall not exceed 100 mΩ, except as allowed by 8.6.4 *b).*

For ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD the impedance between the protective earth pin in the MAINS PLUG and any part that is PROTECTIVELY EARTHED shall not exceed 200 mΩ, except as allowed by 8.6.4 *b).*

Compliance is checked by the following test:

A current of 25 A or 1,5 times the highest RATED current of the relevant circuit(s), whichever is greater (± 10 %), from a current source with a frequency of 50 Hz or 60 Hz and with a no-load voltage not exceeding 6 V, is passed for 5 s to 10 s through the PROTECTIVE EARTH TERMINAL or the protective earth contact in the APPLIANCE INLET or the protective earth pin in the MAINS PLUG and each PROTECTIVELY EARTHED part.

The voltage drop between the parts described is measured and the impedance determined from the current and voltage drop.

Where the product of the test current as specified above and the total impedance (i.e. the impedance being measured plus the impedance of the test leads and the contact impedances) would exceed 6 V, the impedance is first measured with a source voltage not exceeding 6 V. If the measured impedance is within the permitted limit, either the impedance measurement is then repeated using a current source with a no-load voltage sufficient to deliver the specified current into the total impedance, or the current-carrying

ability of the relevant PROTECTIVE EARTH CONNECTION is confirmed by checking that its cross sectional area is at least equal to that of the relevant current-carrying conductors.[88]

b) *The impedance of PROTECTIVE EARTH CONNECTIONS is allowed to exceed the values specified above if the relevant circuits have limited current capability such that, in case of short circuit of relevant insulation, the allowable values of the TOUCH CURRENT and the PATIENT LEAKAGE CURRENT in SINGLE FAULT CONDITION are not exceeded.

Compliance is checked by inspection and if necessary by measurement of LEAKAGE CURRENT in the relevant SINGLE FAULT CONDITION. Transient currents occurring during the first 50 ms following the short-circuit are disregarded.

8.6.5 Surface coatings

Conductive elements of ME EQUIPMENT that have surface coatings of poorly conducting material such as paint, and between which electrical contact is essential to a PROTECTIVE EARTH CONNECTION, shall have the coatings removed at the point of contact unless an investigation of the joint construction and the manufacturing PROCESS has demonstrated that the requirements for impedance and current-carrying capacity are assured without the removal of the surface coating.

Compliance is checked by inspection.

8.6.6 Plugs and sockets

Where the connection between the SUPPLY MAINS and ME EQUIPMENT or between separate parts of ME EQUIPMENT that can be operated by the OPERATOR is made via a plug and socket device, the PROTECTIVE EARTH CONNECTION shall be made before and interrupted after the supply connections are made or interrupted. This applies also where interchangeable parts are PROTECTIVELY EARTHED.

Compliance is checked by inspection.

8.6.7 *POTENTIAL EQUALIZATION CONDUCTOR

If ME EQUIPMENT is provided with a terminal for the connection of a POTENTIAL EQUALIZATION CONDUCTOR the following requirements apply:

– the terminal shall be accessible to the OPERATOR with the ME EQUIPMENT in any position of NORMAL USE;

– the RISK of accidental disconnection shall be minimized in NORMAL USE;

– the terminal shall allow the conductor to be detached without the use of a TOOL;

– the terminal shall not be used for a PROTECTIVE EARTH CONNECTION;

– the terminal shall be marked with Symbol IEC 60417-5021 (see Table D1, Symbol 8);

– the instructions for use shall contain information on the function and use of the POTENTIAL EQUALIZATION CONDUCTOR together with a reference to the requirements of this standard for ME SYSTEMS.

The POWER SUPPLY CORD shall not incorporate a POTENTIAL EQUALIZATION CONDUCTOR.

Compliance is checked by inspection.

8.6.8 FUNCTIONAL EARTH TERMINAL

A FUNCTIONAL EARTH TERMINAL of ME EQUIPMENT shall not be used to provide a PROTECTIVE EARTH CONNECTION.

Compliance is checked by inspection.

8.6.9 *CLASS II ME EQUIPMENT

If CLASS II ME EQUIPMENT with isolated internal screens is supplied with a POWER SUPPLY CORD having three conductors, the third conductor (connected to the protective earth contact of the MAINS PLUG) shall be used only as the functional earth connection to a FUNCTIONAL EARTH TERMINAL for these screens and shall be coloured green and yellow.

The insulation of such internal screens and all internal wiring connected to them shall provide two MEANS OF PROTECTION. In such case, there shall be an explanation in the technical description.

Compliance is checked by inspection and measurement. The insulation is tested as described in 8.8.

8.7 LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

8.7.1 General requirements

a) The electrical insulation providing protection against electric shock shall be of such quality that currents flowing through it are limited to the values specified in 8.7.3.

b) The specified values of the EARTH LEAKAGE CURRENT, the TOUCH CURRENT, the PATIENT LEAKAGE CURRENT and the PATIENT AUXILIARY CURRENT apply in any combination of the following conditions:

- At operating temperature following the humidity preconditioning treatment, as described in 5.7.
- In NORMAL CONDITION and in the SINGLE FAULT CONDITIONS specified in 8.7.2.
- With ME EQUIPMENT energized in stand-by condition and fully operating and with any switch in the MAINS PART in any position.
- With the highest RATED supply frequency.
- With a supply equal to 110 % of the highest RATED MAINS VOLTAGE.[89]

8.7.2 *SINGLE FAULT CONDITIONS

The allowable values specified in 8.7.3 apply in the SINGLE FAULT CONDITIONS specified in 8.1 *b)* except that:

- where insulation is used in conjunction with a PROTECTIVE EARTH CONNECTION, short-circuit of the insulation applies only in the circumstances specified in 8.6.4 *b)*;
- the only SINGLE FAULT CONDITION for the EARTH LEAKAGE CURRENT is the interruption of one supply conductor at a time.
- LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENT are not measured in the SINGLE FAULT CONDITION of short circuiting of one constituent part of DOUBLE INSULATION.

8.7.3 Allowable values

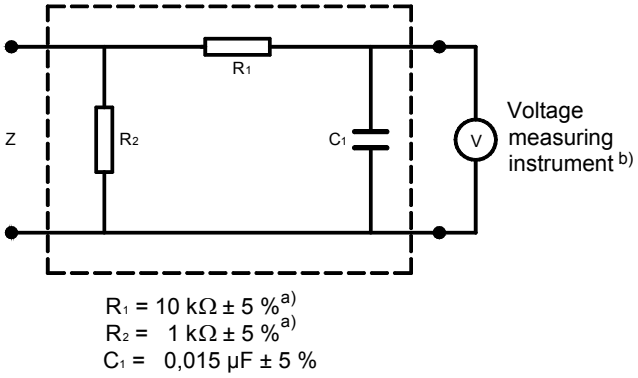
a) The allowable values specified in 8.7.3 *b)*, *c)* and *d)* apply to currents flowing through the network of Figure 11 a) and measured as shown in this figure (or by a device measuring the frequency contents of the currents as defined in Figure 11 b)). The values apply to d.c. and a.c. and composite waveforms. Unless stated otherwise they may be d.c. or r.m.s.

b) The allowable values of the PATIENT LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS are stated in Table 2. The values of a.c. apply to currents having a frequency not less than 0,1 Hz.

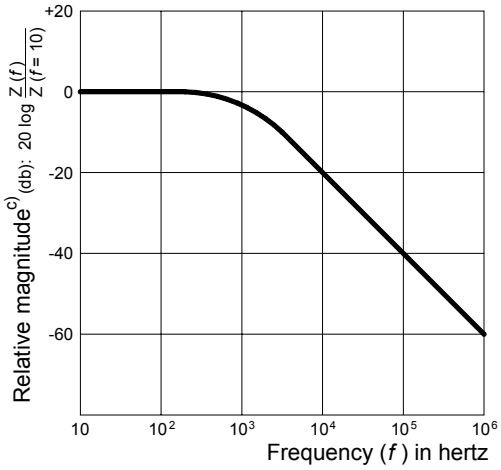
c) The allowable values of the TOUCH CURRENT are 100 μA in NORMAL CONDITION and 500 μA in SINGLE FAULT CONDITION.

d) The allowable values of the EARTH LEAKAGE CURRENT are 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION.

e) *Additionally, regardless of waveform and frequency, no LEAKAGE CURRENT shall exceed 10 mA r.m.s. in NORMAL CONDITION or in SINGLE FAULT CONDITION when measured with a non-frequency-weighted device.



a) Measuring device



b) Frequency characteristics

NOTE The network and voltage measuring instrument above are replaced by the symbol MD in the following figures.

a) Non-inductive components
b) Impedance >> measuring impedance Z
c) $Z(f)$ is the transfer impedance of the network, i.e. $V_{out/in}$, for a current of frequency f.

Figure 11 – Example of a measuring device and its frequency characteristics (see 8.7.3)

2392 **Table 2 – Allowable values of PATIENT LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS**

2393 Current in microamperes

CURRENT	TYPE B APPLIED PART		TYPE BF APPLIED PART		TYPE CF APPLIED PART	
	NORMAL CONDITION	SINGLE FAULT CONDITION	NORMAL CONDITION	SINGLE FAULT CONDITION	NORMAL CONDITION	SINGLE FAULT CONDITION
PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT d.c.	10	50	10	50	10	50
PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT a.c.	100	500	100	500	10	50
Total PATIENT LEAKAGE CURRENT d.c.	50	100	50	100	50	100
Total PATIENT LEAKAGE CURRENT a.c.	500	1000	500	1000	50	100
PATIENT LEAKAGE CURRENT with MAXIMUM MAINS VOLTAGE on non-PROTECTIVELY EARTHED ACCESSIBLE PART	500		500		Note 4	
Total PATIENT LEAKAGE CURRENT with MAXIMUM MAINS VOLTAGE on unearthed ACCESSIBLE PART	1000		1000		Note 4	
PATIENT LEAKAGE CURRENT with MAXIMUM MAINS VOLTAGE on APPLIED PART	—		5000		50	
Total PATIENT LEAKAGE CURRENT with MAXIMUM MAINS VOLTAGE on APPLIED PART	—		5000		100	

NOTE 1 For EARTH LEAKAGE CURRENT see 8.7.3 *d)*.

NOTE 2 For TOUCH CURRENT see 8.7.3 *c)*.

NOTE 3 The condition referred to in Table IV of the 2nd edition as "MAINS VOLTAGE on APPLIED PART", and treated in that edition as a SINGLE FAULT CONDITION, is treated in this edition as a special test condition. The test with MAXIMUM MAINS VOLTAGE on a non-PROTECTIVELY EARTHED ACCESSIBLE PART is also a special test condition, but the allowable values are the same as for SINGLE FAULT CONDITION. See also the rationales for 8.5.2.2 and 8.7.4.7 *d)*.

NOTE 4 This condition is not tested with TYPE CF APPLIED PARTS because it is covered by the test with MAXIMUM MAINS VOLTAGE on the APPLIED PART. See also the rationale for 8.7.4.7 *d)*.

2394 **8.7.4 Measurements**

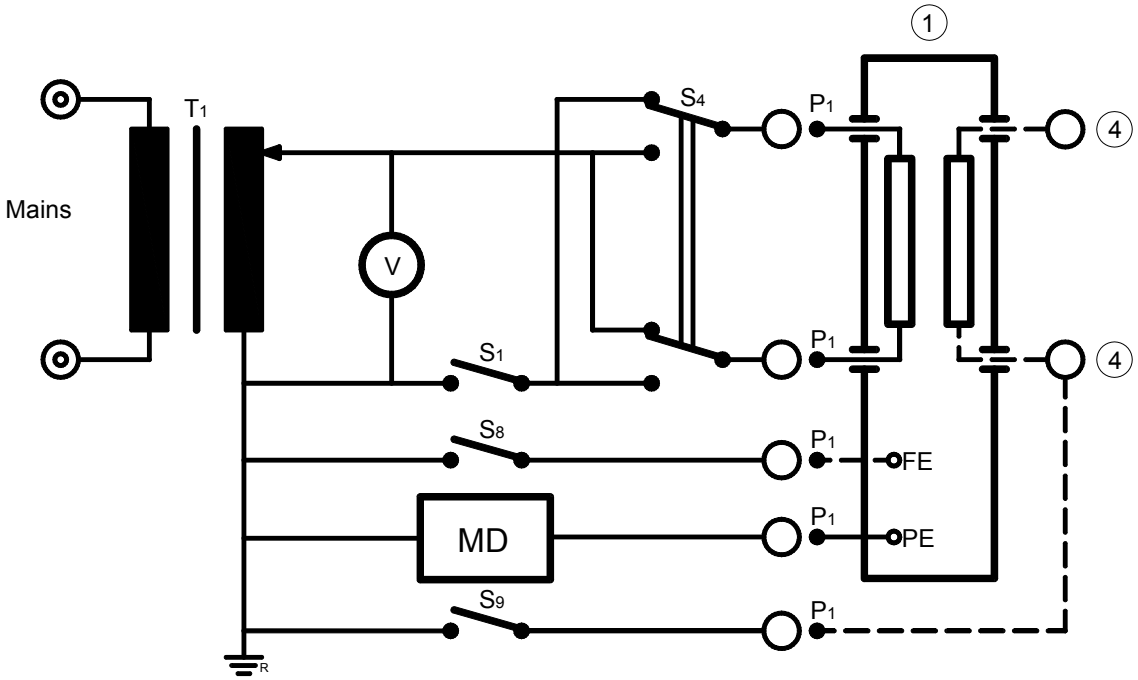
2395 **8.7.4.1 General**

2396 *The LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT test figures referenced in 8.7.4.5 to*
2397 *8.7.4.8 (Figure 12 to Figure 18 inclusive) show suitable test configurations for use in*
2398 *conjunction with the test PROCEDURES specified in these subclauses. It is recognized that*
2399 *other test figures may yield accurate results. However if the test results are close to the*
2400 *allowed values or if there is any doubt as to the validity of the test results, the applicable test*
2401 *figure is to be used as the deciding factor.*

2402 a) *The EARTH LEAKAGE CURRENT, the TOUCH CURRENT, the PATIENT LEAKAGE CURRENT and the*
2403 *PATIENT AUXILIARY CURRENT are measured after the ME EQUIPMENT has been brought up to*
2404 *operating temperature in accordance with the requirements of 11.1.3 c).*

2405 b) *ME EQUIPMENT is connected to a supply with a voltage equal to 110 % of the highest RATED*
2406 *MAINS VOLTAGE.*

c) *Where examination of the circuit arrangement and the arrangement of components and material of the ME EQUIPMENT shows no possibility of any HAZARD, the number of tests may be reduced.*



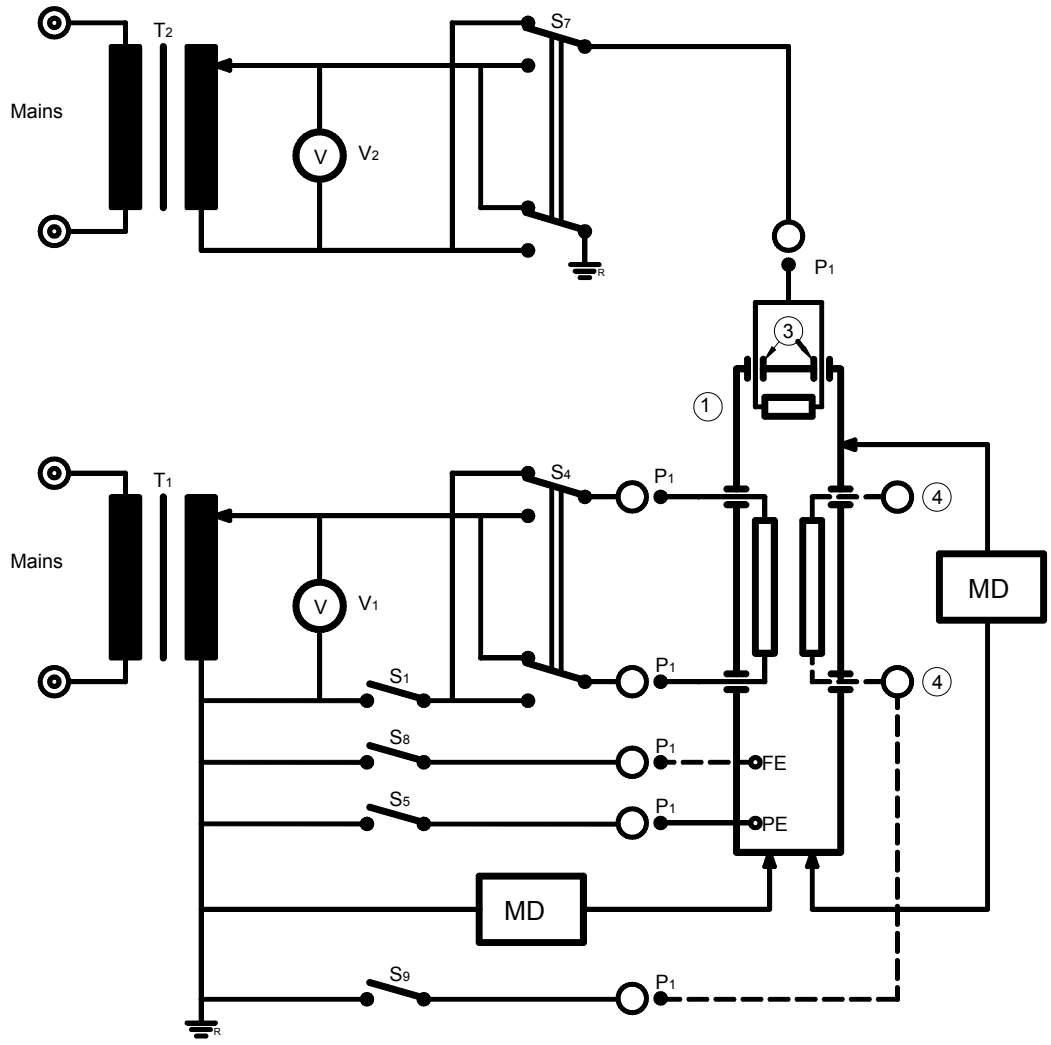
See legends page 87

Measure in all possible combinations of positions of S_4, S_8 and S_9 with:

S_1 closed (NORMAL CONDITION), and
S_1 open (SINGLE FAULT CONDITION).

Figure 12 – Measuring circuit for the EARTH LEAKAGE CURRENT of CLASS I equipment, with or without APPLIED PART (see 8.7.4.5)

Example with the measuring supply circuit of Figure F1



2415

See legends page 87

Measure (with S_5 closed if CLASS I equipment) under all possible combinations of positions of S_1, S_4, S_7, S_8, and S_9,
S_1 open is SINGLE FAULT CONDITION.

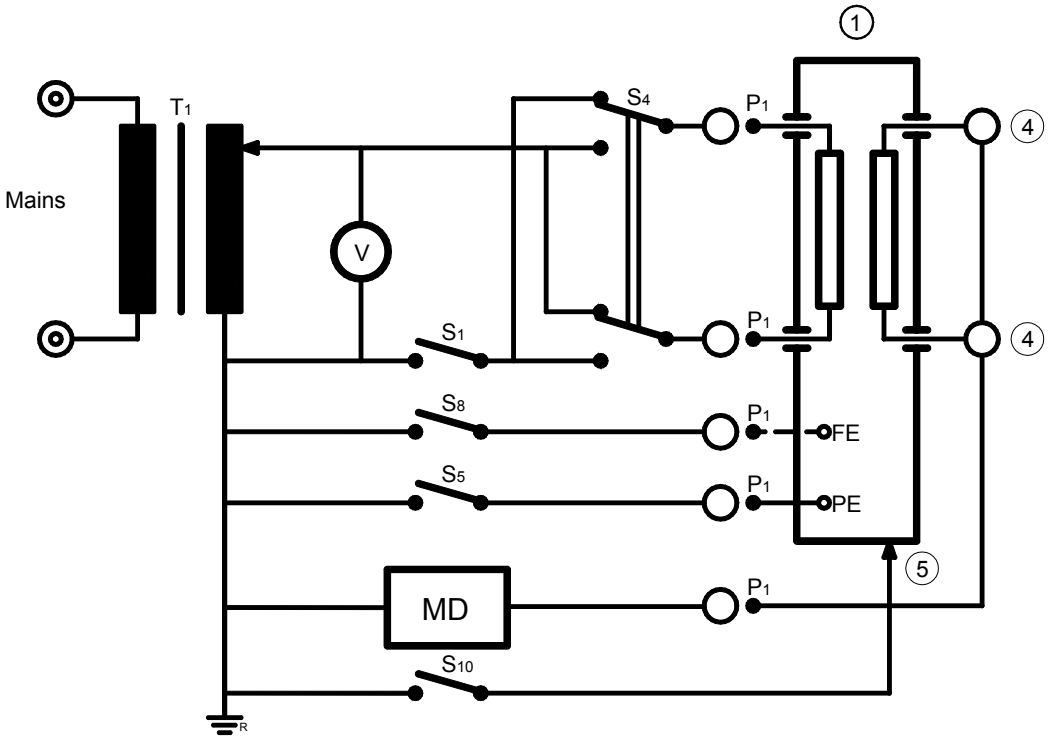
CLASS I equipment only:
Measure with S_5 open (SINGLE FAULT CONDITION) and with S_1 closed under all possible combinations of S_4, S_7, S_8 and S_9.

For CLASS II equipment, the PROTECTIVE EARTH CONNECTION and S_5 are not used.

Transformer T_2 is used if required (see 8.1 *a)*)

2416 **Figure 13 – Measuring circuit for the TOUCH CURRENT**
2417 **(see 8.7.4.6)**

2418 Example with the measuring supply circuit of Figure F1.



2419

See legends page 87

Measure (with S_5 closed if CLASS I ME EQUIPMENT) under all possible combinations of positions of S_1, S_4, S_8 and S_{10}.

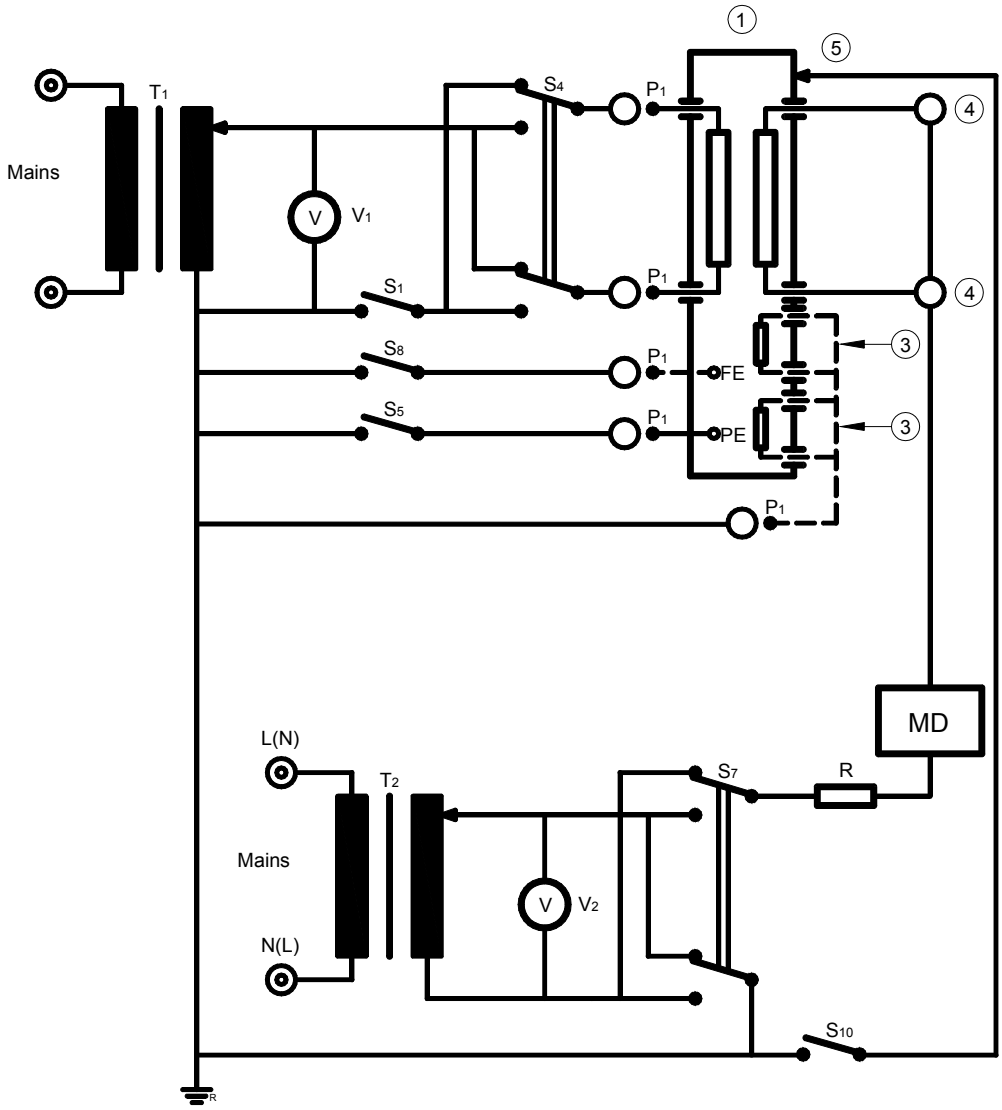
S1 open is SINGLE FAULT CONDITION.

CLASS I ME EQUIPMENT only:
Measure with S_5 open (SINGLE FAULT CONDITION) and with S_1 closed under all possible combinations of S_4, S_8 and S_{10}.

For CLASS II ME EQUIPMENT, the PROTECTIVE EARTH CONNECTION and S_5 are not used.

2420 **Figure 14 – Measuring circuit for the PATIENT LEAKAGE CURRENT from the**
2421 **PATIENT CONNECTION to earth.**
2422 **(see 8.7.4.7 *a)*)**

2423 Example with the measuring supply circuit of Figure F1.



2424

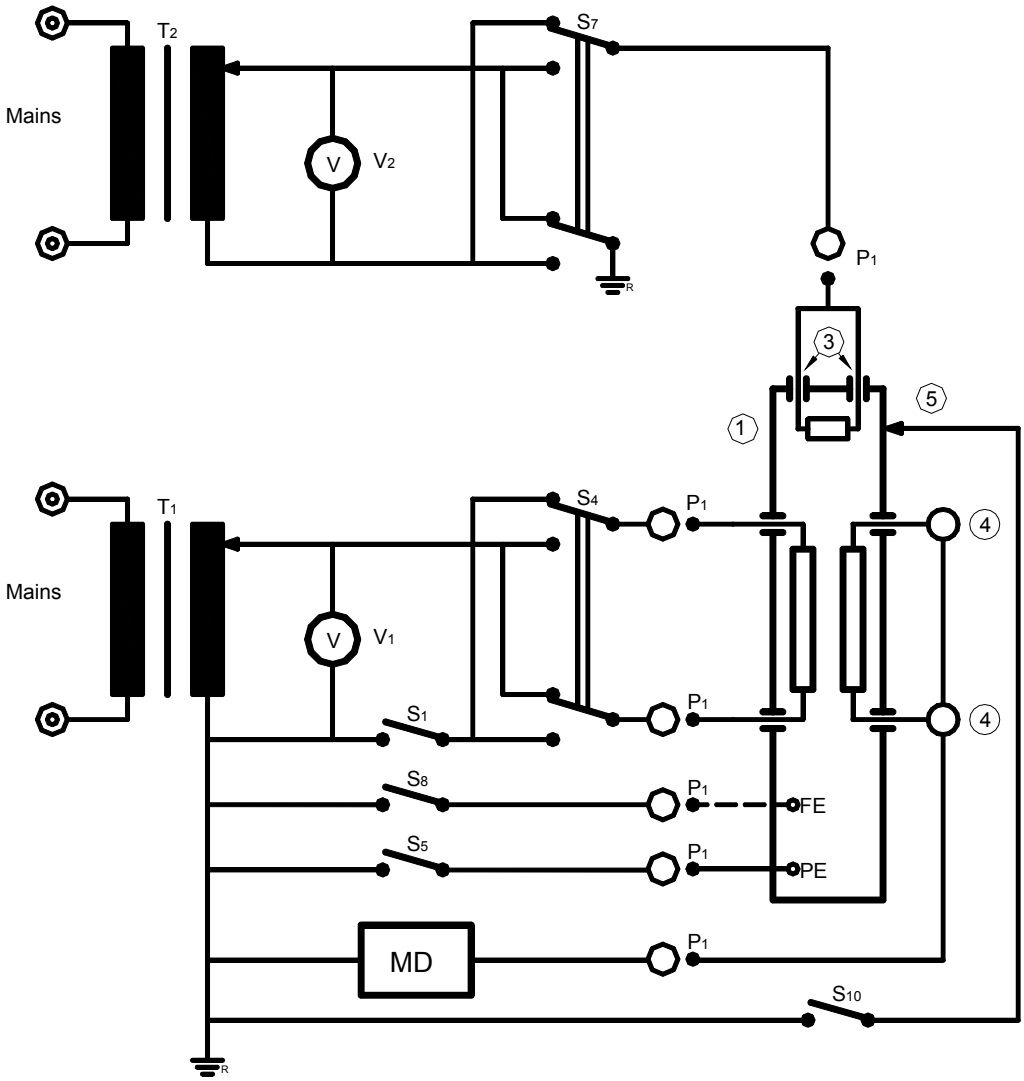
See legends page 87

Measure (with S_5 closed, if CLASS I ME EQUIPMENT) WITH S_1 closed under all possible combinations of positions of S_4, S_7, S_8 and S_{10}.

For CLASS II ME EQUIPMENT, the PROTECTIVE EARTH CONNECTION and S_5 are not used.

2425 **Figure 15 – Measuring circuit for the PATIENT LEAKAGE CURRENT via the PATIENT CONNECTION(S) of an**
2426 **F-TYPE APPLIED PART to earth caused by an external voltage on the PATIENT CONNECTION(S).**
2427 **(see 8.7.4.7 *b)*)**

2428 Example with the measuring supply circuit of Figure F1.



2429

See legends page 87

Measure (with S_5 closed, if CLASS I ME EQUIPMENT) under all possible combinations of positions of S_1, S_4, S_7, S_8 and S_{10} (S_1 open is SINGLE FAULT CONDITION).

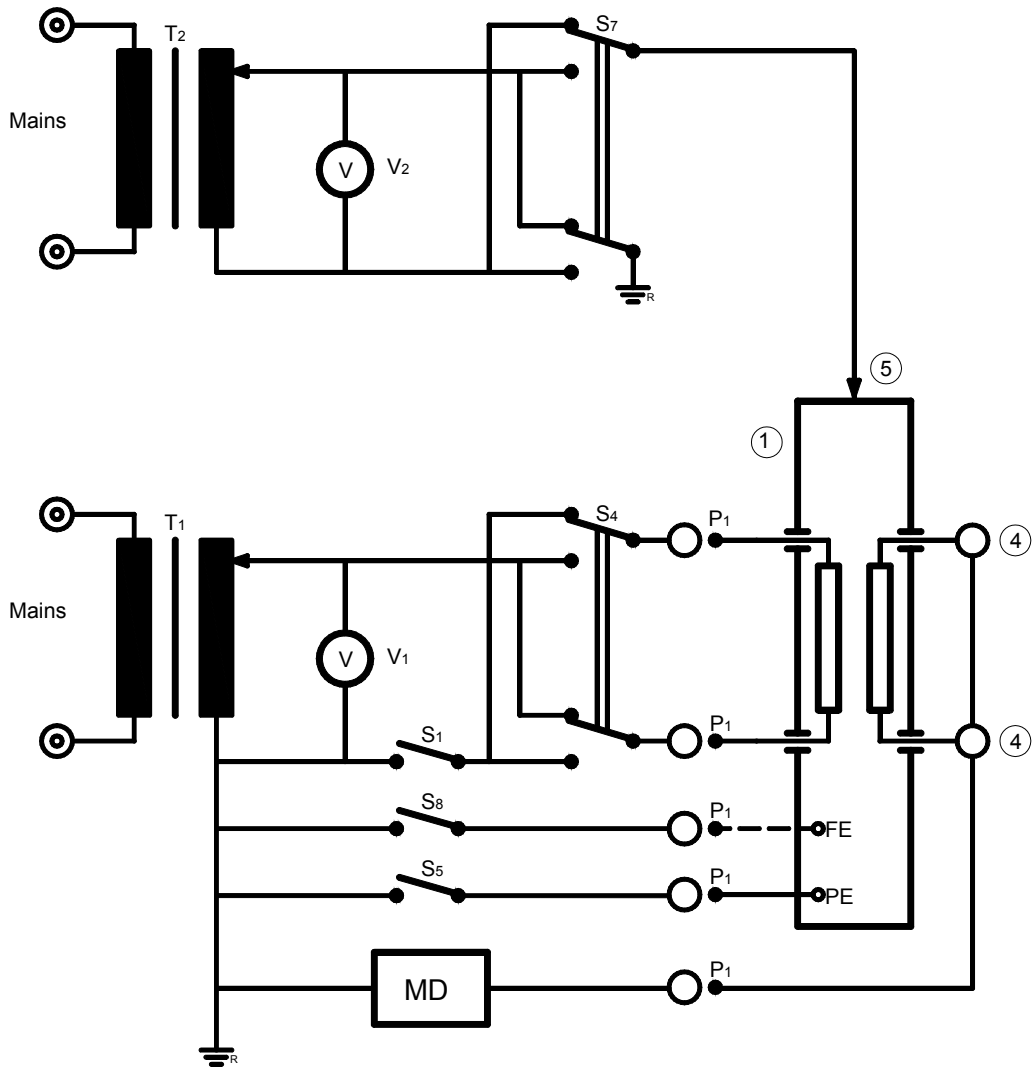
CLASS I ME EQUIPMENT only:
Measure with S_5 open (SINGLE FAULT CONDITION) and with S_1 closed under all possible combinations of S_4, S_7, S_8 and S_{10}.

For CLASS II ME EQUIPMENT, the PROTECTIVE EARTH CONNECTION and S_5 are not used.

2430 **Figure 16 – Measuring circuit for the PATIENT LEAKAGE CURRENT from PATIENT CONNECTION(S) to earth**
2431 **caused by an external voltage on a SIGNAL INPUT/OUTPUT PART**
2432 **(see 8.7.4.7 *c)*)**

2433 Example with the measuring supply circuit of Figure F1.

2434



2435

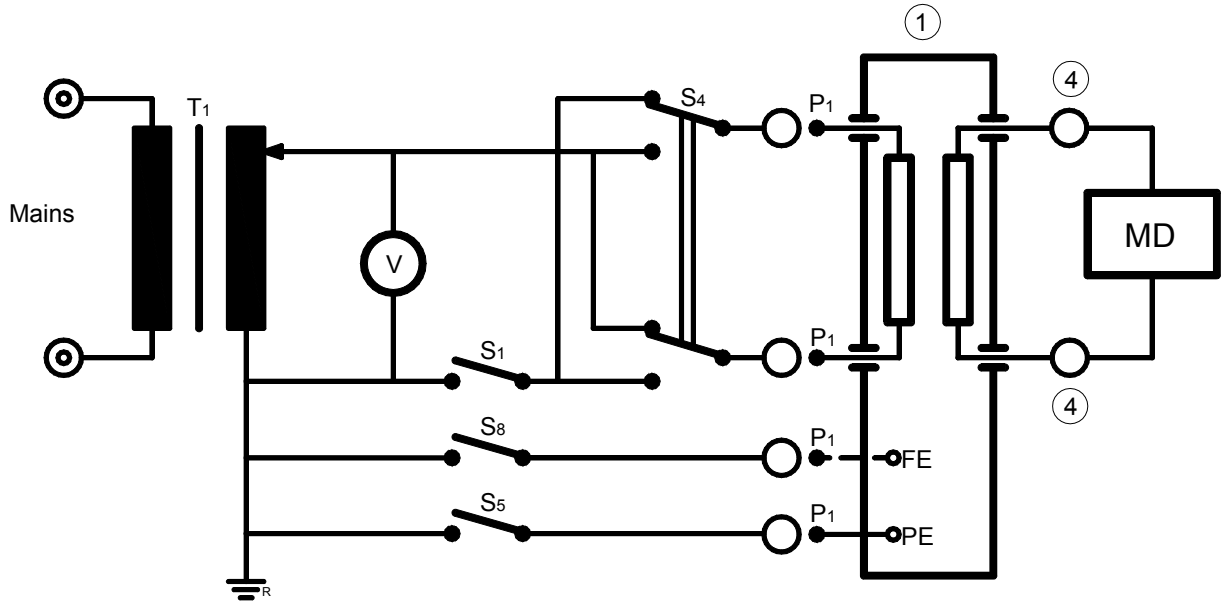
See legends page 87

Measure with S_1 closed (and with S_5 closed, if CLASS I ME EQUIPMENT) under all possible combinations of positions of S_4, S_7 S, and S_8

For CLASS II ME EQUIPMENT, the PROTECTIVE EARTH CONNECTION and S_5 are not used.

2436 **Figure 17 – Measuring circuit for the PATIENT LEAKAGE CURRENT from PATIENT CONNECTION(S) to earth**
2437 **caused by an external voltage on a metal ACCESSIBLE PART that is not PROTECTIVELY EARTHED**
2438 **(see 8.7.4.7 *d)*)**

2439 Example with the measuring supply circuit of Figure F1.



2440

See legends page 87

Measure (with S_5 closed if CLASS I ME EQUIPMENT) under all possible combinations of positions of S_1, S_4, and S_8.

S_1 open is SINGLE FAULT CONDITION.

CLASS I ME EQUIPMENT only:
Measure with S_5 open (SINGLE FAULT CONDITION) and with S_1 closed under all possible combinations of positions of S_4, and S_8.

For CLASS II ME EQUIPMENT, the PROTECTIVE EARTH CONNECTION and S_5 are not used.

2441 **Figure 18 – Measuring circuit for the PATIENT AUXILIARY CURRENT**
2442 **(see 8.7.4.8)**

2443 Example with the measuring supply circuit of Figure F1.

Legends of symbols for Figure 9 to Figure 18, Annex E and Annex F

(1)	ME EQUIPMENT ENCLOSURE
(2)	Separate power supply unit or other electrical equipment in an ME SYSTEM that supplies power to the ME EQUIPMENT (see 5.5 *g)* and Annex F)
(3)	SIGNAL INPUT/OUTPUT PART short-circuited or loaded
(4)	PATIENT CONNECTIONS
(5)	Metal ACCESSIBLE PART not being a PATIENT CONNECTION and not PROTECTIVELY EARTHED
MAINS	Any electrical source that is able to generate, alone or together with the isolation transformer, a condition equivalent to a SUPPLY MAINS.
T_1, T_2	Single- or polyphase isolation transformers with sufficient power rating and adjustable output voltage See also the rationale for 8.7.4.2."
V(1,2,3)	Voltmeter including r.m.s. value, using, if relevant and possible, one meter with a commutator switch
S_1, S_2, S_3	Single-pole switches, simulating the interruption of a power supply conductor (SINGLE FAULT CONDITION)
S_4, S_7	Commutator switches to reverse the polarity of the MAINS VOLTAGE
S_5 S_6	Single-pole switches, simulating the interruption of a single PROTECTIVE EARTH CONDUCTOR (SINGLE FAULT CONDITION)
S_8	Switches for connecting a FUNCTIONAL EARTH TERMINAL to the earthed point of the measuring supply system
S_9	Switch for connecting a PATIENT CONNECTION to the earthed point of the measuring supply circuit
S_{10}	Switch for connecting to earth a metal ACCESSIBLE PART not being a PATIENT CONNECTION and not PROTECTIVELY EARTHED
P_1	Sockets, plugs or terminals for the supply connection of the ME EQUIPMENT
P_2	Sockets, plugs or terminals for the connection to a separate power supply or other electrical equipment in an ME SYSTEM that supplies power to the ME EQUIPMENT (see Figure F5)
MD	Measuring device (see Figure 11)
FE	FUNCTIONAL EARTH TERMINAL
PE	PROTECTIVE EARTH TERMINAL
R	Impedance to protect the circuitry and the person performing the test, but low enough to accept currents higher than the allowable values of the LEAKAGE CURRENT to be measured.
– – – –	Optional connection
R	Reference earth (for LEAKAGE CURRENT measurements and for testing of DEFIBRILLATION-PROOF APPLIED PARTS, not connected to protective earth of the SUPPLY MAINS).

8.7.4.2 *Measuring supply circuits

ME EQUIPMENT specified for connection to a SUPPLY MAINS is connected to an appropriate power source. For single-phase ME EQUIPMENT, the polarity of the supply is reversible and tests are conducted at both polarities.

NOTE Figure F1 to Figure F5 (inclusive) show some suitable arrangements but do not cover all possibilities, for example, delta-connected 3-phase supplies.

8.7.4.3 Connection to the measuring supply circuit

a) *ME EQUIPMENT provided with a POWER SUPPLY CORD is tested using this cord.*

b) *ME EQUIPMENT provided with an APPLIANCE INLET is tested while connected to the measuring supply circuit via a DETACHABLE POWER SUPPLY CORD having a length of 3 m or a length and type specified by the MANUFACTURER.*

c) *PERMANENTLY INSTALLED ME EQUIPMENT is tested while connected to the measuring supply circuit by the shortest possible connection.*

d) *Measuring arrangement*

1) *External parts of the APPLIED PART, including PATIENT cords (when present), shall be placed on an insulating surface with a dielectric constant of approximately 1 (for example, expanded polystyrene) and approximately 200 mm above an earthed metal surface.*

NOTE The measuring supply circuit and the measuring circuit should be positioned as far as possible away from unscreened power source leads. Placing the ME EQUIPMENT on or near a large earthed metal surface should be avoided.

2) *If an isolating transformer is not used for LEAKAGE CURRENT measurements, the reference earth of the measuring circuits in not connected to protective earth of the SUPPLY MAINS.*

8.7.4.4 Measuring device (MD)

a) *The measuring device shall load the source of LEAKAGE CURRENT or PATIENT AUXILIARY CURRENT with a resistive impedance of approximately 1 000 Ω for d.c. and a.c. and for composite waveforms with frequencies up to and including 1 MHz.*

b) *The evaluation of current or current components according to 8.7.3 a) is obtained automatically if a measuring device according to Figure 11 a) or a similar circuit with the same frequency characteristic is used. This allows measurement of the total effect of all frequencies with a single instrument.*

If significant currents or current components with frequencies exceeding 1 kHz are likely to occur, these are measured by other appropriate means.

c) *The measuring instrument as shown in Figure 11 a) shall have an input resistance of at least 1 MΩ and input capacitance of no more than 150 pF. It shall indicate the true r.m.s. value of the voltage across the measuring impedance being d.c. or a.c. or a composite waveform having components with frequencies from 0,1 Hz[90] up to and including 1 MHz, with an indicating error not exceeding ± 5 % of the indicated value.*

The scale may indicate the current through the measuring device including automatic evaluation of components with frequencies above 1 kHz so as to enable direct comparison of the reading with the limit values specified in 8.7.3.

These requirements may be limited to a frequency range with an upper limit lower than 1 MHz if it can be proven (for example, by the use of an oscilloscope) that frequencies above such an upper limit do not occur in the measured current.

8.7.4.5 *Measurement of the EARTH LEAKAGE CURRENT

a) *CLASS I ME EQUIPMENT is tested according to Figure 12.*

b) *If ME EQUIPMENT has more than one PROTECTIVE EARTH CONDUCTOR (for example one connected to the main ENCLOSURE and one to a separate power supply unit) then the current to be measured is the aggregate current that would flow into the protective earthing system of the installation.*

c) *For FIXED ME EQUIPMENT that may have connections to earth through the building structure, the MANUFACTURER shall specify a suitable test PROCEDURE and configuration for measurement of EARTH LEAKAGE CURRENT.*[91]

8.7.4.6 *Measurement of the TOUCH CURRENT

a) *ME EQUIPMENT is tested according to Figure 13, using an appropriate measuring supply circuit.*

Measure with MD between earth and each part of the ENCLOSURE(S) that is not PROTECTIVELY EARTHED.

Measure with MD between parts of the ENCLOSURE(S) that are not PROTECTIVELY EARTHED.

In the SINGLE FAULT CONDITION of interruption of any one PROTECTIVE EARTH CONDUCTOR (where applicable, see 8.1 b)*), measure with MD between earth and any part of the ENCLOSURE that is normally PROTECTIVELY EARTHED.*

NOTE It is not necessary to make separate measurements from more than one part that is PROTECTIVELY EARTHED.

INTERNALLY POWERED ME EQUIPMENT is investigated for TOUCH CURRENT but only between parts of the ENCLOSURE, not between the ENCLOSURE and earth unless 8.7.4.6 c) *applies.*[92]

b) If ME EQUIPMENT has an ENCLOSURE or a part of the ENCLOSURE made of insulating material, metal foil of maximum 20 cm x 10 cm is applied in intimate contact with the ENCLOSURE or relevant part of the ENCLOSURE.

[93]*The metal foil is shifted, if possible, to determine the highest value of the TOUCH CURRENT. The metal foil should not touch any metal parts of the ENCLOSURE that are possibly PROTECTIVELY EARTHED; however, metal parts of the ENCLOSURE that are not PROTECTIVELY EARTHED may be covered partly or totally by the metal foil.*

Where it is intended to measure the TOUCH CURRENT in the SINGLE FAULT CONDITION of interruption of a PROTECTIVE EARTH CONDUCTOR, the metal foil may be arranged to contact parts of the ENCLOSURE that are normally PROTECTIVELY EARTHED.

Where the surface of the ENCLOSURE contacted by the PATIENT or OPERATOR may be larger than 20 cm x 10 cm,[94] *the size of the foil is increased corresponding to the area of contact.*

c) ME EQUIPMENT with a SIGNAL INPUT/OUTPUT PART is, when required (see 8.1 a)), additionally tested using transformer T_2.

The value of the voltage set at the transformer T_2 is equal to 110 % of the MAXIMUM MAINS VOLTAGE. The SIGNAL INPUT/OUTPUT PART is short-circuited unless a load is prescribed by the MANUFACTURER, in which case the test voltage is applied in turn to all poles of the SIGNAL INPUT/OUTPUT PART.

8.7.4.7 Measurement of the PATIENT LEAKAGE CURRENT

a) *ME EQUIPMENT with an APPLIED PART is tested according to Figure 14.*

An ENCLOSURE made of insulating material is placed in any position of NORMAL USE upon a flat metal surface connected to earth with dimensions at least equal to the plan-projection of the ENCLOSURE.

b) **ME EQUIPMENT with an F-TYPE APPLIED PART is additionally tested according to Figure 15.*

SIGNAL INPUT/OUTPUT PARTS are connected to earth, if not already permanently earthed in the ME EQUIPMENT.

The value of the voltage to be set at the transformer T_2 in Figure 15 is equal to 110 % of the MAXIMUM MAINS VOLTAGE.

For this measurement, non-PROTECTIVELY EARTHED metal ACCESSIBLE PARTS (if present) are connected to earth.

c) **ME EQUIPMENT with an APPLIED PART and a SIGNAL INPUT/OUTPUT PART is, when required (see 8.1 a)), additionally tested according to Figure 16.*

The value of the voltage set at the transformer T_2 is equal to 110 % of the MAXIMUM MAINS VOLTAGE. The SIGNAL INPUT/OUTPUT PART is short-circuited unless a load is prescribed by the MANUFACTURER, in which case the test voltage is applied in turn to all poles of the SIGNAL INPUT/OUTPUT PART.

d) **ME EQUIPMENT with a PATIENT CONNECTION of a TYPE B APPLIED PART that is not PROTECTIVELY EARTHED or a TYPE BF APPLIED PART and with metal ACCESSIBLE PARTS that are not PROTECTIVELY EARTHED is additionally tested according to Figure 17.*

The value of the voltage set at the transformer T_2 is equal to 110 % of the MAXIMUM MAINS VOLTAGE.

e) *An APPLIED PART consisting of a surface made of insulating material is tested using metal foil as mentioned under 8.7.4.6. Alternatively a 0,9 % saline solution may be used in which the APPLIED PART is immersed.*

Where the surface of the APPLIED PART intended to contact the PATIENT is considerably larger than that of a foil of 20 cm x 10 cm, the size of the foil is increased to correspond to the area of contact.

Such foil or saline solution is considered as the only PATIENT CONNECTION for the APPLIED PART concerned.

f) *Where the PATIENT CONNECTION is formed by a fluid which contacts the PATIENT, the fluid is replaced by 0,9 % saline solution, an electrode is placed in the saline and this electrode is considered as the PATIENT CONNECTION for the APPLIED PART concerned.*

g) *The PATIENT LEAKAGE CURRENT is measured (see Annex E):*[95]

- *for TYPE B APPLIED PARTS and TYPE BF APPLIED PARTS, from and to all PATIENT CONNECTIONS of a single function either connected directly together or loaded according to the MANUFACTURER'S instructions;*
- *in TYPE CF APPLIED PARTS, from and to every PATIENT CONNECTION in turn.*

If the MANUFACTURER specifies alternatives for a detachable part of the APPLIED PART (for example, PATIENT leads and electrodes), the PATIENT LEAKAGE CURRENT measurements are made with the least favourable specified detachable part.

h) *The total PATIENT LEAKAGE CURRENT is measured from and to all PATIENT CONNECTIONS of all APPLIED PARTS of the same type (TYPE B APPLIED PARTS, TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS) connected together.*

i) *If loading of the PATIENT CONNECTIONS of the APPLIED PART is specified by the MANUFACTURER, the measuring device is connected to each PATIENT CONNECTION in turn.*

8.7.4.8 *Measurement of the PATIENT AUXILIARY CURRENT

For connections to the PATIENT CONNECTION(S) of the APPLIED PART(S), see Figure E4.

ME EQUIPMENT with an APPLIED PART is tested according to Figure 18, using an appropriate measuring supply circuit unless the ME EQUIPMENT has only a single PATIENT CONNECTION.

The PATIENT AUXILIARY CURRENT is measured between any single PATIENT CONNECTION and all other PATIENT CONNECTIONS, either connected directly together or loaded as specified by the MANUFACTURER (see Annex E).[96]

8.7.4.9 *ME EQUIPMENT with multiple PATIENT CONNECTIONS[97]

ME EQUIPMENT with multiple PATIENT CONNECTIONS is investigated to ensure that the PATIENT LEAKAGE CURRENT and the PATIENT AUXILIARY CURRENT do not exceed the allowable values for NORMAL CONDITION while one or more PATIENT CONNECTIONS are:

– *disconnected from the PATIENT; and*

– *disconnected from the PATIENT and earthed.*

Testing is carried out if an examination of the ME EQUIPMENT circuit indicates that the PATIENT LEAKAGE CURRENT or the PATIENT AUXILIARY CURRENT can increase to excessive levels under the above conditions. Actual measurements should be limited to a representative number of combinations.

8.8 Insulation

8.8.1 *General

Only the following insulation shall be subject to testing:

– insulation that is relied upon as a MEANS OF PROTECTION, including REINFORCED INSULATION;

– insulation between poles of the MAINS PART on the SUPPLY MAINS side of any mains fuse or OVER-CURRENT RELEASE, which shall be tested as one MEANS OF PROTECTION.

Insulation forming part of a component is exempt provided that the component complies with 4.6.

Insulation forming MEANS OF OPERATOR PROTECTION is exempt from the tests of 8.8 if it complies with the requirements and tests of IEC 60950-1 for insulation co-ordination.

8.8.2 *Distance through solid insulation or use of thin sheet material

Attention of National Committees is drawn to the rationale for this new subclause.

There is no minimum thickness requirement for BASIC INSULATION, nor for REFERENCE VOLTAGES (*U*)up to 71 V.

Solid insulation which forms SUPPLEMENTARY INSULATION or REINFORCED INSULATION for a REFERENCE VOLTAGE (*U*) greater than 71 V either:

a) shall have a distance through insulation of at least 0,4 mm, or

b) shall not form part of an ENCLOSURE, shall not be subject to handling or abrasion during NORMAL USE, and shall comprise:

– at least two layers of material, each of which will pass the appropriate dielectric strength test; or

– three layers of material, for which all combinations of two layers together will pass the appropriate dielectric strength test.

The appropriate dielectric strength test for the one or two layers is the test for one MEANS OF PROTECTION in the case of SUPPLEMENTARY INSULATION or the test for two MEANS OF PROTECTION in the case of REINFORCED INSULATION, respectively.

Note: There is no requirement for all layers of insulation to be of the same material.

Compliance is checked by inspection, by measurement of thickness and by the dielectric strength test of 8.8.3.

8.8.3 *Dielectric strength

The dielectric strength of solid electrical insulation of ME EQUIPMENT at operating temperature as well as following the humidity preconditioning treatment and after any sterilization PROCEDURE specified in the instructions for use (see 7.10.2.12), shall be sufficient to withstand the test voltages as specified in Table 3.

Compliance is checked by applying the test voltage specified in Table 3 for 1 min:

– *immediately after the humidity preconditioning treatment (as described in 5.7) with the* ME EQUIPMENT *de-energized during the test, and*

– *after any required sterilization* PROCEDURE *(see 11.6.7) with the* ME EQUIPMENT *de-energized.*

Additionally, heating elements are tested while energized by application of the circuit of Figure 19.

NOTE Heating elements may be tested separately from the rest of the ME EQUIPMENT.

Initially, not more than half the test voltage is applied, and then it is gradually raised over a period of 10 s to the full value, which is maintained for 1 min, after which it is gradually lowered over a period of 10 s to less than half the full value.

The test conditions are as follows:

a) **The test voltage is to have a waveform and frequency such that the dielectric stress on the insulation is at least equal to that which would occur if the waveform and the frequency of the test voltage were equal to those of the voltage applied to the various parts in* NORMAL USE. *Where the voltage to which the relevant insulation is subjected in* NORMAL USE *is non-sinusoidal a.c., the test may be performed using a sinusoidal 50 Hz or 60 Hz test voltage.*[98]

Alternatively, a d.c. test voltage equal to the peak value of the a.c. test voltage may be used.

The test voltage is greater than or equal to that specified in Table 3.

b) *During the test, flashover or breakdown is considered a failure. Slight corona discharges are neglected, provided that they cease when the test voltage is temporarily dropped to a value that is lower than the specified value, but still higher than the* REFERENCE VOLTAGE *(*U*) and provided that the discharges do not provoke a drop in test voltage.*

c) *Where an* ENCLOSURE *or part of* ENCLOSURE *consists of non-conductive surfaces, metal foil is applied. Care is taken that the metal foil is positioned in such a manner that flashover does not occur at the edges of insulation linings. If applicable, the metal foil is moved so as to test all parts of the surface*.

d) *The terminals of the* MAINS PART, *the* SIGNAL INPUT/OUTPUT PART *and the* PATIENT CONNECTION(S) *(if applicable) respectively are short-circuited during the test*.

e) *Where there are capacitors across the insulation under test (e.g. radio-frequency filter capacitors), they may be disconnected during the test, if they are certified to IEC 60384-14.*

2657 **Table 3 – Test voltages for solid insulation forming MEANS OF PROTECTION**

REFERENCE VOLTAGE (*U*)	A.C. test voltages in volts r.m.s.							
	MEANS OF OPERATOR PROTECTION				MEANS OF PATIENT PROTECTION			
	Protection from MAINS PART		Protection from SECONDARY CIRCUITS		Protection from MAINS PART		Protection from SECONDARY CIRCUITS	
	1 MOOP	2 MOOP	1 MOOP	2 MOOP	1 MOPP	2 MOPP	1 MOPP	2 MOPP
U < 42,4 V peak or 60 V d.c.	1 000	2 000	No test	No test	1 500	3 000	500	1 000
42,4 V peak or 60 V d.c. < *U* ≤ 71	1 000	2 000	See Table 4	See Table 4	1 500	3 000	750	1 500
71 < *U* ≤ 184	1 000	2 000	See Table 4	See Table 4	1 500	3 000	1 000	2 000
184 < *U* ≤ 212	1 500	3 000	See Table 4	See Table 4	1 500	4 000 [a)]	1 000	2 000
212 < *U* ≤ 354	1 500	3 000	See Table 4	See Table 4	1 500	4 000 [a)]	1 500	3 000
354 < *U* ≤ 848	See Table 4	3 000	See Table 4	See Table 4	√2*U* + 1 000	2 x (√2*U* + 1 500)	√2*U* + 1 000	2 x (√2*U* + 1 500)
848 < *U* ≤ 1 414	See Table 4	3 000	See Table 4	See Table 4	√2*U* + 1 000	2 x (√2*U* + 1 500)	√2*U* + 1 000	2 x (√2*U* + 1 500)
1 414 < *U* ≤ 10 000	See Table 4	See Table 4	See Table 4	See Table 4	*U*/√2 + 2 000	√2*U* + 5 000	*U*/√2 + 2 000	√2*U* + 5 000
10 000 < *U* ≤ 14 140	1,06 x *U*/√2	1,06 x *U*/√2	1,06 x *U*/√2	1,06 x *U*/√2	*U*/√2 + 2 000	√2*U* + 5 000	*U*/√2 + 2 000	√2*U* + 5 000
U<10 000	If necessary, to be prescribed by particular standards							

[a)] For any single MOPP forming part of this insulation, the test voltage is 1 500V.

2658

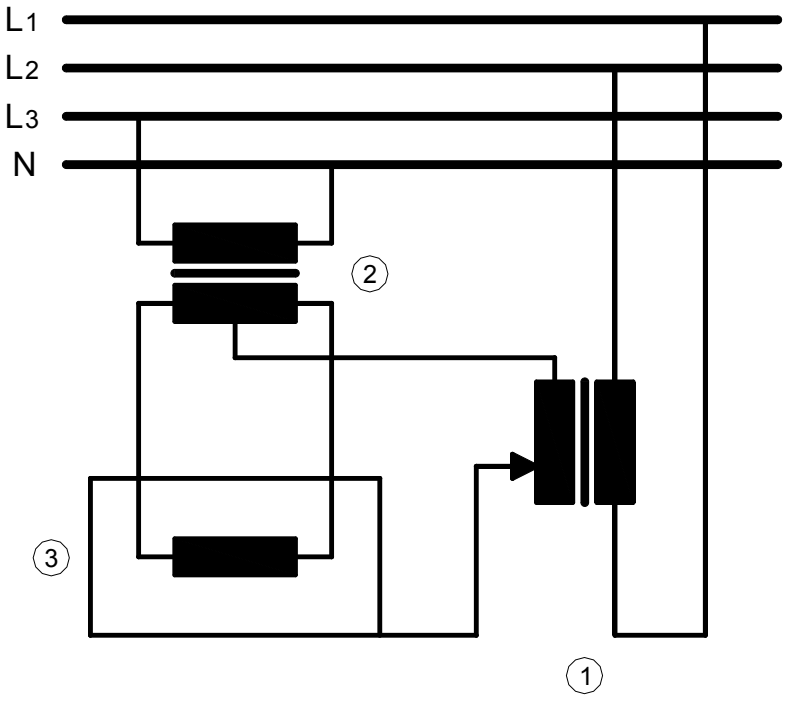
2659 **Attention of National Committees is drawn to the following:**

2660 The values for “U” in the first column of Table 3 were formerly given as r.m.s. but are now
2661 given as peak values. Therefore the formulae referring to “U” and “2U” have been changed to
2662 refer to U/√2 and √2U respectively.

2663 **Table 4 – Test voltages for MEANS OF OPERATOR PROTECTION**

2664 Test voltage in volts r.m.s.

REFERENCE VOLTAGE (U) peak or d.c.	1 MOOP	2 MOOP	*REFERENCE VOLTAGE (U)* peak or d.c.	1 MOOP	2 MOOP	*REFERENCE VOLTAGE (U)* peak or d.c.	1 MOOP	2 MOOP
34	500	800	250	1 261	2 018	1 750	3 257	3 257
35	507	811	260	1 285	2 055	1 800	3 320	3 320
36	513	821	270	1 307	2 092	1 900	3 444	3 444
38	526	842	280	1 330	2 127	2 000	3 566	3 566
40	539	863	290	1 351	2 162	2 100	3 685	3 685
42	551	882	300	1 373	2 196	2 200	3 803	3 803
44	564	902	310	1 394	2 230	2 300	3 920	3 920
46	575	920	320	1 414	2 263	2 400	4 034	4 034
48	587	939	330	1 435	2 296	2 500	4 147	4 147
50	598	957	340	1 455	2 328	2 600	4 259	4 259
52	609	974	350	1 474	2 359	2 700	4 369	4 369
54	620	991	360	1 494	2 390	2 800	4 478	4 478
56	630	1 008	380	1 532	2 451	2 900	4 586	4 586
58	641	1 025	400	1 569	2 510	3 000	4 693	4 693
60	651	1 041	420	1 605	2 567	3 100	4 798	4 798
62	661	1 057	440	1 640	2 623	3 200	4 902	4 902
64	670	1 073	460	1 674	2 678	3 300	5 006	5 006
66	680	1 088	480	1 707	2 731	3 400	5 108	5 108
68	690	1 103	500	1 740	2 784	3 500	5 209	5 209
70	699	1 118	520	1 772	2 835	3 600	5 309	5 309
72	708	1 133	540	1 803	2 885	3 800	5 507	5 507
74	717	1 147	560	1 834	2 934	4 000	5 702	5 702
76	726	1 162	580	1 864	2 982	4 200	5 894	5 894
78	735	1 176	588	1 875	3 000	4 400	6 082	6 082
80	744	1 190	600	1 893	3 000	4 600	6 268	6 268
85	765	1 224	620	1 922	3 000	4 800	6 452	6 452
90	785	1 257	640	1 951	3 000	5 000	6 633	6 633
95	805	1 288	660	1 979	3 000	5 200	6 811	6 811
100	825	1 319	680	2 006	3 000	5 400	6 987	6 987
105	844	1 350	700	2 034	3 000	5 600	7 162	7 162
110	862	1 379	720	2 060	3 000	5 800	7 334	7 334
115	880	1 408	740	2 087	3 000	6 000	7 504	7 504
120	897	1 436	760	2 113	3 000	6 200	7 673	7 673
125	915	1 463	780	2 138	3 000	6 400	7 840	7 840
130	931	1 490	800	2 164	3 000	6 600	8 005	8 005
135	948	1 517	850	2 225	3 000	6 800	8 168	8 168
140	964	1 542	900	2 285	3 000	7 000	8 330	8 330
145	980	1 568	950	2 343	3 000	7 200	8 491	8 491
150	995	1 593	1 000	2 399	3 000	7 400	8 650	8 650
152	1 000	1 600	1 050	2 454	3 000	7 600	8 807	8 807
155	1 000	1 617	1 100	2 508	3 000	7 800	8 964	8 964
160	1 000	1 641	1 150	2 560	3 000	8 000	9 119	9 119
165	1 000	1 664	1 200	2 611	3 000	8 200	9 273	9 273
170	1 000	1 688	1 250	2 661	3 000	8 400	9 425	9 425
175	1 000	1 711	1 300	2 710	3 000	8 600	9 577	9 577
180	1 000	1 733	1 350	2 758	3 000	8 800	9 727	9 727
184	1 000	1 751	1 400	2 805	3 000	9 000	9 876	9 876
185	1 097	1 755	1 410	2 814	3 000	9 200	10 024	10 024
190	1 111	1 777	1 450	2 868	3 000	9 400	10 171	10 171
200	1 137	1 820	1 500	2 934	3 000	9 600	10 317	10 317
210	1 163	1 861	1 550	3 000	3 000	9 800	10 463	10 463
220	1 189	1 902	1 600	3 065	3 065	10 000	10 607	10 607
230	1 214	1 942	1 650	3 130	3 130			
240	1 238	1 980	1 700	3 194	3 194			



2665

1 Dielectric strength tester

2 Isolating transformer

3 ME EQUIPMENT with heating element

2666

2667 **Figure 19 – Circuit for dielectric strength test at operating temperature for heating elements**
2668 **(see 8.8.3)**

2669 **8.8.4 [99]Insulation other than wire insulation**

2670 **8.8.4.1 *Mechanical strength and resistance to heat and fire**

2671 The insulating characteristics, mechanical strength, and resistance to heat and fire shall be
2672 retained by all types of insulation, including insulating partition walls, over the useful life of the
2673 ME EQUIPMENT.

2674 *Compliance is checked by inspection of the ME EQUIPMENT and the RISK MANAGEMENT FILE and,*
2675 *if necessary, in conjunction with the following tests:*

2676 – *resistance to moisture, etc. (see 11.6);*

2677 – *dielectric strength (see 8.8.3);*

2678 – *mechanical strength(see 15.3).*

2679 *Resistance to heat is established by the following tests, which need not be performed if*
2680 *satisfactory evidence of compliance is provided:*

2681 a) *For parts of the ENCLOSURE and other external insulating parts, the deterioration of which*
2682 *could influence the SAFETY of the ME EQUIPMENT, by the ball-pressure test:*

2683 *ENCLOSURES and other external parts of insulating material, except the insulation of flexible*
2684 *cords, are subjected to a ball-pressure test using the test apparatus shown in Figure 20.*
2685 *The surface of the part to be tested is placed in the horizontal position and a steel ball of*
2686 *5 mm diameter is pressed against the surface with a force of 20 N. The test is performed*

in a heating cabinet at a temperature of 75 °C ± 2 °C or at a temperature of 40 °C ± 2 °C plus the temperature rise of the relevant part of insulating material measured during the test of 11.1, whichever is the higher.

The ball is withdrawn after 1 h and the diameter of the impression made by the ball is measured. An impression greater than 2 mm is considered a failure. The test is not performed on parts of ceramic material.

b) *For parts of insulating material that support uninsulated parts of the MAINS PART, the deterioration of which could influence the safety of the ME EQUIPMENT, by the ball-pressure test:*

A test is performed as described in a) *above*, *but at a temperature of 125 °C ± 2 °C or at a temperature of 40 °C ± 2 °C plus the temperature rise that was determined during the test of 11.1 of the relevant part, whichever is the higher.*

The test is not performed on parts of ceramic material, insulating parts of commutators, brush-caps and the like, on coil formers not used as REINFORCED INSULATION and the insulation of cords.

NOTE For SUPPLEMENTARY INSULATION and REINFORCED INSULATION of thermoplastic materials, see also 13.1.2.

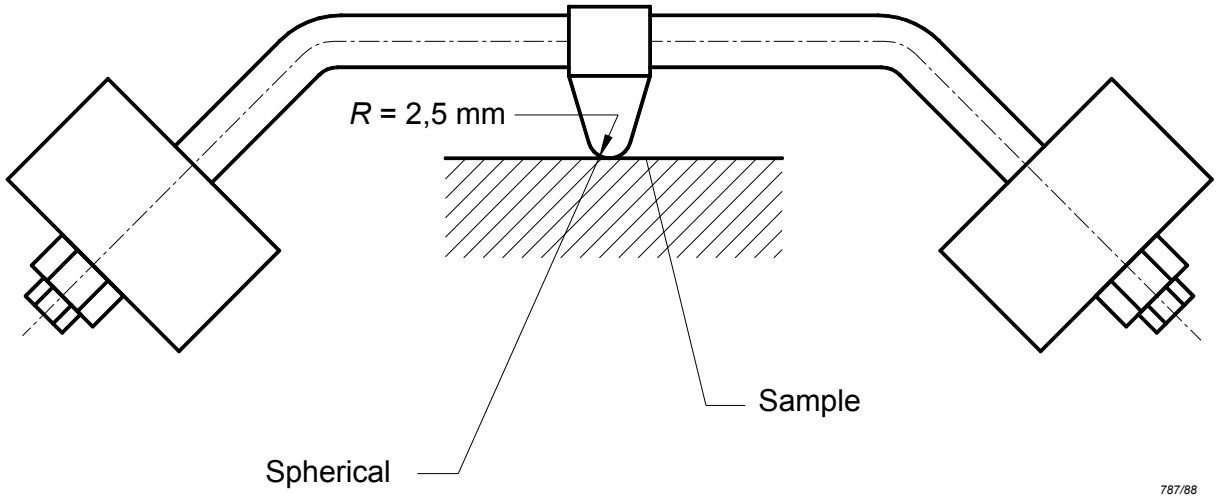


Figure 20 – Ball-pressure test apparatus (see 8.8.4.1)

8.8.4.2 Resistance to environmental stress

MEANS OF PROTECTION shall be so designed or protected that they are not likely to be impaired by deposition of dirt or by dust resulting from wear of parts within the ME EQUIPMENT to such an extent that CREEPAGE DISTANCES and AIR CLEARANCES are reduced below the values specified in 8.9.

Ceramic material not tightly sintered, and the like, and beads alone shall not be used as SUPPLEMENTARY INSULATION or REINFORCED INSULATION.

[100]Insulating material in which heating conductors are embedded may be considered as one MEANS OF PROTECTION but shall not be used as two MEANS OF PROTECTION.

Compliance is checked by inspection, by measurement and for natural latex rubber by the following test:

Parts of natural latex rubber are aged in an atmosphere of oxygen under pressure. The samples are suspended freely in an oxygen cylinder, the effective capacity of the cylinder is at least ten times the volume of the samples. The cylinder is filled with commercial oxygen not less than 97 % pure, to a pressure of 210 ± 7 N/cm^2.

The samples are kept in the cylinder at a temperature of 70 °C ± 2 °C for 96 h. Immediately afterwards, they are taken out of the cylinder and left at room temperature for at least 16 h. After the test, the samples are examined. Crack visible to the naked eye constitute a failure.

8.9 *CREEPAGE DISTANCES and AIR CLEARANCES

8.9.1 Values

8.9.1.1 General

CREEPAGE DISTANCES and AIR CLEARANCES of ME EQUIPMENT shall be equal or greater than the values of Table 7 to Table 12 (inclusive) except as specified in 8.9.1.2 to 8.9.1.14. See also 8.9.2 to 8.9.4.

8.9.1.2 CREEPAGE DISTANCES and AIR CLEARANCES complying with IEC 60950-1

The values of Table 7 to Table 12 (inclusive) do not apply to CREEPAGE DISTANCES and AIR CLEARANCES forming MEANS OF OPERATOR PROTECTION that comply with the requirements of IEC 60950-1 for insulation co-ordination.

8.9.1.3 CREEPAGE DISTANCES across glass, mica, ceramic and similar materials

For CREEPAGE DISTANCES across glass, mica, ceramic and similar materials, the specified minimum value of AIR CLEARANCE shall be applied as the minimum CREEPAGE DISTANCE.

8.9.1.4 Minimum CREEPAGE DISTANCE

If the minimum CREEPAGE DISTANCE derived from Table 7 to Table 12 (inclusive) is less than the applicable minimum AIR CLEARANCE, that value of minimum AIR CLEARANCE shall be applied as the minimum CREEPAGE DISTANCE.

8.9.1.5 ME EQUIPMENT RATED for high altitudes

If the ME EQUIPMENT is RATED to operate at an altitude greater than 2 000 m, the AIR CLEARANCE is multiplied by a factor derived from Table 5. These factors are not applied to CREEPAGE DISTANCES, but CREEPAGE DISTANCES shall always be at least as large as the resulting value for AIR CLEARANCE.

Table 5 – Multiplication factors for AIR CLEARANCES for altitudes up to 5 000 m

Rated operating altitude (*a*) m	Multiplication factor
2 000 ≤ *a*	1,00
2 000 < *a* ≤ 3 000	1,14
3 000 < *a* ≤ 4 000	1,29
a > 5 000	1,48

8.9.1.6 *Interpolation

If the REFERENCE VOLTAGE (*U*) has a value between those given in Table 7 to Table 12 (inclusive):

– for determining CREEPAGE DISTANCES, linear interpolation is permitted between the nearest two values, the calculated spacing being rounded to the next higher 0,1 mm increment;

– for determining AIR CLEARANCES for REFERENCE VOLTAGES (U) above 2 000 V r.m.s. or 2 800 V d.c., linear interpolation is permitted between the nearest two values, the calculated spacing being rounded to the next higher 0,1 mm increment;

– for determining AIR CLEARANCES for REFERENCE VOLTAGES (U) up to 2 000 V r.m.s. or 2 800 V d.c., the higher of the two values shall be applied. [101]

8.9.1.7 Material Groups classification

Material Groups are classified as shown in Table 6

Table 6 – Material Group classification

Material Group	Comparative tracking index (CTI)
I	600 ≤ CTI
II	400 ≤ CTI < 600
IIIa	175 ≤ CTI < 400
IIIb	100 ≤ CTI < 175

The Material Group is verified by evaluation of the test data for the material according to IEC 60112 using 50 drops of solution A.

If the Material Group is not known, Material Group IIIb shall be assumed.

8.9.1.8 Pollution Degree classification

Pollution degrees are classified as follows:

– Pollution Degree 1 is used to describe components and assemblies that are sealed so as to exclude dust and moisture.

– Pollution Degree 2 is used generally for electrical equipment employed in an office type of environment.

– Pollution Degree 3 is used to describe a local internal environment within an electrical equipment, which is subject to conductive pollution, or to dry non-conductive pollution, which could become conductive due to expected condensation.

8.9.1.9 AIR CLEARANCE for MAINS PARTS

For MAINS PARTS operating on RATED SUPPLY MAINS voltages up to 300 V, if the REFERENCE VOLTAGE (U) for insulation of the MAINS PART exceeds the RATED SUPPLY MAINS voltage, the required AIR CLEARANCE is the value in Table 9 plus the additional AIR CLEARANCE in Table 10.

8.9.1.10 SUPPLY MAINS overvoltage

If ME EQUIPMENT is intended to be used in locations where the SUPPLY MAINS is in overvoltage category III or IV, the values specified in Table 9 to Table 11 will be inadequate and values should be taken from IEC 60950-1.

8.9.1.11 Floating SECONDARY CIRCUITS

The values in Table 11 apply to floating SECONDARY CIRCUITS if either the SECONDARY CIRCUIT IS separated from the MAINS PART by a functionally earthed or PROTECTIVELY EARTHED metal screen or transients on the SECONDARY CIRCUIT are below the transient rating (for example due to being attenuated by connecting a component, such as a capacitor, between the SECONDARY CIRCUIT and earth).

The column for circuits not subject to transient overvoltages applies to:

– d.c. SECONDARY CIRCUITS that are reliably connected to earth and have capacitive filtering which limits the peak-to-peak ripple to 10 % of the dc voltage; and

– circuits in INTERNALLY POWERED ME EQUIPMENT.

AIR CLEARANCES for MEANS OF OPERATOR PROTECTION in other floating SECONDARY CIRCUITS are subject to the values for MAINS PARTS.

8.9.1.12 REFERENCE VOLTAGES above 1 400 V peak or d.c. or 1 000 V r.m.s.

The values in Table 11 for REFERENCE VOLTAGES (*U*) above 1 400 V peak or d.c. or 1 000 V r.m.s. do not apply if all the following conditions are satisfied:

– the AIR CLEARANCE is at least 5 mm;

– the insulation involved passes a dielectric strength test according to 8.8.3 using:

- an a.c. test voltage whose r.m.s. value is equal to 1,06 times the REFERENCE VOLTAGE (*U*) or
- a d.c. test voltage equal to the peak value of the a.c. test voltage prescribed above;

NOTE The peak or d.c. test voltage is therefore √2 times 1,06 times the REFERENCE VOLTAGE (*U*).

and

– the AIR CLEARANCE path is partly or entirely through air and/or along the surface of an insulating material of Material Group I.

If the AIR CLEARANCE path is also partly along the surface of a material that is not Material Group I, the dielectric strength test is conducted only across the part(s) of the path that are through air and/or along the surface of an insulating material of Material Group I.

8.9.1.13 Minimum CREEPAGE DISTANCES for two MEANS OF OPERATOR PROTECTION

Minimum CREEPAGE DISTANCES for two MEANS OF OPERATOR PROTECTION are obtained by doubling the values shown in Table 12 for one MEANS OF OPERATOR PROTECTION .

8.9.1.14 *CREEPAGE DISTANCES and AIR CLEARANCES for DEFIBRILLATION-PROOF APPLIED PARTS

CREEPAGE DISTANCES and AIR CLEARANCES needed to satisfy 8.5.5 for DEFIBRILLATION-PROOF APPLIED PARTS shall not be less than 4 mm.

Table 7 – Minimum CREEPAGE DISTANCES and AIR CLEARANCES between parts of opposite polarity of the MAINS PART[102]

REFERENCE VOLTAGE (*U*) d.c. up to and including	REFERENCE VOLTAGE (*U*) a.c. up to and including	AIR CLEARANCE mm	CREEPAGE DISTANCE mm
15	12	0,4	0,8
36	30	0,5	1
75	60	0,7	1,3
150	125	1	2
300	250	1,6	3
450	400	2,4	4
600	500	3	5,5
800	660	4	7
900	750	4,5	8
1200	1000	6	11

2818 **Table 8 – Minimum CREEPAGE DISTANCES and AIR CLEARANCES providing**
2819 **MEANS OF PATIENT PROTECTION[103]**

REFERENCE VOLTAGE (*U*) V d.c. up to and including	REFERENCE VOLTAGE (*U*) V a.c. up to and including	Spacing providing one MEANS OF PATIENT PROTECTION		Spacing providing two MEANS OF PATIENT PROTECTION	
		AIR CLEARANCE mm	CREEPAGE DISTANCE mm	AIR CLEARANCE mm	CREEPAGE DISTANCE mm
15	12	0,8	1,7	1,6	3,4
36	30	1	2	2	4
75	60	1,2	2,3	22,4	4,6
150	125	1,6	3	3,2	6
300	250	2,5	4	5	8
450	400	3,5	6	7	12
600	500	4,5	8	9	16
800	660	6	10,5	12	21
900	750	6,5	12	13	24
1200	1000	9	16	18	32

2820 **Table 9 – Minimum AIR CLEARANCES providing MEANS OF OPERATOR PROTECTION from the MAINS**
2821 **PART**

2822 AIR CLEARANCE in millimetres

REFERENCE VOLTAGE(*U*) up to and including		NOMINAL SUPPLY MAINS Voltage ≤ 150 V (Mains Transient Voltage 1 500 V)				150 V < NOMINAL SUPPLY MAINS voltage ≤ 300 V (Mains Transient Voltage 2 500 V)				300 V < NOMINAL SUPPLY MAINS voltage ≤ 600 V (Mains Transient Voltage 4 000V)	
Voltage peak or d.c.	Voltage r.m.s	Pollution Degrees 1 and 2		Pollution Degree 3		Pollution Degrees 1 and 2		Pollution Degree 3		Pollution Degrees 1, 2 and 3	
V	V	1 MOOP	2 MOOP	1 MOOP	2 MOOP	1 MOOP	2 MOOP	1 MOOP	2 MOOP	1 MOOP	2 MOOP
71	50	1,0	2,0	1,3	2,6	2,0	4,0	2,0	4,0	3,2	6,4
210	150	2,0	2,0	1,3	2,6	2,0	4,0	2,0	4,0	3,2	6,4
420	300	1 MOOP 2,0 2 MOOP 4,0								3,2	6,4
840	600	1 MOOP 3,2 2 MOOP 6,4									
1 400	1 000	1 MOOP 4,2 2 MOOP 6,4									
2 800	2 000	1 or 2 MOOP 8,4									
7 000	5 000	1 or 2 MOOP 17,5									
9 800	7 000	1 or 2 MOOP 25									
14 000	10 000	1 or 2 MOOP 37									
28 000	20 000	1 or 2 MOOP 80									
AIR CLEARANCES for REFERENCE VOLTAGES above 30 kV r.m.s. or 42 kV d.c. are to be prescribed by particular standards If necessary											

2823 **Table 10 – Additional AIR CLEARANCES for insulation in MAINS PARTS with REFERENCE VOLTAGES**
2824 **exceeding the peak value of the NOMINAL SUPPLY MAINS voltage (See 8.9.1.9.)**

NOMINAL SUPPLY MAINS voltage ≤ 150 V r.m.s. or 210 V dc		150 V r.m.s. or 210 V dc < NOMINAL SUPPLY MAINS voltage ≤ 300 V r.m.s. or 420 V dc	Additional AIR CLEARANCE mm	
Pollution Degrees 1 and 2	Pollution Degree 3	Pollution Degrees 1, 2 and 3	1 MOOP	2 MOOP
REFERENCE VOLTAGE (*U*) V	REFERENCE VOLTAGE (*U*) V	REFERENCE VOLTAGE (*U*) V		
210	210	420	0	0
298	294	493	0,1	0,2
386	379	567	0,2	0,4
474	463	640	0,3	0,6
562	547	713	0,4	0,8
650	632	787	0,5	1,0
738	715	860	0,6	1,2
826	800	933	0,7	1,4
914		1 006	0,8	1,6
1 002		1 080	0,9	1,8
1 090		1 153	1,0	2,0
		1 226	1,1	2,2
		1 300	1,2	2,4

Select the appropriate column for the RATED SUPPLY MAINS VOLTAGE and Pollution Degree and choose the row in that column which covers the actual REFERENCE VOLTAGE. Read the additional AIR CLEARANCE required from the relevant right hand column (for one or two MEANS OF OPERATOR PROTECTION and add this to the minimum AIR CLEARANCE from Table 9 to give the total minimum AIR CLEARANCE.

2825 **Table 11 – Minimum AIR CLEARANCES for MEANS OF OPERATOR PROTECTION in SECONDARY CIRCUITS**
2826 **(See 8.9.1.11.)**

2827 AIR CLEARANCES in millimetres

REFERENCE VOLTAGE (*U*) up to and including		Transient rating for SECONDARY CIRCUIT 800 V (NOMINAL SUPPLY MAINS voltage ≤ 150 V)				Transient rating for SECONDARY CIRCUIT 1 500 V (150 V < NOMINAL SUPPLY MAINS voltage ≤ 300 V)				Transient rating for SECONDARY CIRCUIT 2 500 V (300 V < NOMINAL SUPPLY MAINS voltage ≤600 V)		Circuit not subject to transient overvoltages	
Voltage peak or d.c.	Voltage r.m.s. (sinu-soidal)	Pollution Degrees 1 and 2		Pollution Degree 3		Pollution Degrees 1 and 2		Pollution Degree 3		Pollution Degrees 1, 2 and 3		Pollution Degrees 1 and 2 only	
		1 MOOP	2 MOOP	1 MOOP	2 MOOP	1 MOOP	2 MOOP	1 MOOP	2 MOOP	1 MOOP	2 MOOP	1 MOOP	2 MOOP
71	50	0,7	1,4	1,3	2,6	1,0	2,0	1,3	2,6	2,0	4,0	0,4	0,8
140	100	0,7	1,4	1,3	2,6	1,0	2,0	1,3	2,6	2,0	4,0	0,7	1,4
210	150	0,9	1,8	1,3	2,6	1,0	2,0	1,3	2,6	2,0	4,0	0,7	1,4
280	200	1 MOOP 1,4 2 MOOP 2,8								2,0	4,0	1,1	2,2
420	300	1 MOOP 1,9 2 MOOP 3,8								2,0	4,0	1,4	2,8
700	500	1 MOOP 2,5 2 MOOP 5,0											
840	600	1 MOOP 3,2 2 MOOP 5,0											
1 400	1 000	1 MOOP 4,2 2 MOOP 5,0											
2 800	2 000	1 or 2 MOOP 8,4 but see 8.9.1.12											
7 000	5 000	1 or 2 MOOP 17,5 but see 8.9.1.12											
9 800	7 000	1 or 2 MOOP 25 but see 8.9.1.12											
14 000	10 000	1 or 2 MOOP 37 but see 8.9.1.12											
28 000	20 000	1 or 2 MOOP 80 but see 8.9.1.12											
42 000	30 000	1 or 2 MOOP 130 but see 8.9.1.12											

Table 12 – Minimum CREEPAGE DISTANCES providing MEANS OF OPERATOR PROTECTION[104]

CREEPAGE DISTANCE in millimetres

REFERENCE VOLTAGE (*U*) V r.m.s or d.c.	Spacing for one MEANS OF OPERATOR PROTECTION						
	Pollution Degree 1	Pollution Degree 2			Pollution Degree 3		
	Material Group	Material Group			Material Group		
	I, II, IIIa, IIIb	I	II	IIIa or IIIb	I	II	IIIa or IIIb
50	Use the AIR CLEARANCE from the appropriate table	0,6	0,9	1,2	1,5	1,7	1,9
100		0.7	1,0	1,4	1,8	2,0	2,2
125		0.8	1,1	1,5	1,9	2,1	2,4
150		0,8	1,1	1,6	2,0	2,2	2,5
200		1.0	1,4	2,0	2,5	2,8	3,2
250		1.3	1,8	2,5	3,2	3,6	4,0
300		1.6	2,2	3,2	4,0	4,5	5,0
400		2.0	2,8	4,0	5,0	5,6	6,3
600		3.2	4,5	6,3	8,0	9,6	10,0
800		4.0	5,6	8,0	10,0	11,0	12,5
1000		5.0	7,1	10,0	12,5	14,0	16,0

8.9.2 *Application

a) For insulation in the MAINS PART between parts of opposite polarity, the minimum CREEPAGE DISTANCES and AIR CLEARANCES are not required if short-circuiting of each single one of these CREEPAGE DISTANCES and AIR CLEARANCES in turn does not produce a HAZARD.[105]

b) The contribution to the CREEPAGE DISTANCES of any groove or air gap less than 1 mm wide shall be limited to its width (see Figure 22 to Figure 30 [inclusive]).[106] [107]

c) If AIR CLEARANCE provides MEANS OF PROTECTION, the relative positioning shall be such that the relevant parts are rigid and located by moulding or the design shall be otherwise such that there is no likelihood of a distance being reduced below the specified value by deformation or movement of the parts.

Where limited movement of one of the relevant parts is normal or likely, this shall be taken into account when computing the minimum AIR CLEARANCE.

8.9.3 *Spaces filled by insulating compound

Attention of National Committees is drawn to the rationale for this new subclause.

8.9.3.1 General

Where distances between conductive parts are filled with insulating compound, including where insulation is reliably cemented together with insulating compound, so that AIR CLEARANCES and CREEPAGE DISTANCES do not exist, only the requirements for solid insulation apply.

NOTE Examples of such treatment include potting, encapsulation and vacuum impregnation, components or subassemblies that are treated with an insulating compound that fills voids; and internal insulation between adjacent tracks on one layer of a multi-layer printed board.

Compliance is checked by inspection, measurement and test of samples. Requirements for CREEPAGE DISTANCES and AIR CLEARANCES do not apply if samples pass the thermal cycling, humidity preconditioning and dielectric strength tests specified in either 8.9.3.2 and 8.9.3.4 or 8.9.3.3 and 8.9.3.4.

8.9.3.2 Insulating compound forming solid insulation between conductive parts

For situations where insulating compound forms solid insulation between conductive parts, a single finished sample is tested. The sample is subjected to the thermal cycling PROCEDURE as specified in 8.9.3.4, followed by humidity preconditioning according to 5.7 except for 48 hours only, followed by a dielectric strength test according to 15.2 except that the test voltage is multiplied by 1,6. The tests are followed by inspection, including sectioning, and measurement. Cracks or voids in the insulating compound such as would affect the homogeneity of the material constitute a failure.

8.9.3.3 Insulating compound forming a cemented joint with other insulating parts

For situations where insulating compound forms a cemented joint with other insulating parts, the reliability of the joint is checked by testing three samples. If a winding of solvent-based enamelled wire is used, it is replaced for the test by a metal foil or by a few turns of bare wire, placed close to the cemented joint. The three samples are then tested as follows:

– *One of the samples is subjected to the thermal cycling PROCEDURE as specified in 8.9.3.4. Immediately after the last period at highest temperature during thermal cycling it is subjected to a dielectric strength test according to 8.8.2 except that the test voltage is multiplied by 1,6;*

– *The other two samples are subjected to humidity preconditioning according to 5.7 except for 48 hours only, followed by a dielectric strength test according to 8.8.2 except that the test voltage is multiplied by 1,6.*

8.9.3.4 Thermal cycling

The sample is subjected 10 times to the following sequence of temperature cycles:

68 h at T_1 ± 2 °C;

1 h at 25 °C ± 2 °C;

2 h at 0 °C ± 2 °C;

not less than 1 h at 25 °C ± 2 °C,

where T_1 is the higher of

– *10 °C above the maximum temperature of the relevant part as determined according to 11.1.1; or*

– *85 °C*

However, the 10 °C margin is not added if the temperature is measured by an embedded thermocouple.

The period of time taken for the transition from one temperature to another is not specified, but the transition is permitted to be gradual.

8.9.4 *Measurement of CREEPAGE DISTANCES AND AIR CLEARANCES

Compliance is checked by measurement taking into account the rules in Figure 21 to Figure 30 (inclusive). In each figure, the dotted line represents AIR CLEARANCE and the solid line represents CREEPAGE DISTANCE.

Any corner with included angle less than 80° is assumed to be bridged with an insulating link of 1 mm moved into the least favourable position (see Figure 24).

Where the distance across the top of a groove is 1 mm or more, no CREEPAGE DISTANCE exists across the air space (see Figure 23).

CREEPAGE DISTANCES and AIR CLEARANCES between parts moving relative to each other are measured with the parts in their least favourable positions.

Computed CREEPAGE DISTANCE is never less than measured AIR CLEARANCE.

Any air gap less than 1 mm wide is ignored in computing the total AIR CLEARANCE.

Coatings of varnish, enamel or oxide are ignored. Coverings of any insulating material, however, are considered as insulation, if the covering is equivalent to a foil of insulating material of equal thickness with respect to its electrical, thermal and mechanical properties.

If CREEPAGE DISTANCES or AIR CLEARANCES are interrupted by a floating conductive part, the minimum value specified in Table 5 to Table 12 (inclusive) applies to the sum of the sections, except that distances less than 1 mm are not taken into consideration.

If there are grooves transverse to the CREEPAGE DISTANCE, the wall of the groove is counted as CREEPAGE DISTANCE only if the width of the groove is more than 1 mm (see Figure 23). In all other cases the groove is neglected.

In the case of a barrier placed on the surface of insulation or held in a recess, the CREEPAGE DISTANCES may be measured over the barrier only if the latter is so affixed that dust and moisture cannot penetrate into the joint or recess.

For ME EQUIPMENT provided with an APPLIANCE INLET, the measurements are made with an appropriate connector inserted. For other ME EQUIPMENT incorporating POWER SUPPLY CORDS, they are made with supply conductors of the largest cross-sectional area specified by the MANUFACTURER and also without conductors.

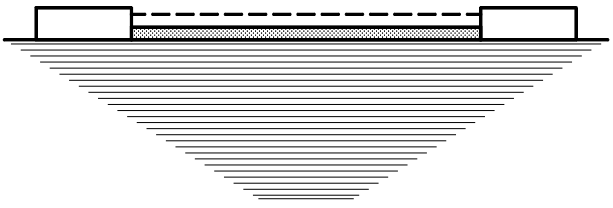
Movable parts are placed in the least favourable position; nuts and screws with non-circular heads are tightened in the least favourable position.

CREEPAGE DISTANCES and AIR CLEARANCES through slots or openings in external parts are measured to the standard test finger of Figure 6. If necessary, a force is applied to any point on bare conductors and to the outside of metal ENCLOSURES in an endeavour to reduce the CREEPAGE DISTANCES and AIR CLEARANCES while taking the measurements.

The force is applied by means of a standard test finger having a tip as shown in Figure 6 and has a value of:

2 N for bare conductors;
30 N for ENCLOSURES.

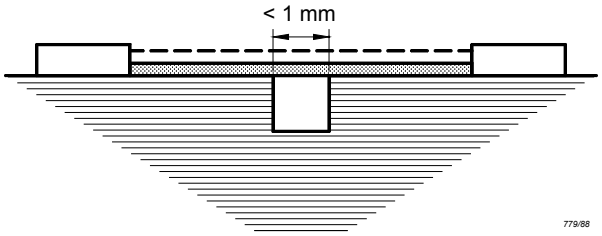
CREEPAGE DISTANCE and AIR CLEARANCES are measured after use of the test hook according to 5.9.2.2, if relevant.



Condition: Path under consideration is a flat surface.

Rule: CREEPAGE DISTANCE and AIR CLEARANCE are measured directly across the surface.

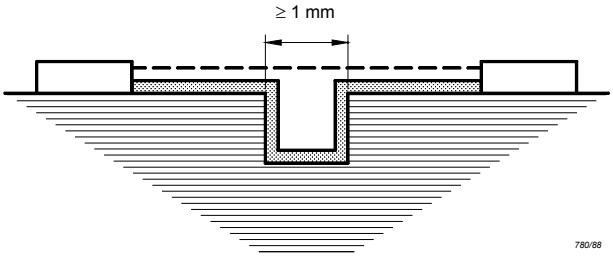
Figure 21 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 1 (see 8.9.4)



Condition: Path under consideration includes a parallel- or converging-sided groove of any depth with a width less than 1 mm.

Rule: CREEPAGE DISTANCE and AIR CLEARANCE are measured directly across the groove as shown.

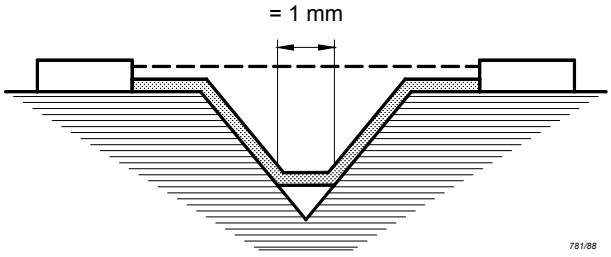
Figure 22 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 2 (see 8.9.2 *b)*)



Condition: Path under consideration includes a parallel-sided groove of any depth and equal to or more than 1 mm.

Rule: AIR CLEARANCE is the "line of sight" distance. CREEPAGE DISTANCE path follows the contour of the groove.

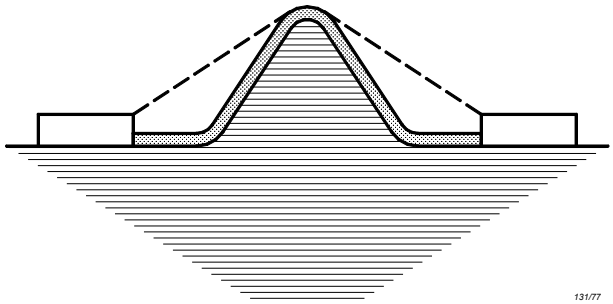
Figure 23 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 3 (see 8.9.2 *b)*)



Condition: Path under consideration includes a V-shaped groove with a width greater than 1 mm and an internal angle of less than 80 º.

Rule: AIR CLEARANCE is the "line of sight" distance. CREEPAGE DISTANCE path follows the contour of the groove but "short-circuits" the bottom of the groove by a 1 mm link.

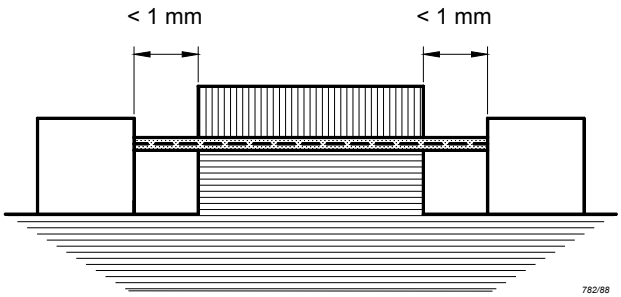
Figure 24 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 4 (see 8.9.2 *b)*)



Condition: Path under consideration includes a rib.

Rule: AIR CLEARANCE is the shortest direct air path over the top of the rib. CREEPAGE DISTANCE path follows the contour of the rib.

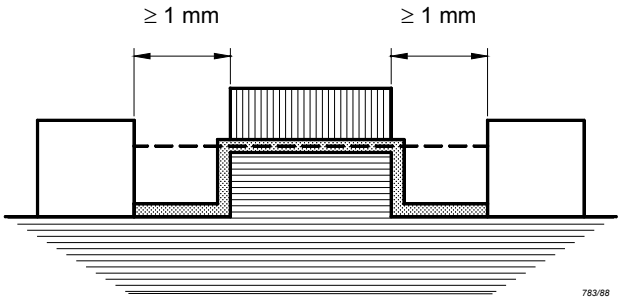
Figure 25 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 5 (see 8.9.2 *b)*)



Condition: Path under consideration includes an uncemented joint (see 8.9.3) with grooves less than 1 mm wide on each side.

Rule: CREEPAGE DISTANCE and AIR CLEARANCE path are the "line of sight" distance shown.

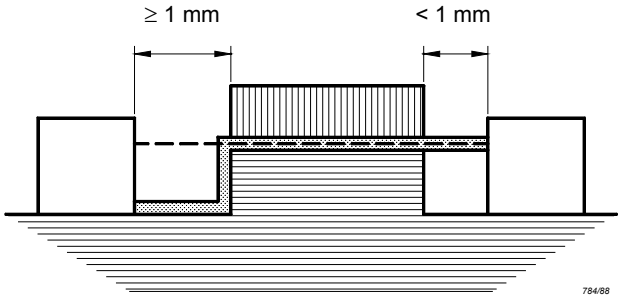
Figure 26 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 6 (see 8.9.2 *b)*)



Condition: Path under consideration includes an uncemented joint (see 8.9.3) with grooves equal to or more that 1 mm wide on each side.

Rule: AIR CLEARANCE is the "line of sight" distance. CREEPAGE DISTANCE path follows the contour of the groove.

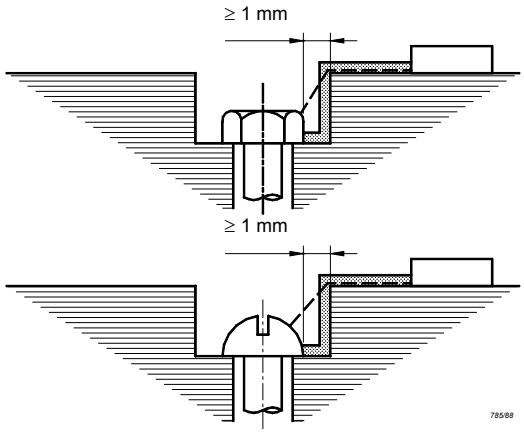
Figure 27 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 7 (see 8.9.2 *b)*)



Condition: Path under consideration includes an uncemented joint (see 8.9.3) with a groove on one side less than 1 mm wide and the groove on the other side equal to or more than 1 mm wide.

Rule: AIR CLEARANCE and CREEPAGE DISTANCE are as shown.

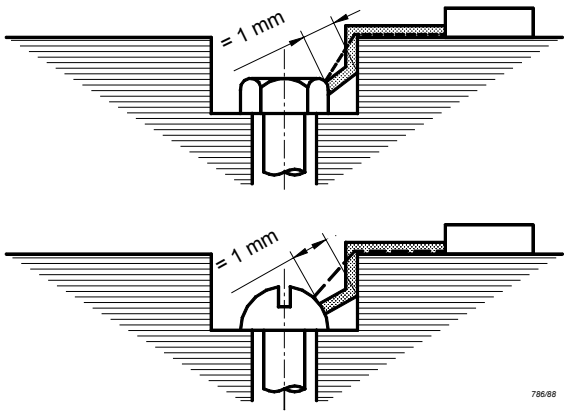
Figure 28 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 8 (see 8.9.2 *b)*)



Condition: Gap between head of screw and wall of recess wide enough to be taken into account.

Rule: The AIR CLEARNACE is the shortest distance to any point on the head of the screw. CREEPAGE DISTANCE path follows the surface.

Figure 29 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 9 (see 8.9.2 *b)*)



Condition: Gap between head of screw and wall of recess too narrow to be taken into account.

Rule: Measurement of CREEPAGE DISTANCE is from screw to wall at any point where the distance is equal to 1 mm. The AIR CLEARNACE is the shortest distance to any point on the head of the screw.

Figure 30 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 10[108] (see 8.9.2 *b)*)

8.10 Components and wiring[109 110 111]

8.10.1 *Fixing of components

Components of ME EQUIPMENT, the unwanted movement of which could result in an unacceptable RISK, shall be mounted securely to prevent such movement.

Compliance is checked by inspection of the ME EQUIPMENT and the RISK MANAGEMENT FILE.

8.10.2 *Fixing of wiring

Conductors and connectors of ME EQUIPMENT shall be so secured or insulated that accidental detachment shall not result in a HAZARD. They are not considered to be adequately secured if on breaking free at their joint and moving about their support point they are capable of touching circuit points giving rise to a HAZARD.

One instance of breaking free shall be considered to be a SINGLE FAULT CONDITION.

Stranded conductors shall not be solder-coated if they are affixed by any clamping means and poor contact could lead to a HAZARD.

Compliance is checked by inspection of the ME EQUIPMENT and the RISK MANAGEMENT FILE.

8.10.3 Connections between different parts of ME EQUIPMENT

Flexible cords detachable without the use of a TOOL that are used for interconnection of different parts of ME EQUIPMENT shall be provided with means for connection such that compliance of metal ACCESSIBLE PARTS with 8.2 is not compromised when a connection is loosened or broken due to the disengagement of one of the connecting means.

Compliance is checked by inspection and measurement and, if necessary, by a test with the standard test finger according to 5.9.2.

8.10.4 *Cord-connected HAND-HELD parts and cord-connected foot-operated control devices (See also 15.4.7.)

8.10.4.1 Limitation of operating voltages

Cord-connected HAND-HELD and foot-operated control devices of ME EQUIPMENT and their associated connection cords shall contain only conductors and components operating at voltages not exceeding 42,4 V peak a.c. or 60 V d.c. in circuits isolated from the MAINS PART by two MEANS OF PROTECTION. The d.c. limit of 60 V applies to d.c. with not more than 10 % peak-to-peak ripple. If the ripple exceeds that amount, the 42,4 V peak limit applies.

Compliance is checked by inspection and, if necessary, voltage measurements.

8.10.4.2 Connection cords

The connection and anchorage of a flexible cord to a HAND-HELD or foot-operated control device of ME EQUIPMENT at the entry point to the control device shall comply with the requirements specified for POWER SUPPLY CORDS in 8.11.3. This requirement also applies to other HAND-HELD parts if disturbance or breaking of one or more of the connections could cause a HAZARD.[112]

Compliance is checked by performance of the tests of 8.11.3.[113]

8.10.5 *Mechanical protection of wiring

a) Internal cables and wiring shall be adequately protected against contact with a moving part or from friction at sharp corners and edges.

b) ME EQUIPMENT shall be so designed that wiring, cord forms or components are not likely to be damaged in the normal PROCESS of assembly or the opening or closing of ACCESS COVERS.

Compliance is checked by inspection and, where appropriate, by manual test or reference to the RISK MANAGEMENT FILE.

8.10.6 *Bending of leads

Guiding rollers of leads of ME EQUIPMENT shall be constructed in such a manner that movable leads in NORMAL USE are not bent round a radius of less than five times the outer diameter of the lead concerned.

Compliance is checked by inspection and measurement of the relevant dimensions.

8.10.7 *Insulation of internal wiring

a) If insulating sleeving is needed on internal wiring of ME EQUIPMENT, it shall be adequately secured. Sleeving that can only be removed by breaking or cutting or that is secured at both ends may be used to satisfy this requirement.

b) Inside ME EQUIPMENT the sheath of a flexible cord shall not be used as a MEANS OF PROTECTION if it is subject to mechanical or thermal stresses outside its RATED characteristics.

c) Insulated conductors of ME EQUIPMENT that in NORMAL USE are subject to temperatures exceeding 70 °C shall have insulation of heat-resistant material if compliance with this standard is likely to be impaired by deterioration of the insulation.

Compliance is checked by inspection and, if necessary, by special tests. Temperatures are determined as indicated in 11.1.[114]

8.11 MAINS PARTS, components and layout

8.11.1 Isolation from the SUPPLY MAINS

a) *ME EQUIPMENT shall have means to isolate its circuits electrically from the SUPPLY MAINS on all poles simultaneously, except that PERMANENTLY INSTALLED ME EQUIPMENT connected to a polyphase SUPPLY MAINS may be provided with a device that does not interrupt the neutral conductor, provided that local installation conditions are such that in NORMAL CONDITION the voltage on the neutral conductor can be expected not to exceed the limits specified in 8.4.2 *c)*.

b) Means for isolation either shall be incorporated in ME EQUIPMENT or, if external, shall be described in the technical description (see 7.10.3.1).

c) A SUPPLY MAINS switch that is used to comply with 8.11.1 *a)* shall comply with the CREEPAGE DISTANCES and AIR CLEARANCES as specified in IEC 61058-1.

d) A SUPPLY MAINS switch shall not be incorporated in a POWER SUPPLY CORD or any other external, flexible lead.

e) The direction of movement of the actuator of a SUPPLY MAINS switch that is used to comply with 8.11.1 *a)* shall comply with IEC 60447.

f) In non-PERMANENTLY INSTALLED ME EQUIPMENT a suitable plug device used to isolate ME EQUIPMENT from the SUPPLY MAINS shall be considered as complying with the requirements of 8.11.1 *a).* An APPLIANCE COUPLER or a flexible cord with a MAINS PLUG may be used.

g) A fuse or a semiconductor device shall not be used as an isolating means in the sense of this subclause.

h) *ME EQUIPMENT shall not include a device that causes disconnection of the ME EQUIPMENT from the SUPPLY MAINS by producing a short-circuit that results in operation of an overcurrent protection device.

i) *Any part within the ENCLOSURE of ME EQUIPMENT with a circuit voltage exceeding 42,4 V peak a.c. or 60 V d.c. that cannot be disconnected from its supply by an external switch or a plug device that is accessible at all times shall be protected against being touched even after opening of the ENCLOSURE by an additional covering or, in the case of a spatially separated arrangement, shall be marked clearly as exceeding the permitted voltage for parts that can be touched. The use of the Symbol ISO 7000-0434 (see Table D1, Symbol 10) is not sufficient. A warning notice on the outside of the ME EQUIPMENT may be used.[115]

Compliance is checked by inspection.

For a part that cannot be disconnected from the supply by an external switch or a plug device that is accessible at all times, compliance is checked by inspection of the required cover or warning notice (if present) and, if necessary, by application of the standard test finger of Figure 6.

8.11.2 *MULTIPLE SOCKET-OUTLETS

MULTIPLE SOCKET-OUTLETS that are integral with ME EQUIPMENT shall comply with the requirements of 16.9.2.1[116].

[117]*Compliance is checked by inspection.*

8.11.3 POWER SUPPLY CORDS

8.11.3.1 Application

The MAINS PLUG of ME EQUIPMENT shall not be fitted with more than one POWER SUPPLY CORD.

Compliance is checked by inspection.

8.11.3.2 Types

Any POWER SUPPLY CORD of ME EQUIPMENT shall be not less robust than ordinary tough rubber-sheathed flexible cord (IEC 60245-1: 1998, Annex A, designation 53) or ordinary polyvinyl chloride sheathed flexible cord (IEC 60227-1: 1998, Annex A, designation 53).

A polyvinyl chloride insulated POWER SUPPLY CORD shall not be used for ME EQUIPMENT having external metal parts with a temperature exceeding 75 °C and which may be touched in NORMAL USE by the cord, unless it is RATED for that temperature. See also Table 18.

Compliance is checked by inspection and measurement.

8.11.3.3 Cross-sectional area of POWER SUPPLY CORD conductors

The NOMINAL cross-sectional area of conductors of any POWER SUPPLY CORD of ME EQUIPMENT shall be not less than that shown in Table 13.

NOTE The RATED current is the long-term rating unless a momentary or short-term rating significantly heats the cord: see 18.2.4.3.

Compliance is checked by inspection.

Table 13 – NOMINAL cross-sectional area of conductors of a POWER SUPPLY CORD

RATED current (*I*) of ME EQUIPMENT A	NOMINAL Cross-sectional area mm^2 Cu
$I \leq 6$	0,75
$6 < I \leq 10$	1
$10< I \leq 16$	1,5
$16< I \leq 25$	2,5
$25< I \leq 32$	4
$32< I \leq 40$	6
$40< I \leq 63$	10

8.11.3.4 *Cord anchorage

a) The conductors of a POWER SUPPLY CORD shall be relieved from strain, including twisting, and the insulation of the conductors shall be protected from abrasion at the point of entry to ME EQUIPMENT or a MAINS CONNECTOR by a cord anchorage.

b) The cord anchorages of a POWER SUPPLY CORD shall be made:

- of insulating material, or
- of metal, insulated from conductive ACCESSIBLE PARTS not PROTECTIVELY EARTHED by a MEANS OF PROTECTION, or
- of metal provided with an insulating lining, if otherwise a total insulation failure of the POWER SUPPLY CORD could cause conductive ACCESSIBLE PARTS that are not PROTECTIVELY EARTHED to exceed the limits specified in 8.4. This lining shall be FIXED to the cord anchorage, unless it is a flexible bushing that forms part of the cord guard specified in this subclause, and shall comply with the requirements for one MEANS OF PROTECTION.

c) The cord anchorage of a POWER SUPPLY CORD shall be so designed that the cord is not clamped by a screw that bears directly on the cord insulation.

d) Screws, if any, which have to be operated when replacing the POWER SUPPLY CORD shall not serve to fix any component other than parts of the cord anchorage.

e) Conductors of the POWER SUPPLY CORD shall be so arranged that if the cord anchorage fails the PROTECTIVE EARTH CONDUCTOR is not subject to strain as long as the phase conductors are in contact with their terminals.

f) The cord anchorage shall prevent the POWER SUPPLY CORD from being pushed into the ME EQUIPMENT or MAINS CONNECTOR.

Compliance is checked by inspection and by the following tests:

ME EQUIPMENT, if designed for a POWER SUPPLY CORD, is tested with the cord supplied by the MANUFACTURER.

The POWER SUPPLY CORD conductors are, if possible, disconnected from the terminals or from the MAINS CONNECTOR.

The cord is subjected 25 times to a pull on the sheath of the value shown in Table 14. The pulls are applied in the most unfavourable direction without jerks, each time for 1 s.

Immediately afterwards, the cord is subjected for 1 min to a torque of the value shown in Table 14.

Table 14 – Testing of cord anchorages

Mass (*m*) of ME EQUIPMENT kg	Pull N	Torque Nm
$m \leq 1$	30	0,1
$1 < m \leq 4$	60	0,25
$m > 4$	100	0,35

A cord anchorage that allows the cord sheath to be longitudinally displaced by more than 2 mm or the conductor ends to move over a distance of more than 1 mm from their normally connected position is considered to fail.

CREEPAGE DISTANCES and AIR CLEARANCES that are reduced below the values specified in 8.9 are considered a failure.

Attempt to push the cord into the ME EQUIPMENT or the MAINS CONNECTOR. If the cord can be pushed into the ME EQUIPMENT or the MAINS CONNECTOR to such an extent that the cord or internal parts are damaged, the cord anchorage is considered to fail.

8.11.3.5 *Cord guards

POWER SUPPLY CORDS of other than STATIONARY ME EQUIPMENT shall be protected against excessive bending at the inlet opening of the equipment by means of a cord guard of insulating material or by means of an appropriately shaped opening in the equipment.

Compliance is checked by inspection and by either the test described in IEC 60335-1: 2001, subclause 25.14 or the following test. An arrangement that passes either test is considered to comply with the requirement.

ME EQUIPMENT having a cord guard or opening is fitted with a section of POWER SUPPLY CORD such that the exposed length is approximately 100 mm. The ME EQUIPMENT is so held that the axis of the cord guard, where the cord leaves it, projects upward at an angle of 45° to the horizontal when the cord is free from stress.

A mass equal to 10 x D^2 *gram is then attached to the free end of the cord,* D *being the overall diameter, in millimetres, or, for flat cords, the minor overall dimension of the POWER SUPPLY CORD delivered with the ME EQUIPMENT.*

Flat cords are bent in a direction perpendicular to the plane containing the axis of the cores.

Immediately after the mass has been attached, a curvature of the cord that is less than 1,5 x D*, being checked by a cylindrical rod with a diameter of 1,5 x* D*, is considered a failure.*

8.11.3.6 Accessibility of the connection

The space inside ME EQUIPMENT designed for FIXED wiring or a rewirable POWER SUPPLY CORD shall be adequate to allow conductors to be easily introduced and connected, and covers, if any, to be fitted without RISK of damage to the conductors or their insulation. It shall be possible to check that the conductors are correctly connected and positioned before the ACCESS COVER is fitted.

Compliance is checked by inspection and by an installation test.

8.11.3.7 *APPLIANCE COUPLERS

In ME EQUIPMENT, APPLIANCE COUPLERS not complying with IEC 60320-1, the connection of the POWER SUPPLY CORD to the MAINS CONNECTOR shall comply with 8.11.3.4 and 8.11.3.5.

Compliance is checked as specified in 8.11.3.4 and 8.11.3.5.

8.11.4 MAINS TERMINAL DEVICES

8.11.4.1 *General requirements for MAINS TERMINAL DEVICES

PERMANENTLY INSTALLED ME EQUIPMENT and ME EQUIPMENT having a non-DETACHABLE POWER SUPPLY CORD that is replaceable by the SERVICE PERSONNEL shall be provided with MAINS TERMINAL DEVICES that ensure reliable connection.

Reliance shall not be placed upon the terminals alone to maintain the conductors in position, unless barriers are provided such that CREEPAGE DISTANCES and AIR CLEARANCES that serve as a MEANS OF PROTECTION cannot be reduced to less than the values specified in 8.9, if any conductor breaks away.

Terminals of components other than terminal blocks may be used as terminals intended for external conductors if they comply with the requirements of this subclause and are properly marked according to 7.3.7.

Screws and nuts that clamp external conductors shall not serve to fix any other component, except that they may also clamp internal conductors if these are so arranged that they are unlikely to be displaced when fitting the supply conductors.

Compliance is checked by inspection.

8.11.4.2 Arrangement of MAINS TERMINAL DEVICES

a) For ME EQUIPMENT with rewirable cords where terminals are provided for the connection of external cords or POWER SUPPLY CORDS, these terminals together with any PROTECTIVE EARTH TERMINAL shall be closely grouped, so as to provide a convenient means of connection.

b) For details of PROTECTIVE EARTH CONDUCTOR connections, see 8.6.

c) For marking of MAINS TERMINAL DEVICES, see 7.3.

d) MAINS TERMINAL DEVICES shall not be accessible without the use of a TOOL.

Compliance is checked by inspection.

e) MAINS TERMINAL DEVICES shall be so located or shielded that, if a wire of a stranded conductor escapes when the conductors are fitted, short-circuiting a MEANS OF PROTECTION is unlikely.

Compliance is checked by inspection and, if necessary, by the following test:

The end of a flexible conductor having the NOMINAL cross-sectional area specified in Table 13 is stripped of its insulation for a length of 8 mm.

A single wire of the stranded conductor is left free and the rest of the conductor is secured to the terminal.

The free wire is bent in every possible direction without pulling back the insulating sheath and without making sharp bends around partitions.

Contact between the free wire and any other part such that a MEANS OF PROTECTION is short-circuited is considered a failure.

8.11.4.3 Fixing of mains terminals

Terminals shall be FIXED such that, when the means for clamping the conductors are tightened or loosened, the internal wiring is not subjected to stress and CREEPAGE DISTANCES and AIR CLEARANCES are not reduced below the values specified in 8.9.

Compliance is checked by inspection and by measurement after fastening and loosening a conductor of the largest cross-sectional area specified 10 times.

8.11.4.4 *Connections to mains terminals

Cord terminals with clamping means for a rewirable flexible cord shall not require special preparation of the conductors in order to effect correct connection, and they shall be so designed or placed that the conductors are not damaged and cannot slip out when the clamping means are tightened. See also 8.10.2.

Compliance is checked by inspection of the terminals and of the conductors after the test of 8.11.3.7.

8.11.5 *Mains fuses and OVER-CURRENT RELEASES

A fuse or OVER-CURRENT RELEASE shall be provided in each supply lead for CLASS I ME EQUIPMENT and CLASS II ME EQUIPMENT having a functional earth connection according to 8.6.9, and in at least one supply lead for other single-phase CLASS II ME EQUIPMENT, except that:

– a PROTECTIVE EARTH CONDUCTOR shall not be fused;

– for PERMANENTLY INSTALLED ME EQUIPMENT, the neutral conductor shall not be fused;

– if examination shows that two MEANS OF PROTECTION are present between all parts of opposite polarity within the MAINS PART, and between all parts of the MAINS PART and earth, then the fuses or OVER-CURRENT RELEASES may be omitted. These insulation requirements shall be continued up to and within any component. The effect of short circuit fault conditions in other circuits shall be considered before eliminating fuses or OVER-CURRENT RELEASES.

Protective devices shall have adequate breaking capacity to interrupt the maximum fault current (including short circuit current) which can flow.

NOTE If fuses complying with IEC 60127 are used and the prospective short-circuit current exceeds 35 A or 10 times the current rating of the fuse, whichever is greater, the fuses should have high breaking capacity (1500 A).

The RISK MANAGEMENT FILE shall include a justification for the rating of the fuses or OVER-CURRENT RELEASES or for their omission.

Compliance is checked by inspection of the ME EQUIPMENT and of the RISK MANAGEMENT FILE*.*

8.11.6 Internal wiring of the MAINS PART

a) Internal wiring in a MAINS PART between the MAINS TERMINAL DEVICE and the protective devices shall have a cross-sectional area not less than the minimum required for the POWER SUPPLY CORD as specified in 8.11.3.3.

Compliance is checked by inspection.

b) The cross-sectional area of other wiring in the MAINS PART and the sizes of tracks on printed wiring circuits of ME EQUIPMENT shall be sufficient to prevent any fire HAZARD in case of possible fault currents.

When necessary, compliance is checked by connecting the ME EQUIPMENT to a specified SUPPLY MAINS from which the most unfavourable short-circuit current expected can be drawn in the event of a fault in the MAINS PART. Subsequently, a fault in a single insulation in the MAINS PART is simulated so that the fault current is the least favourable. The occurrence of any HAZARD listed in 13.1.2 constitutes a failure.

9. *Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

9.1 MECHANICAL HAZARDS of ME EQUIPMENT

For general requirements on design and manufacture of ME EQUIPMENT, see Clauses 4 and 15.3.

Table 15 lists the MECHANICAL HAZARDS and the corresponding clauses which need to be fulfilled in order to reduce the RISK against the HAZARDS covered by this clause.[118]

Table 15 – MECHANICAL HAZARDS covered by this clause

MECHANICAL HAZARD	Covered by Subclause No.
Crushing HAZARD	9.2, 9.4 and 9.8
Shearing HAZARD	9.2 and 9.8
Cutting or severing HAZARD	9.2, 9.3 and 9.8
Entanglement HAZARD	9.2
Trapping HAZARD	9.2
Stabbing or puncturing HAZARD	9.2, 9.3 and 9.8
Friction or abrasion HAZARD	9.2 and 9.3
Expelled parts HAZARD	9.5
High pressure fluid injection HAZARD	9.7
Falling HAZARD	9.8
Instability HAZARD	9.4
Impact HAZARD	9.2 and 9.8
Moving and positioning of PATIENT	9.2 and 9.4
Vibration and noise	9.6

9.2 *Moving parts

9.2.1 *General

Equipment with moving parts shall be designed, built and laid out so that, when PROPERLY INSTALLED and used as intended by the MANUFACTURER, the RISKS associated with those moving parts are reduced to an acceptable level.

Where HAZARDS persist, the RISK of HARM from contact with the moving parts shall be reduced to an acceptable level by use of protective measures, bearing in mind the ease of access, the equipment's function, the shape of the parts, the energy and speed of the motion and the benefits to the PATIENT.

NOTE The possible types of HAZARD from moving parts include crushing, impact, shearing, cutting, entanglement, drawing in or trapping, stabbing and abrasion. Moving parts may also cause HAZARDS relating to movement and positioning of the PATIENT.

The RESIDUAL RISK associated with accessible moving parts is considered acceptable if exposure is needed for the equipment to perform its intended function. If after all reasonable protective measures have been implemented, a HAZARD persists, warnings shall be marked on the equipment or given in the instructions for use.

NOTE Requirements for parts subject to wear are found in 15.2.

9.2.2 TRAPPING ZONE

9.2.2.1 General

Equipment with a TRAPPING ZONE shall meet the requirements of one or more of the following:

– Gaps as specified in 9.2.2.2; or

– Safe distances as specified in 9.2.2.3; or

– GUARDS and protective measures as specified in 9.2.2.4; or

– Continuous activation as specified in 9.2.2.5.

When implementation of the above protective measures is inconsistent with the INTENDED USE/INTENDED PURPOSE of the ME EQUIPMENT or the ME SYSTEM, control of the relevant motion shall comply with 9.2.2.6.

9.2.2.2 Gaps

The gaps of the TRAPPING ZONE shall comply with the dimensions specified in Table 16.

NOTE In general the values for adults should be used. However, in the case of devices specifically designed for use with children, the dimensions given for children should be applied.

9.2.2.3 Safe distances

The distances separating the OPERATOR, PATIENT and other persons from the TRAPPING ZONES shall exceed the values specified in ISO 13852. The distances are measured from the expected positions of the OPERATOR, PATIENT and other persons near the ME EQUIPMENT in NORMAL USE as indicated in the instructions for use.

9.2.2.4 *GUARDS and protective measures

9.2.2.4.1 Access to TRAPPING ZONES

GUARDS and protective measures shall:

– be of robust construction.

– not be easy to bypass or render non-operational.

– not introduce any additional unacceptable RISK.

Compliance is checked by the applicable tests of 15.3 for ENCLOSURES.

9.2.2.4.2 FIXED GUARDS

FIXED GUARDS shall be securely held in place by systems that cannot be dismantled without the use of a TOOL.

Compliance is checked by inspection.

9.2.2.4.3 Movable GUARDS

Movable GUARDS:

– Shall remain attached to the equipment when the GUARD is open.

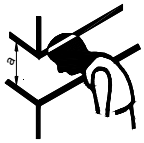
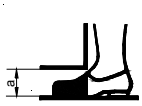
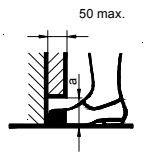
– Can be opened without the use of a TOOL.

– Shall be associated with an interlock device that prevents the relevant moving parts from starting to move while the TRAPPING ZONE is accessible and stops movement when the GUARD is opened.

– Shall be so designed that the absence or failure of one of their components prevents starting, and stops moving parts.

Compliance is checked by inspection.

3290 **Table 16 – Acceptable gaps in millimetres**

Part of body	Adult Gap *a* mm	Children Gap *a* mm	Illustration
Body	>500	>500	
Head	>300 or <120	>300 or <60	
Leg	>180	>180	
Foot	>120 or <35	>120 or <25	
Toes	>50	>50	
Arm	>120	>120	
Hand, Wrist, Fist	>100	>100	
Finger	> 25 or < 8	> 25 or < 4	

9.2.2.4.4 Protective measures

Protective measures shall be designed and incorporated into the control system so that:

– Moving parts cannot start to move while they are in the reach of persons.

– The TRAPPING ZONE cannot be reached once the ME EQUIPMENT has started to move.

– If in a SINGLE FAULT CONDITION of the protective measure, an unacceptable RISK could arise, one or more emergency stopping function(s) in the equipment shall be provided (see 9.2.4).

Compliance is checked by inspection of the equipment and review of the RISK MANAGEMENT FILE.

9.2.2.5 Continuous activation

a) Where it is impractical to make the TRAPPING ZONE inaccessible, movement of the equipment shall be possible only by the continuous activation of the control by the OPERATOR of these equipment parts as long as this continuous activation allows the OPERATOR to have adequate control of positioning without endangering the PATIENT or the OPERATOR.[119]

Compliance is checked by inspection.

b) If in a SINGLE FAULT CONDITION of the continuous activation system, including use error, an unacceptable RISK could arise, one or more emergency stopping function(s) shall be provided in the equipment (see 9.2.4).

Compliance is checked by inspection of the equipment and review of the RISK MANAGEMENT FILE.

9.2.2.6 *Speed of motion

The speed of motions that position the equipment or PATIENT in such a way that the equipment could contact the PATIENT with a RISK of injury, shall be limited so that the OPERATOR will have adequate control of positioning without endangering the PATIENT.

The overtravel of such motion, occurring after actuation of a control to stop the motion, shall not cause an unacceptable RISK.

Compliance is checked by inspection of the equipment and review of the RISK MANAGEMENT FILE.

9.2.3 Other HAZARDS related to moving parts

9.2.3.1 Unintended movement

a) Movements of equipment or its parts that may cause physical injury shall be possible only where either:

– Such motion requires the continuous activation of a control that stops the mechanical motions on release, or

– An emergency stop switch is provided; unless the response of the OPERATOR to actuate it cannot be relied on to prevent an injury.

All such controls and emergency stops shall be located at a position where the movements can be visually observed.[120]

Compliance is checked by inspection.

b) Controls shall be so positioned, recessed, or protected by other means so that they cannot be accidentally actuated, resulting in a physical injury, unless ergonomic considerations for the intended PATIENT dictate otherwise (e.g. PATIENT with special needs).

Compliance is checked by inspection.[121]

9.2.3.2 Overtravel

The RISK of injury due to overtravel of equipment parts shall be reduced to an acceptable level. End stops or other stopping means shall be provided to act as the ultimate travel limiting measure in both NORMAL CONDITION and SINGLE FAULT CONDITION.

Such measures shall have the mechanical strength to withstand the conditions of maximum intended loading and REASONABLY FORESEEABLE MISUSE.

Compliance is checked by inspection of the equipment, the MANUFACTURER'S relevant information (e.g. calculations, test results, the RISK MANAGEMENT FILE, etc.), specifications of materials used and the processing specifications for these materials.

9.2.4 *Emergency stopping devices

Where it is considered necessary to have one or more emergency stop function(s), the emergency stopping device shall comply with all the following requirements:

– The emergency stopping device shall remove the HAZARD.[122]

– The device actuator shall be readily accessible to the OPERATOR.

– Emergency stopping devices shall not be part of the normal operation of the equipment.

– Operation of an emergency switching or stopping means shall neither introduce a further HAZARD nor interfere with the complete operation necessary to remove the original HAZARD.

– Devices for emergency stopping shall be able to break the full load of the relevant circuit, taking into account possible stalled motor currents and the like.

– Means for stopping of movements shall operate as a result of one single action.

– The device shall have an actuator coloured red designed to be distinctive and easily identifiable from that of other controls.

– An actuator that interrupts/opens mechanical movements shall be marked on, or immediately adjacent to, the face of the actuator with Symbol IEC 60417-5638 (see Table D1, Symbol 17) or the word “STOP”.

NOTE If the actuator is a switch that interrupts all power, compliance with the above marking requirement is not required.

– The device, once actuated, shall maintain the equipment in the disabled condition until a deliberate action, different from that used to actuate it, is performed.

– Emergency stops shall be shown to be suitable for their application.

Compliance is checked by inspection of the equipment, and of the MANUFACTURER'S relevant information (e.g. test results, relevant component ratings, the RISK MANAGEMENT FILE, etc.).

9.2.5 *Release of PATIENT

Means shall be provided to permit the release of the PATIENT quickly and safely in the event of breakdown of the equipment or failure of the power supply (see 11.8), activation of a protective measure or emergency stopping. Special attention shall be given to the following:

– Uncontrolled motion and unintended movement of the equipment that may result in an unacceptable RISK shall be prevented.

– Situations where the PATIENT is subjected to unacceptable RISKS due to the proximity of moving parts, removal of normal exit routes, or other HAZARDS, shall be prevented.

– When, after removal of counterbalanced parts, other parts of the ME EQUIPMENT can move in a hazardous way, measures shall be provided to reduce the RISK to an acceptable level.

Compliance is checked by inspection of the ME EQUIPMENT, and the MANUFACTURER'S relevant information (e.g. calculations, test results, the RISK MANAGEMENT FILE, etc.).

9.3 *Surfaces, corners and edges

Rough surfaces, sharp corners and edges of ME EQUIPMENT that may cause an unacceptable RISK shall be avoided or covered.

In particular, attention shall be paid to flange or frame edges and the removal of burrs.

Compliance is checked by inspection of the equipment and review of the RISK MANAGEMENT FILE.

9.4 *Instability

9.4.1 General

Equipment, other than FIXED equipment and HAND-HELD equipment, intended to be used on a surface such as a floor or a table shall not become physically unstable during NORMAL USE, due to overbalance or unintended movement, to the degree that it could present an unacceptable RISK to the PATIENT, OPERATOR or other person.

Compliance is checked by the tests in 9.4.2 to 9.4.4 (inclusive). Each test is carried out separately.

9.4.2 Instability due to overbalance

9.4.2.1 Instability excluding transport

Equipment or its parts shall not overbalance when placed in any position of NORMAL USE, excluding any transport positions, on a plane inclined at an angle of 5º from the horizontal plane.

If the equipment or its parts overbalances when placed in any position of NORMAL USE, excluding any transport positions, on a plane inclined at an angle of 10º from the horizontal plane, it shall carry a warning notice stating that transport should only be undertaken in a certain condition that shall be clearly described in the instructions for use or marked on the ME EQUIPMENT with an indication of the level of RISK created if the ME EQUIPMENT or its parts overbalances.

NOTE For warning notice requirements, see 7.5.

Compliance is checked by placing the equipment or the equipment parts on a plane inclined at an angle of 10° from the horizontal plane, or, if a warning notice is present, compliance is checked by inspection of the warning notice and the equipment or its parts is placed on a plane inclined at an angle of 5° from the horizontal plane. The ME EQUIPMENT or its parts shall not overbalance. Prior to conducting test, the equipment is prepared as follows:

a) *Equipment is provided with all specified connection leads: the POWER SUPPLY CORD and any interconnecting cords. It is provided with the least favourable combination of possible detachable parts, ACCESSORIES and load as specified in NORMAL USE.*

b) *Equipment having an APPLIANCE INLET is provided with the specified DETACHABLE POWER SUPPLY CORD.*

c) *The connection leads shall be laid down on the inclined plane in the position most unfavourable for stability.*

d) *If castors/wheels are present, they shall be temporarily immobilized, if necessary by blocking, in their most disadvantageous position.*

e) *Doors and drawers and the like shall be placed in the most disadvantageous position as specified in NORMAL USE.*[123]

f) *Equipment having containers for liquids is tested with these containers completely or partly filled or empty, whichever is least favourable.*

g) *The equipment is not connected to the SUPPLY MAINS.*

h) *The test floor surface is to be hard and smooth and covered with 2 mm to 4 mm thick vinyl flooring material.*[124]

9.4.2.2 Instability in transport

Equipment or its parts shall not overbalance when placed in any transport position of NORMAL USE on a plane inclined at an angle of 10° from the horizontal plane.

NOTE The meaning of transport in this subclause is moving TRANSPORTABLE equipment from room to room during NORMAL USE.

Compliance is checked by placing the equipment or its parts on a plane inclined at an angle 10° from the horizontal plane. The equipment or its parts shall not overbalance. Prior to the test the equipment is prepared as specified by the MANUFACTURER (or, if not specified, as in 9.4.2.1).

9.4.2.3 Instability from lateral force

Equipment, other than FIXED equipment, which is intended to be used on the floor, and having a mass of 25 kg or more shall not overbalance due to pushing, leaning, resting etc.

Surfaces of the equipment where a RISK of overbalancing the equipment exists from pushing, leaning, resting etc., shall be permanently marked with a legible warning of this RISK, e.g. by use of Safety sign ISO 7010-xxx2 (see Table D2, Safety sign 2).

Compliance is checked by inspection and the following test:

The equipment is placed on a horizontal plane and a force equal to 25 % of the weight of the ME EQUIPMENT, but not more than 220 N, is applied in any horizontal or downward direction, but not in an upward direction or with an upward component. Unless otherwise marked, the force shall be applied at the highest point of the EQUIPMENT but not exceeding 1,5 m from the floor. The ME EQUIPMENT is prevented from sliding on the floor by a horizontal obstruction, not exceeding 20 mm high, which is FIXED flat on the floor. Prior to the test, the equipment is prepared as described in 9.4.2.1.

9.4.2.4 Instability from downward force[125]

Equipment, other than FIXED equipment, which is intended to be used on the floor or on a table, shall not overbalance due to sitting or stepping unless a legible warning of this RISK is provided on the equipment, e.g. by use of Safety signs ISO 7010-xxx3 or ISO 7010-xxx4 as appropriate (see Table D2, Safety signs 3 and 4).

NOTE Requirements for PATIENT support surfaces are found in 9.8.3.

Compliance is checked by inspection and by the following test:

The equipment is placed on a horizontal plane and a constant downward force of 800 N is applied at the point of maximum moment to any working surface, excluding PATIENT support surfaces, offering an obvious foothold or sitting surface of a minimum 20 cm by 20 cm area, and at a height not exceeding 1 m from the floor. Prior to the test the equipment is prepared as described in 9.4.2.1.

9.4.2.5 Instability due to an obstruction

MOBILE equipment shall not overbalance when subjected to the threshold test indicated in 15.3.1.4 b).

Compliance is checked by the test in 15.3.1.4 b), in which the equipment shall not overbalance.[126]

3466 **9.4.2.6 Castors and wheels**

3467 The means used for transportation of MOBILE equipment, i.e. castors or wheels, shall not
3468 create RISK of injury when the MOBILE equipment is moved or stationary, according to the
3469 instructions for use. This requirement is considered to be met if all the following
3470 specifications are fulfilled.

3471 *a)* The force required for moving MOBILE equipment along a hard and smooth horizontal
3472 surface shall not exceed 200 N unless the instructions for use state that more than one
3473 person is needed.

3474 *b)* Castors or wheels used for transportation of MOBILE equipment shall permit the MOBILE
3475 equipment to sustain the tests indicated in 15.3.1.4, and shall remain in compliance with
3476 the requirements of this standard.

3477 [127]*Compliance is checked by examination of MANUFACTURER'S technical documentation and the*
3478 *compliance to the mentioned tests.*

3479 **9.4.3 Instability from unwanted lateral movement (including sliding)**

3480 *a)* Brakes of power-driven MOBILE ME EQUIPMENT shall be designed so that they are normally
3481 activated and can only be released by continuous actuation of a control.

3482 *Compliance is checked by inspection.*

3483 *b)* MOBILE equipment shall be provided with wheel locks or with a braking system appropriate
3484 to the intended modes of use and sufficient to ensure that unintended movement is
3485 prevented on an incline of 5°.

3486 *Compliance is checked by putting the MOBILE equipment on a plane inclined at an angle of*
3487 *5° from the horizontal plane. The MOBILE equipment shall not move by its own weight.*
3488 *Prior to the test, the equipment is prepared as described in 9.4.2.1.*

3489 *c)* MOBILE equipment shall be fitted with means (such as locking devices) to prevent any
3490 unwanted movement of the equipment or its parts in the transport position.[128]

3491 *Compliance is checked by inspection.*

3492 *d)* Equipment that is intended to be used on the floor shall not create an unacceptable RISK
3493 due to unwanted lateral movement.

3494 *Compliance is checked by the following tests:*

3495 1) *The equipment is placed in its transport position (or, if no transport position is defined in*
3496 *the instructions for use, in the worst case NORMAL USE position) with the SAFE WORKING LOAD*
3497 *in place, and the locking device (e.g. brakes) activated, on a plane inclined at 10° from the*
3498 *horizontal plane. If casters are incorporated, they shall be positioned in their worst-case*
3499 *position. Following the initial elastic movement, initial creepage, and initial pivoting of*
3500 *castors, there shall be no movement of the equipment greater than 50 mm (in relation to*
3501 *the inclined plane). Any initial movement shall not result in an unacceptable RISK, taking*
3502 *into account the NORMAL USE of the ME EQUIPMENT. Prior to the test, the equipment is*
3503 *prepared as described in 9.4.2.1.*

3504 2) *The equipment is placed on a horizontal plane with the SAFE WORKING LOAD in place, and*
3505 *the locking device (e.g. brakes) activated. If castors are incorporated, they shall be*
3506 *positioned in their worst-case position. A force equal to 25 % of the weight of the unit, but*
3507 *not more than 220 N, is applied in any direction except upwards, at the highest point of the*
3508 *equipment but not exceeding 1,5 m from the floor. No movement of the equipment greater*
3509 *than 50 mm (in relation to the horizontal plane) shall occur. Following the initial elastic*
3510 *movement, initial creepage, and initial pivoting of castors, there shall be no movement of*
3511 *the equipment greater than 50 mm (in relation to the horizontal plane). Any initial*

movement shall not result in an unacceptable RISK, taking into account the NORMAL USE of the equipment. Prior to the test, the equipment is prepared as described in 9.4.2.1.

9.4.4 Grips and other handling devices

a) Equipment or equipment parts with a mass of more than 20 kg that needs to be lifted in NORMAL USE and transport shall either be provided with suitable handling devices (for example handles, lifting eyes, etc.) or the ACCOMPANYING DOCUMENTS shall indicate the points where it can be lifted safely, unless the method of handling is obvious and no HAZARDS can develop when this is done. The means for lifting shall be suitably placed to enable the equipment or its parts to be carried by two or more persons.[129]

Compliance is checked by weighing (if necessary) and by inspection of the equipment or the equipment parts or the ACCOMPANYING DOCUMENTS.

b) Equipment specified by the MANUFACTURER as PORTABLE equipment with a mass of more than 20 kg shall have (a) carrying-handle(s) suitably placed to enable the equipment to be carried by two or more persons.

Compliance is checked by weighing (if necessary) and by carrying.

c) Carrying handles or grips furnished on PORTABLE equipment shall withstand loading as described in the following test:

The handles and their means of attachment are subjected to a force equal to four times the weight of the equipment in any direction of NORMAL USE and transport.

If more than one handle is furnished on PORTABLE equipment, the force shall be distributed between the handles. The distribution of forces shall be determined by measuring the percentage of the equipment mass sustained by each handle with the equipment in the normal carrying position. If the equipment is furnished with more than one handle but is so designed that it may readily be carried by only one handle, each handle shall be capable of sustaining the total force. The handles shall not break loose from the equipment and there shall not be any permanent distortion, cracking or other evidence of failure.

The force is applied uniformly over a 7 cm length of the handle at the centre, without clamping, started at zero and gradually increased so that the test value will be attained in 5 s to 10 s and maintained for a period of 1 min.

9.5 *Expelled parts

9.5.1 Protective means

Where expelled parts would constitute an unacceptable RISK, the equipment shall be provided with a means for protecting against such RISK.

Compliance is checked by assessment of the suitability of the protective means and by inspection of the RISK MANAGEMENT FILE.

9.5.2 Cathode ray tubes

A cathode ray tube shall comply with the applicable requirements of IEC 60065: 2001, Clause 18.[130]

Compliance is checked by inspection of a certificate of compliance or by the relevant tests of IEC 60065: 2001, Clause 18. [131]

9.6 Noise and vibration

9.6.1 *General

Equipment shall be designed so that human exposure to noise and vibration shall not result in an unacceptable RISK.

Compliance is checked by review of the RISK MANAGEMENT FILE (taking into account the audibility of auditory alarm signals and PATIENT sensitivity) and compliance with the tests indicated in 9.6.2 and 9.6.3.

9.6.2 *Noise

In NORMAL USE, the PATIENT, OPERATOR and other persons shall not be exposed to noise from equipment, except sound from auditory alarm signals, exceeding those specified below.

– 75 dBA for a cumulative exposure of 24 h over a 24 h period; an offset of 3 dBA is to be added to this value when halving the cumulative exposure time over 24 h (e.g. 78 dBA for 12 h).

– 140 dB un-weighted sound pressure level for impulsive or impact noise.

NOTE 1 Interpolation and/or extrapolation is allowed for exposure times.

NOTE 2 Since PATIENTS might have a higher sensitivity to noise, a lower level may be more appropriate. Consideration should also be given to perception of auditory alarm signals. The World Health Organization recommended a maximum impulse or impact noise level for children of 120 dB.

Compliance is checked by measuring the maximum A-weighted sound pressure level at the minimum NOMINAL distances of PATIENT, OPERATOR and other persons from the source of noise, and, if necessary, calculating the A-weighted sound power level produced by the equipment in accordance with either ISO 3746 or ISO 9614-1. The following conditions apply:

a) *The equipment shall be operated under worst-case NORMAL CONDITION.*

b) *Any protective means provided or called for in ACCOMPANYING DOCUMENTS shall be in place during sound measurement.*

c) *Sound level meters used in the measurement conform either to type 1 of IEC 60651 or, if an integrated sound level meter, to type 1 of IEC 60804.*

d) *The test room is semi-reverberant with a hard reflecting floor. The distance between any wall or other object and the surface of the equipment is not less than 3 m.*

9.6.3 *Hand Transmitted Vibration

Except for vibrations directly required in order to carry out the INTENDED USE/INTENDED PURPOSE of the equipment, means shall be provided to protect the PATIENT, OPERATOR and other persons if in NORMAL USE the hand transmitted frequency weighted r.m.s. acceleration generated by the equipment exceeds the value below:

– 2,8 m/s^2 for a cumulative time period of 8 hours during a 24 hour period.

– Allowable accelerations for different times are inversely proportional to the square root of the time (e.g. the allowable acceleration for 2 hours would be 5,6 m/s^2).

Compliance is checked by measurements at points of equipment in hand contact with PATIENT, OPERATOR or other persons. Measurements shall be made in accordance with ISO 5349-1.

9.7 *Pressure vessels and parts subject to pneumatic and hydraulic PRESSURE

9.7.1 General

The requirements of this clause apply to vessels and parts of equipment subject to PRESSURE, the rupture of which could cause an unacceptable RISK.

The parts of a pneumatic or hydraulic system that are used as a support system shall additionally comply with the requirements in 9.8.

9.7.2 Pneumatic and hydraulic parts

Pneumatic and hydraulic parts of equipment or ACCESSORIES shall be so designed that:

– No unacceptable RISK shall result from PRESSURE losses, PRESSURE drops or losses of vacuum.

– No fluid jet that could result in an unacceptable RISK shall result from leakages or component failures.

– Elements of the equipment or an ACCESSORY, and especially pipes and hoses, which could lead to an unacceptable RISK shall be protected against harmful external effects.

– Reservoirs and similar vessels (e.g. hydro-pneumatic accumulators) that could lead to an unacceptable RISK shall be automatically depressurized when the ME EQUIPMENT is isolated from its power supply. If this is not possible, means shall be provided for the isolation or local depressurizing of reservoirs and similar vessels, and PRESSURE indication.

– All elements that may remain under PRESSURE after isolation of the equipment or an ACCESSORY from its power supply and that could cause an unacceptable RISK shall be provided with clearly identified exhaust devices, and a warning label drawing attention to the necessity of depressurizing these elements before any setting or maintenance activity on the equipment or ACCESSORIES.

Compliance is checked by inspection and examination of RISK MANAGEMENT FILE.

9.7.3 *PRESSURE vessels

A PRESSURE vessel or part of equipment shall withstand a HYDRAULIC TEST PRESSURE if one or more of the following conditions apply:

a) It is subject to a pneumatic PRESSURE volume greater than 200 kPa x l (where "l" is the volume in litres), and PRESSURE greater than 50 kPa.

b) It is subject to a hydraulic PRESSURE, where a high PRESSURE fluid ejection could result in an unacceptable RISK.

c) It is subject to a pneumatic or hydraulic PRESSURE of a toxic, flammable, or otherwise hazardous substance.

Compliance is checked by the following tests:

The HYDRAULIC TEST PRESSURE shall be the MAXIMUM PERMISSIBLE WORKING PRESSURE multiplied by a factor obtained from Figure 31.

The PRESSURE is raised gradually to the specified test value and is held at that value for 1 min. The sample shall not burst nor suffer from permanent (plastic) deformation nor leak. For pressure vessels falling under 9.7.3 a), *leakage at a gasket during this test is not considered to constitute failure unless it occurs at a PRESSURE below 40 % of the required test value, or below the MAXIMUM PERMISSIBLE WORKING PRESSURE, whichever is greater.*

No leakage is allowed for PRESSURE vessels or parts falling under 9.7.3 b) *or 9.7.3* c).

Where unmarked PRESSURE vessels and pipes cannot be hydraulically tested, integrity shall be verified by other suitable tests, e.g. pneumatic using suitable media, at the same test PRESSURE as for the hydraulic test.

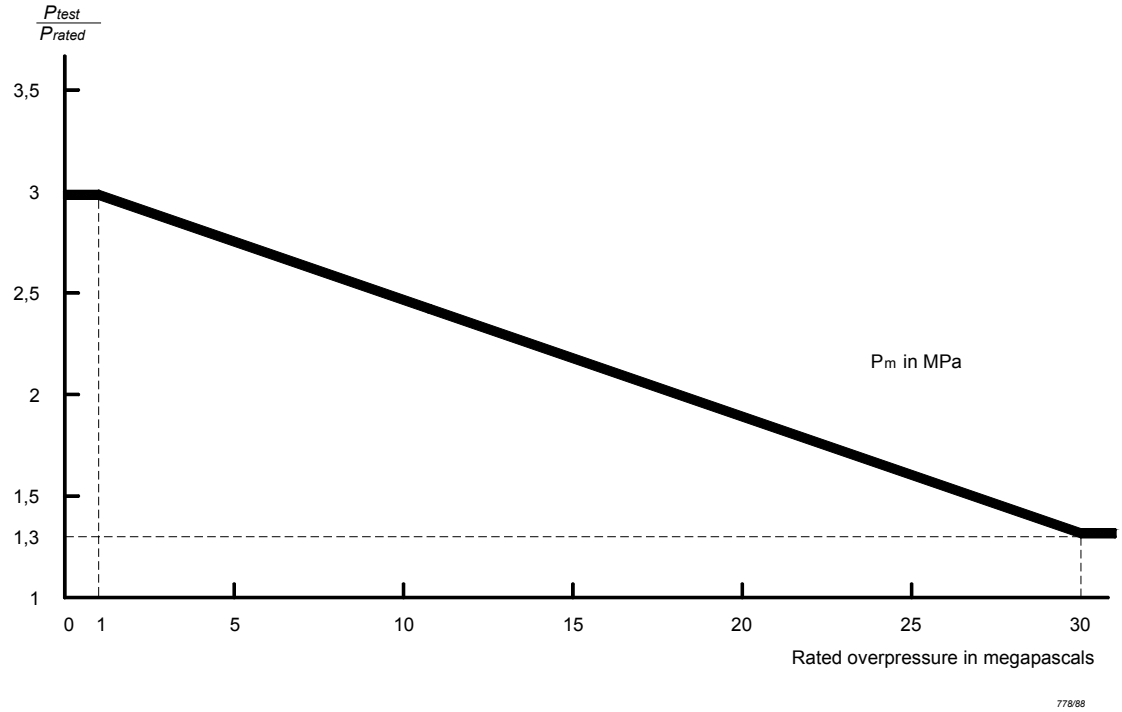


Figure 31 – Ratio between HYDRAULIC TEST PRESSURE and MAXIMUM PERMISSIBLE WORKING PRESSURE (see 9.7.3)

9.7.4 Maximum PRESSURE

The maximum PRESSURE to which a part of equipment can be subjected in NORMAL CONDITION and SINGLE FAULT CONDITION shall not exceed the MAXIMUM PERMISSIBLE WORKING PRESSURE for the part.

The maximum PRESSURE in use shall be considered to be whichever is the highest of the following:

a) the RATED maximum supply PRESSURE from an external source;

b) the PRESSURE setting of a pressure-relief device provided as part of the assembly;

c) the maximum PRESSURE that can be developed by a source of PRESSURE that is part of the assembly, unless the PRESSURE is limited by a pressure-relief device.

Compliance is checked by inspection.

9.7.5 PRESSURE-relief device

Equipment shall incorporate PRESSURE-relief device(s) where the MAXIMUM PERMISSIBLE WORKING PRESSURE could otherwise be exceeded.

A PRESSURE-relief device shall comply with all of the following requirements:

a) it shall be connected as close as reasonably practical to the PRESSURE vessel or parts of the system that it is intended to protect;

b) it shall be so installed that it is readily accessible for inspection, maintenance and repair;

c) it shall not be capable of being adjusted or rendered inoperative without the use of a TOOL;

d) it shall have its discharge opening so located and directed that the released material is not directed towards any person;

e) it shall have its discharge opening so located and directed that operation of the device will not deposit material on parts that may cause a HAZARD;

f) it shall be of adequate discharge capacity to ensure that the PRESSURE will not exceed the MAXIMUM PERMISSIBLE WORKING PRESSURE of the system to which it is connected by more than 10 % in the event of a failure in the control of the supply PRESSURE;

g) there shall be no shut-off valve between a PRESSURE-relief device and the parts that it is intended to protect;

h) the minimum number of cycles of operation shall be 100 000, except for one-time use devices such as bursting disks.

The control device responsible for limiting the PRESSURE in the vessel shall be capable of performing under RATED load for 100 000 cycles of operation and shall prevent the PRESSURE from exceeding 90 % of the setting of the PRESSURE-relief device under any condition of NORMAL USE.

Compliance is checked by inspection, functional test and examination of the RISK MANAGEMENT FILE.

9.7.6 RATED maximum supply PRESSURE[132]

See 7.2.16.

9.8 *Support systems

9.8.1 General

Where equipment parts are designed to support loads or to provide actuating forces, the following requirements shall be applied if a mechanical fault could constitute an unacceptable RISK.

– The construction of the support, suspension or actuation system, including immediate supporting elements, shall be designed based upon Table 17 and the TOTAL LOAD, which shall include the effect of the SAFE WORKING LOAD, where applicable.[133]

– Parts shall be so designed and constructed such that the TENSILE SAFETY FACTORS such that during the useful life of the equipment an unacceptable RISK is not created. [134]

– Means of attachment of ACCESSORIES shall be designed such that any possibility of incorrect attachment that could create an unacceptable RISK is avoided.

– The RISK ANALYSIS of support systems shall consider HAZARDS arising from static, dynamic, vibration, impact and pressure loading, foundation and other movements, temperature, environmental, manufacture and service conditions.

– All likely failure effects shall be considered in the RISK ANALYSIS. These include excessive deflection, plastic deformation, ductile or brittle fracture, fatigue fracture, instability (buckling), stress-assisted corrosion cracking, wear, material creep, material deterioration and residual stresses, e.g. machining, assembling, welding, heat treatment or surface coating.

– Attachment of structures to a floor, wall, ceiling, etc. shall make adequate allowances for quality of the materials used to make the connection, workmanship and use. ACCOMPANYING DOCUMENTS shall contain instructions on making the connection and list the required materials. Additionally there shall be advice on checking the adequacy of the surface of the structure to which it will be FIXED.

9.8.2 TENSILE SAFETY FACTOR

TENSILE SAFETY FACTORS shall not be less than those shown in Table 17.

3704 **Table 17 – Determination of TENSILE SAFETY FACTOR**

Situation			Minimum TENSILE SAFETY FACTOR [a]	
			A [b]	B [b]
1	Support system parts not impaired by wear	Material having a specific elongation at break equal to or greater than 5 %	2,5	4
2	Support system parts not impaired by wear	Material having a specific elongation at break of less than 5 %	4	6
3	Support system parts impaired by wear [e] and no SAFETY DEVICE	Material having a specific elongation at break equal to or greater than 5 %	8	8
4	Support system parts impaired by wear [e] and no SAFETY DEVICE	Material having a specific elongation at break of less than 5 %	12	12
5	Support system parts impaired by wear [e] and with SAFETY DEVICE (or primary system of multiple support systems)	Material having a specific elongation at break equal to or greater than 5 %	2,5	4
6	Support system parts impaired by wear [e] and with SAFETY DEVICE (or primary system of multiple support systems)	Material having a specific elongation at break of less than 5 %	4	6
7	SAFETY DEVICE (or back-up system of multiple support system)		4	4

[a] The TENSILE SAFETY FACTORS are intended to take account of conditions defined in 15.3.2 (i.e. useful life, environmental effects, impairing effects of wear, corrosion, material fatigue or ageing). The TENSILE SAFETY FACTORS specified in the table are minimum values at start of life. The minimum values for TENSILE SAFETY FACTORS at end of useful life shall not be less than those values specified in line 1 (column A or B, as applicable).[135]

[b] Case A = The material TENSILE STRENGTH and all external forces to be expected are quantifiable and known.

[c] Case B = other than case A.

[d] Unless all loading conditions are known, PATIENT supports shall be case B.

[e] Components considered impaired by wear include: chains, cables, belts, jack screw nuts, pneumatic or hydraulic hoses.

3705 *Compliance with 9.8.1 and 9.8.2 is checked by inspection of the equipment, the*
3706 *MANUFACTURER'S relevant information (e.g. calculations, test results, the RISK MANAGEMENT*
3707 *FILE, etc.), the specifications of materials used and the processing specifications for these*
3708 *materials. Where impairment by wear or fatigue is expected, compliance is checked by*
3709 *evaluation of the MANUFACTURER'S relevant tests or calculations contained in the RISK*
3710 *MANAGEMENT FILE.*[136]

3711 *When test results are part of relevant information, testing shall consist of gradually applying a*
3712 *test load to the support assembly under test equal to the TOTAL LOAD times the required*
3713 *TENSILE SAFETY FACTOR. The support assembly under test shall be in equilibrium after*
3714 *1 minute, or otherwise not result in an unacceptable RISK.*

3715 NOTE 1 It may be necessary to support assemblies that are connected to the assembly under test but do not
3716 require such a high safety factor, e.g. assembly under test requires TENSILE SAFETY FACTOR = 8 and assembly
3717 supporting it is designed with a TENSILE SAFETY FACTOR = 4. Use of additional support should be explained in the
3718 test report.

3719 NOTE 2 The 1 minute time period may need to be longer for materials which might have creep type problems, such
3720 as plastics or other non-metallic materials.

9.8.3 *Strength of PATIENT or OPERATOR support, or suspension systems

9.8.3.1 General

Equipment parts serving for support or immobilization of PATIENTS shall be designed and manufactured so as to minimize the RISK of physical injuries and of accidental loosening of fixings.

The SAFE WORKING LOAD of equipment or its parts serving for support or suspension of PATIENTS or OPERATORS shall be the sum of the mass of the PATIENTS or the mass of the OPERATORS plus the mass of ACCESSORIES intended by MANUFACTURERS to be supported or suspended by the equipment or equipment parts.

Unless otherwise stated by the MANUFACTURER, supporting and suspending parts for adult human PATIENTS or OPERATORS shall be designed for a PATIENT or OPERATOR having a minimum mass of 135 kg and ACCESSORIES having a minimum mass of 15 kg.

Where a MANUFACTURER specifies particular applications (e.g. paediatric use), the maximum mass of the PATIENT included in the SAFE WORKING LOAD of the equipment or its parts serving for support or suspension of PATIENTS may be adapted. When the maximum allowable value of the mass of the PATIENT is less than 135 kg, that value shall be marked on the equipment and described in ACCOMPANYING DOCUMENTS. When the maximum allowable value of the mass of the PATIENT is more than 135 kg, that value shall be described in ACCOMPANYING DOCUMENTS.

Compliance is checked by inspection.

9.8.3.2 *Static forces due to loading from persons

In analyzing loading forces and torques on support assemblies, the part of the SAFE WORKING LOAD representing the mass of the PATIENTS or OPERATORS is distributed on the support/suspension surface in a manner representing the human body (see the example in Figure A16). For a foot rest, the whole mass of the PATIENT or OPERATOR is distributed over an area of 0,1 m^2.

NOTE The position of the human body varies depending on the configuration of the support/suspension system and therefore the load acting on different sections will vary and should be taken into account.

In analyzing loading forces and torques on support assemblies, the part of the SAFE WORKING LOAD representing the mass of ACCESSORIES should be deployed according to the instructions for use or, if not defined, at the worst case position permitted by the configuration or ACCESSORIES attachment on the support/suspension parts.

Compliance is checked by inspection of the equipment, the MANUFACTURER'S relevant information (e.g. calculations, test results, the RISK MANAGEMENT FILE, etc.), the specifications of materials used and the processing specifications for these materials, and the following test.

A force equal to two times 1350 N or two times the intended person load, whichever is greater is applied to the foot rest over an area of 0,1 m^2 for 1 minute. After the test, the foot rest and its fixings shall show no damage or deflection that could create an unacceptable RISK.

9.8.3.3 Dynamic forces due to loading from persons

Where dynamic forces (due to sitting down, standing up, PATIENT handling PROCESS or the like) can be exerted on equipment parts intended to support or suspend a PATIENT or OPERATOR in NORMAL USE, they shall not cause an unacceptable RISK.

Compliance is checked by the following tests.

For the area of support/suspension where a PATIENT or OPERATOR can sit:

– *A mass (as defined in Figure 32) equivalent to the SAFE WORKING LOAD representing the PATIENTS or OPERATORS as defined in the instructions for use is dropped from a distance of*

150 mm above the seat area. There shall be no loss of function or structural damage that could result in an unacceptable RISK.

– *A mass of 60 % of the part of the SAFE WORKING LOAD representing the PATIENTS or OPERATORS, as defined in the instructions for use, or at a minimum 80 kg, is placed on the support/suspension system with the centre of the load 60 mm from the outer edge of the support/suspension system for a time of at least one minute. There shall be no deflection of the support/suspension system that could result in an unacceptable RISK.*

Prior to performing these tests, the PATIENT support/suspension system is positioned horizontally in its most disadvantageous position according to the instructions for use.

9.8.4 *Systems with SAFETY DEVICES

9.8.4.1 General

a) A SAFETY DEVICE shall be provided:

– where support system parts impaired by wear have TENSILE SAFETY FACTORS lower than rows 3 and 4 of Table 17; or

– where the integrity of a support system depends on parts that may have hidden defects (such as springs, due to their manufacturing PROCESSES), if excess travel in the event of breakdown is not limited.

b) The SAFETY DEVICE shall:

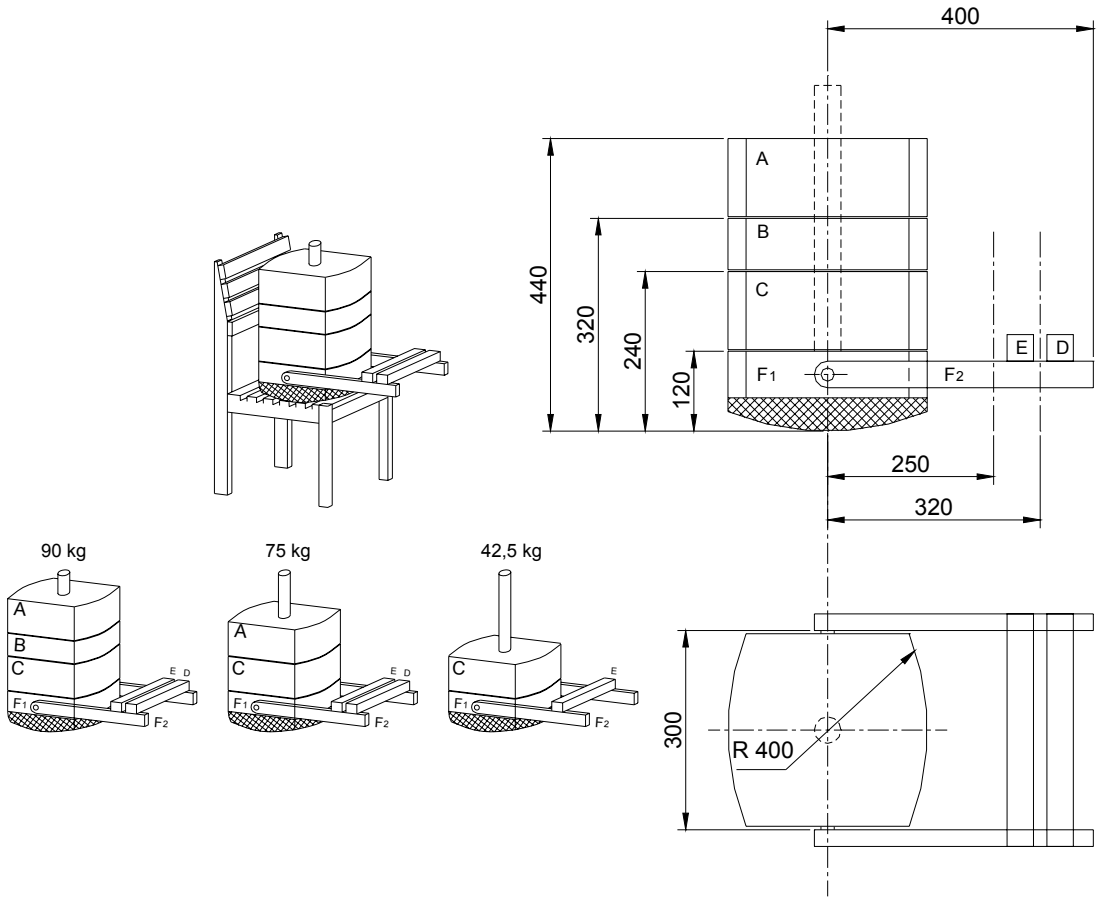
– be designed on the basis of TOTAL LOAD, which shall include the effects of the SAFE WORKING LOAD where applicable;

– have TENSILE SAFETY FACTORS for all parts not less than those in row 7 of Table 17;[137]

– activate before travel produces an unacceptable RISK;

– require the use of a TOOL to be reset or replaced; and[138]

– take into account 9.2.5.



3791

Dimensions in millimetres

Masses: A = 25 kg
B = 15 kg
C = 25 kg
F_1 = 7,5 kg
F_2 = 7,5 kg
D = 7,5 kg
E = 7,5 kg

The material of the base is made of foam, density 50 kg/m^3, thickness 60 mm.

3792 **Figure 32 – Human body test mass**
3793 **(see 9.8.3.3)**

3794 **9.8.4.2 Use after activation of a SAFETY DEVICE**

3795 If equipment can still be used after failure of the suspension or actuation means and activation
3796 of a SAFETY DEVICE (for example a secondary rope), it shall become obvious to the OPERATOR
3797 that the SAFETY DEVICE has been activated.

3798 **9.8.4.3 SAFETY DEVICE intended for single activation**

3799 If a SAFETY DEVICE is intended to function only once, the following requirements shall be
3800 fulfilled:

3801 – It shall become obvious to the OPERATOR that the SAFETY DEVICE has been activated.

3802 – Further use of the equipment shall be impossible until the SAFETY DEVICE has been
3803 replaced.

– The ACCOMPANYING DOCUMENTS for the RESPONSIBLE ORGANIZATION shall indicate that once the SAFETY DEVICE has been activated SERVICE PERSONNEL are to be called, and the SAFETY DEVICE must be replaced before the ME EQUIPMENT can be used again.

– The equipment shall be permanently marked with Symbol ISO 7000-0434 (see Table D1, Symbol 10).

– The marking shall be adjacent to the SAFETY DEVICE or so located that its relation to the SAFETY DEVICE is obvious to the person performing service or repair.

– The ACCOMPANYING DOCUMENTS intended for SERVICE PERSONNEL shall indicate that once the SAFETY DEVICE has been activated, the SAFETY DEVICE is to be replaced before the equipment can be used again.

Compliance with the requirements of 9.8.4 is checked as follows:

– *by inspection of the equipment, the ACCOMPANYING DOCUMENTS, and the MANUFACTURER'S relevant information (e.g. calculations, test results, the RISK MANAGEMENT FILE, etc.), specifications of materials used and the processing specifications for these materials;*

– *in accordance with 15.3.2; and*

– *a chain, cable, band, spring, belt, screw nut, pneumatic or hydraulic hose, structural part or the like, employed to support a load, is defeated (to test the SAFETY DEVICE) by any convenient means, thereby causing the maximum normal load to fall from the most adverse position permitted by the construction of the equipment. If the system supports a PATIENT or OPERATOR, the load is to include the SAFE WORKING LOAD defined in 9.8.3.1.*

There shall be no evidence of damage to a SAFETY DEVICE that would affect its ability to perform its intended function.[139]

10. *Protection against unwanted and excessive radiation HAZARDS[140]

10.1 X-Radiation

For equipment not intended to produce X-radiation for diagnostic or therapeutic purposes, ionizing radiation emitted by vacuum tubes excited by voltages exceeding 5 kV shall not produce an air kerma) exceeding 4,7 µGy in 1 h averaged over any area of 10 cm^2 of which no linear dimension exceeds 5 cm at a distance of 5 cm from any ACCESSIBLE PART of the equipment.[141] For unintended radiation from irradiating apparatus used for diagnostic and therapeutic purposes, refer to the particular standards for that type of equipment.[142]

NOTE Air kerma is a term of art used in numerous standards maintained by IEC/SC 62B and 62C, and is defined in IEC 60788.

Compliance is checked by measurements of exposure or exposure rate with a radiation detector suitable for the energy of the emitted radiation.

Controls and adjustments, internal and external, provided for the purpose of altering the value of the relevant HIGH VOLTAGE source(s) in the equipment, are set at the position resulting in the maximum emission of X-radiation. Single failures of components causing the least favourable conditions are simulated in turn.

Detailed requirements concerning failure of components may be specified in particular standards.

10.2 Alpha, beta, gamma, neutron radiation and other particle radiation

When applicable, the MANUFACTURER shall address the RISKS associated with alpha, beta, gamma, neutron radiation and other particle radiation in the RISK MANAGEMENT PROCESS.[143]

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

10.3 Microwave radiation

When applicable, the MANUFACTURER shall address the RISKS associated with microwave radiation in the RISK MANAGEMENT PROCESS.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

10.4 Lasers and laser light emitting diodes (LEDs)

The relevant requirements of IEC 60825-1 apply. If laser light barriers or similar products are used within equipment, they shall comply with the requirements of IEC 60825-1. In case of laser fibre optics the requirements of IEC 60825-2 shall be met.[144]

10.5 Other visual electromagnetic radiation

When applicable, the MANUFACTURER shall address the RISKS associated with visual electromagnetic radiation, other than that produced by lasers and laser light emitting diodes, in the RISK MANAGEMENT PROCESS.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

10.6 Infrared radiation

In the case of laser infrared diodes, the relevant requirements of the IEC 60825 series apply.

10.7 Ultraviolet radiation

When applicable, the MANUFACTURER shall address the RISKS associated with ultraviolet radiation in the RISK MANAGEMENT PROCESS.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

10.8 *Acoustic pressure (including ultrasonics)

When applicable, the MANUFACTURER shall address the RISKS associated with acoustic pressure in the RISK MANAGEMENT PROCESS.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

NOTE See 9.6.2 for requirements regarding exposure to noise.

3872 # 11. *Protection against excessive temperatures and other HAZARDS

3873 ## 11.1 Excessive temperatures in ME EQUIPMENT

3874 ### 11.1.1 *Maximum temperature during NORMAL USE

3875 ME EQUIPMENT parts that could affect SAFETY, and their environment, shall not attain
3876 temperatures exceeding the values given in Table 18 and Table 19 during NORMAL USE and
3877 NORMAL CONDITION at the maximum ambient operating temperature as specified by the
3878 MANUFACTURER.[145]

3879 **Table 18 – Allowable maximum temperatures of parts**

Parts	Maximum Temperature, °C [a]
Insulation, including winding insulation [b]	
- of Class A Material	105
- of Class E Material	120
- of Class B Material	130
- of Class F Material	155
- of Class H Material	180
Parts with T marking	T [c]
Other components and materials[146]	[d]
Parts in contact with flammable liquid with flash-point of T °C	T-25
Wood	90

[a] Where engineering judgement indicates that temperature limits cannot be exceeded, no measurement is required. However, the rationale for such judgement shall be documented.

[b] The classification of insulating materials is in accordance with IEC 60085. The incompatibility of the materials of an insulating system that could reduce the maximum temperature limit of the system below the limits of the individual materials shall be considered.

[c] T marking refers to the marked maximum operating temperature.

[d] For each material and component, account shall be taken of the temperature ratings for each material or component to determine the appropriate maximum temperature. Each component shall be used in accordance with its temperature rating. Where doubt exists, the ball pressure test of 8.8.4.1 should be performed.

3880 **Table 19 – Allowable maximum temperatures for ME EQUIPMENT parts that are likely to be**
3881 **touched [a]**

ME EQUIPMENT and its parts		Maximum Temperature, °C [b]		
		Metal and Liquids	Glass, Porcelain, Vitreous Material	Moulded Material, Plastic, Rubber, Wood
External surfaces of ME EQUIPMENT that are likely to be touched for a time "*t*".	*t* < 1 s	74	80	86
	1 s ≤ *t* < 10 s	56	66	71
	10 s ≤ *t* < 1 min	51	56	60
	1 min ≤ *t*	48	48	48

[a] The likelihood (probability) of contact and of the duration of contact shall be determined and documented in the RISK MANAGEMENT FILE.

[b] These temperature limit values are applicable for the healthy skin of adults. They are not applicable when large areas of the skin (10% of total body surface or more) can be in contact with a hot surface. This also applies in the case of skin contact with over 10% of the head surface.

3882 **Table 20 – Allowable maximum temperatures for ME EQUIPMENT APPLIED PARTS [a)]**

APPLIED PARTS of ME EQUIPMENT		Maximum Temperature, °C [b) c)]		
		Metal and Liquids	Glass, Porcelain, Vitreous Material	Moulded Material, Plastic, Rubber, Wood
APPLIED PART having contact with the PATIENT for a time "*t*".	*t* < 1 min	51	56	60
	1 min ≤ *t* < 10 min	48	48	48
	10 min ≤ *t*	43	43	43

a) The likelihood (probability) of contact and of the duration of contact shall be determined and documented in the RISK MANAGEMENT FILE.

b) These temperature limit values are applicable for the healthy skin of adults. They are not applicable when large areas of the skin (10% of total body surface or more) can be in contact with a hot surface. They are not applicable in the case of skin contact with over 10% of the head surface.

c) Where it is necessary for APPLIED PARTS to exceed the temperature limits of Table 20 in order to provide clinical benefit, the RISK MANAGEMENT FILE shall contain documentation showing that the resulting benefit exceeds any associated increase in RISK.

3883 **11.1.2 *Temperature of APPLIED PARTS**

3884 **11.1.2.1 APPLIED PARTS intended to supply heat to a PATIENT**[147]

3885 The temperature (hot or cold surfaces) and/or (where appropriate) the clinical effects shall be
3886 determined and documented in the RISK MANAGEMENT FILE. These values shall be disclosed in
3887 the instruction for use.

3888 **11.1.2.2 APPLIED PARTS not intended to supply heat to a PATIENT**

3889 The limits of Table 20 shall apply. If the surface temperature of an APPLIED PART exceeds
3890 41 °C, the maximum temperature shall be disclosed in the instructions for use.

3891 NOTE Cold surfaces may also cause HAZARDS and should be subject of the RISK MANAGEMENT PROCESS.

3892 **11.1.3 Measurements**[148]

3893 *Compliance with the requirements of 11.1.1 and 11.1.2 is checked by operation of*
3894 *ME EQUIPMENT and temperature measurements as follows:*

3895 a) *Positioning*

3896 1) *ME EQUIPMENT* shall be tested in the position of NORMAL USE.

3897 2) *ME EQUIPMENT is placed in a test corner. The test corner consists of two walls at right*
3898 *angles, a floor and, if necessary, a ceiling, all of dull black painted plywood of 20 mm*
3899 *thickness. The linear dimensions of the test corner shall be at least 115 % of the linear*
3900 *dimensions of the ME EQUIPMENT under test.*

3901 *The ME EQUIPMENT is positioned in the test corner as follows:*

3902 – *ME EQUIPMENT normally used on a floor or a table is placed as near to the walls as*
3903 *possible, provided that the MANUFACTURER has not given special instructions*
3904 *concerning its use.*

3905 – *ME EQUIPMENT normally affixed to a wall is mounted on one of the walls, as near to the*
3906 *other wall and to the floor or ceiling as is likely to occur in NORMAL USE, provided the*
3907 *MANUFACTURER has not given special instructions concerning the installation.*

3908 – *ME EQUIPMENT normally affixed to a ceiling is fixed to the ceiling as near to the walls as*
3909 *is likely to occur in NORMAL USE, provided the MANUFACTURER has not given special*
3910 *instructions concerning its installation.*

3911 3) *HAND-HELD ME EQUIPMENT is suspended in its normal position, in still air.*

3912 4) *ME EQUIPMENT intended for installation in a cabinet or wall is built in as required by*
3913 *installation instructions, using dull black painted plywood walls, 10 mm thick when*
3914 *representing cabinet walls if the installation instructions so specify and 20 mm thick when*
3915 *representing building walls.*

3916 b) *Supply*

3917 – *ME EQUIPMENT having heating elements is operated as in NORMAL USE, with all heating*
3918 *elements energized unless prevented by switching interlocks, the supply voltage being*
3919 *equal to 110 % of the maximum RATED voltage.*

3920 – *Motor operated ME EQUIPMENT is operated under normal load and normal DUTY CYCLE*
3921 *and the least favourable voltage between 90 % of the minimum RATED voltage and*
3922 *110 % of the maximum RATED voltage.*

3923 – *Combined heating and motor operated and other ME EQUIPMENT shall be tested both at*
3924 *110 % of the maximum RATED voltage and at 90 % of the minimum RATED voltage.*

3925 – *When modules are tested separately, the configuration for testing shall simulate the*
3926 *worst case conditions of NORMAL USE that might affect the test result.*

3927 c) *DUTY CYCLE*

3928 *The ME EQUIPMENT is operated:*

3929 – *For ME EQUIPMENT intended for non-CONTINUOUS OPERATION:*

3930 *After operating in standby/quiescent mode until THERMAL STABILITY is reached, the*
3931 *ME EQUIPMENT is operated in NORMAL USE over consecutive cycles until THERMAL*
3932 *STABILITY is again achieved, or for seven hours, whichever is shorter. The "on" and*
3933 *"off" periods for each cycle shall be the RATED "on" and "off" periods;*

3934 – *For ME EQUIPMENT for CONTINUOUS OPERATION:*

3935 *The ME EQUIPMENT is operated until THERMAL STABILITY is reached.*

3936 d) *Temperature measurement*

3937 *The temperature of windings is determined by the Resistance Method or by the use of*
3938 *thermocouples, described as follows.*

3939 ***Resistance Method:***

3940 *The value of the temperature rise of a copper winding is calculated from the formula:*

3941 $$\Delta T = \frac{R_2 - R_1}{R_1}(234{,}5 + T_1) - (T_2 - T_1)$$

3942 *where:*

3943 ΔT *is the temperature rise in* °C

3944 R_1 *is the resistance at the beginning of the test in* Ω

3945 R_2 *is the resistance at the end of the test in* Ω

3946 T_1 *is the room temperature at the beginning of the test in* °C

3947 T_2 *is the room temperature at the end of the test in* °C

3948 *At the beginning of the test, windings are to be at room temperature.*

3949 NOTE When the Resistance Method is used, it is recommended that the resistance of windings at the end of
3950 the test be determined by taking measurements as soon as possible after switching off, and then at short
3951 intervals so that a curve of resistance against time can be plotted for ascertaining the value at the instant of
3952 switching off.

Thermocouple Method:

When thermocouples are used to determine the temperature of windings, the temperature limits of Table 18 shall be reduced by 10 °C.

In this case the measurement is made by devices so chosen and positioned that they have a negligible effect on the temperature of the part under test.

As far as possible, the ME EQUIPMENT is positioned so that parts likely to attain the highest temperatures touch the disks.

The temperature of electrical insulation, other than that of windings, is determined on the surface of the insulation at places where failure could cause a short circuit, bridging of a MEANS OF PROTECTION, bridging of insulation or reduction of CREEPAGE DISTANCES or AIR CLEARANCES below the values specified for the insulation type in 8.9.

The point of separation of cores of a multicore cord and where insulated wires enter lampholders are examples of places where temperatures may have to be measured.

e) *Test criteria*

To assure they do not activate under NORMAL CONDITION, during the test THERMAL CUT-OUTS shall not be de-activated and shall not operate. The maximum temperature of a part is determined by measuring the temperature rise of the part under test and adding it to the maximum allowed ambient temperature of NORMAL USE as defined by the MANUFACTURER. Where thermal regulatory devices make this method inappropriate, alternative methods for measurement shall be justified in the RISK MANAGEMENT FILE..

11.1.4 GUARDS

GUARDS intended to prevent contact with hot accessible surfaces of ME EQUIPMENT shall be removable only with the aid of a TOOL.

Compliance is checked by inspection.

11.2 Fire prevention

11.2.1 *Strength and rigidity required to prevent fire HAZARDS in ME EQUIPMENT

ME EQUIPMENT shall have the strength and rigidity necessary to avoid a fire HAZARD that may occur as a result of a total or partial collapse caused by REASONABLY FORESEEABLE MISUSE.

Compliance is checked by the mechanical strength test for ENCLOSURES (see 15.3).

11.2.2 *ME EQUIPMENT and ME SYSTEMS used in conjunction with OXYGEN RICH ENVIRONMENTS

In ME EQUIPMENT and ME SYSTEMS, the RISK of fire in an OXYGEN RICH ENVIRONMENT shall be reduced as far as possible under NORMAL CONDITION and SINGLE FAULT CONDITIONS (as identified in 11.2.3). An unacceptable RISK of fire is considered to exist in an OXYGEN RICH ENVIRONMENT when a source of ignition is in contact with ignitable material and there is no means that would limit the spread of a fire.

NOTE For oxygen concentrations up to 25 % or partial pressures up to 26,5 kPa, the requirements in 13.1.1 are considered to be sufficient.

a) A source of ignition is considered to exist in an OXYGEN RICH ENVIRONMENT when:

1) The temperature of the material is raised to its ignition temperature.

2) Temperatures could affect solder or solder joints causing loosening, short circuiting or other failures that could result in sparking or raising the temperature of the material to its ignition temperature.

3) Parts affecting SAFETY might crack or change their outer shape due to overheating.

4) Temperatures of parts or components could exceed 300 °C.

5) Sparks provide adequate energy for ignition by failing to meet the limits of Figure 34 to Figure 36 (inclusive).

NOTE Items 4) and 5) address the worst case where the atmosphere is 100 % oxygen, the contact material is solder and where the fuel is cotton. Available fuels and oxygen concentrations should be taken into consideration when applying these specific requirements. Where deviations from these worst case limits are made (based on lower oxygen concentrations or less volatile fuels) they shall be justified and documented in the RISK MANAGEMENT FILE.

Alternately, the following test may be used to determine whether a source of ignition exists.

Two contact pins made of the material to be considered are placed in opposition (see Figure 33). One pin has a diameter of 1 mm, the other of 3 mm. The electrical source is connected to the pins as shown in Figure 33 to Figure 36. A piece of cotton is placed close to the contact surfaces of the two pins. The contacts are constantly flushed by oxygen with a speed of less than 0,5 m/s via a tube. The cathode is moved to the anode to close the contacts and pulled back to open them again. A minimum of 300 trials has to be performed before it can be decided that the sparks do not ignite. If the sparks get smaller because of bad surfaces of the electrodes, the electrodes shall be cleaned with a file. If the cotton gets black because it became oxidized than it shall be replaced. For capacitors and inductors, the resistor in series has to be chosen such that it contributes only negligible to the spark. This is tested by visual inspection without the capacitor in place or with the inductor shorted.

The situation with the highest voltage or current respectively and no ignition defines the upper limit. A safe upper limit is given by dividing the upper limit of voltage or current respectively with the SAFETY margin factor of three.

NOTE The SAFETY margin factor is considered to cover the uncertainty of sparking experiments and the variability of the underlying parameters like pressure, quality of cotton or of the contact materials.

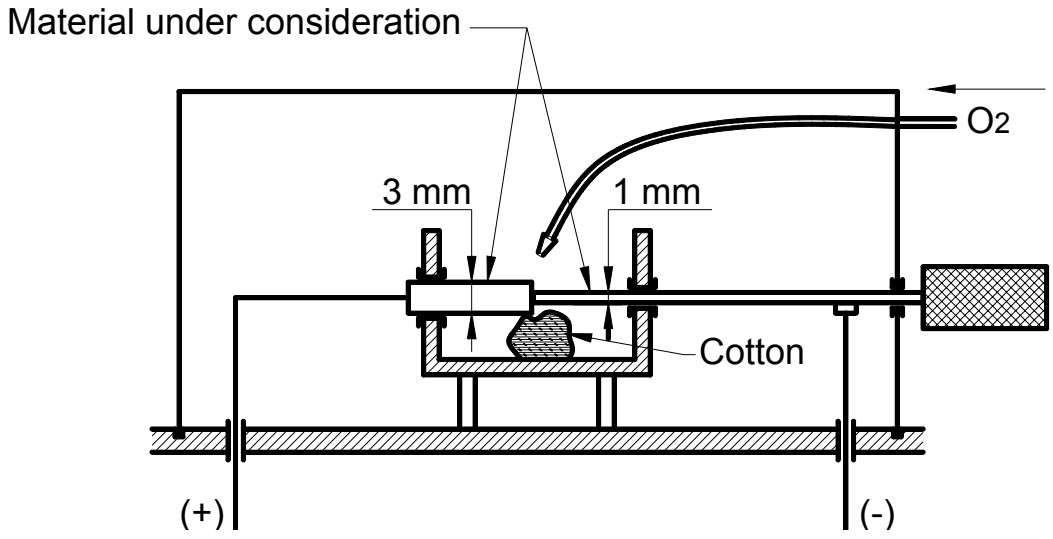


Figure 33 – Spark ignition test apparatus (see 11.2.2)

b) The following configurations, alone or in combination as appropriate (as determined by the application of the RISK MANAGEMENT PROCESS), are considered to provide an acceptable level of RISK of fire in OXYGEN RICH ENVIRONMENT:

1) Electrical components in a compartment with an OXYGEN RICH ENVIRONMENT shall have power supplies with limited energy levels. Those energy levels shall be less than those which are considered to be sufficient for ignition (see 11.2.2 *a)*).

Compliance is checked by inspection of the design and measurement or calculation of power, energy and temperature values in NORMAL CONDITION and SINGLE FAULT CONDITION (as identified in 11.2.3).

AND/OR

2) Compartments that contain parts or components that may be a source of ignition (as defined in 11.2.2 *a)*) only under SINGLE FAULT CONDITION (as identified in 11.2.3) and that may be penetrated by oxygen (e.g. because of a leak) are ventilated such that the oxygen concentration will not exceed 25 %.

Compliance is checked by the following test:

The oxygen concentration is measured for such a period that the highest possible concentration of oxygen occurs. The least favourable control settings are selected. The leaking conditions of oxygen are selected such that they provide the minimum leak that could be detected by the OPERATOR (e.g. because of a failure of the function of the device). The concentration of oxygen shall not exceed 25 % in the presence of parts or components that could be a source of ignition including at the moment energy is applied.

AND/OR

3) A compartment that contains parts of components that may be a source of ignition (as defined in 11.2.2 *a)*) only under SINGLE FAULT CONDITION (as identified in 11.2.3) IS separated from another compartment that contains an OXYGEN RICH ENVIRONMENT by sealing all joints and any holes for cables, shafts or for other purpose. The effect of possible leaks and failures under SINGLE FAULT CONDITION (as identified in 11.2.3) that could cause ignition shall be evaluated using a RISK ASSESSMENT to determine the appropriate maintenance intervals.

Compliance is checked by visual inspection of the documentation provided by the MANUFACTURER including the RISK MANAGEMENT FILE.

AND/OR

4) Electrical components in a compartment containing an OXYGEN RICH ENVIRONMENT that may become a source of ignition (as defined in 11.2.2 *a)*) only under SINGLE FAULT CONDITIONS (as identified in 11.2.3) shall be enclosed in such a way that should ignition occur within the ENCLOSURE, the fire would self-extinguish rapidly and no hazardous amount of toxic gases would reach the PATIENT.

Compliance shall be checked by starting a fire in the ENCLOSURE. If it is not evident that toxic gases cannot reach the PATIENT, the gas that could reach the PATIENT shall be analyzed.

AND/OR

5) External exhaust outlets of an OXYGEN RICH ENVIRONMENT shall not be located so that RISK of ignition occurs because of any electrical component (which could cause a spark in NORMAL USE or SINGLE FAULT CONDITION) (as identified in 11.2.3) mounted on the outside of the ME EQUIPMENT or an ME SYSTEM. RISK of ignition is considered to be sufficiently low if oxygen concentration in the immediate surroundings of the electrical component does not exceed 25 % under the least favourable conditions of operation.

Compliance is checked by inspection.

AND/OR

6) Electrical connections within a compartment containing an OXYGEN RICH ENVIRONMENT under NORMAL USE shall not produce sparks because of loosening or breaking unless they are limited in power and energy to the values identified in 11.2.2 *a) 5)*.

Prevention of loosening or breaking is accomplished by the following or equivalent methods:

– Screw-attachments shall be protected against loosening during use by methods such as varnishing, the use of spring washers or application of adequate torques.

– Soldered, crimped and pin-and-socket connections of cables that exit the ENCLOSURE shall include additional mechanical fixing.

Compliance is checked by visual inspection.[149]

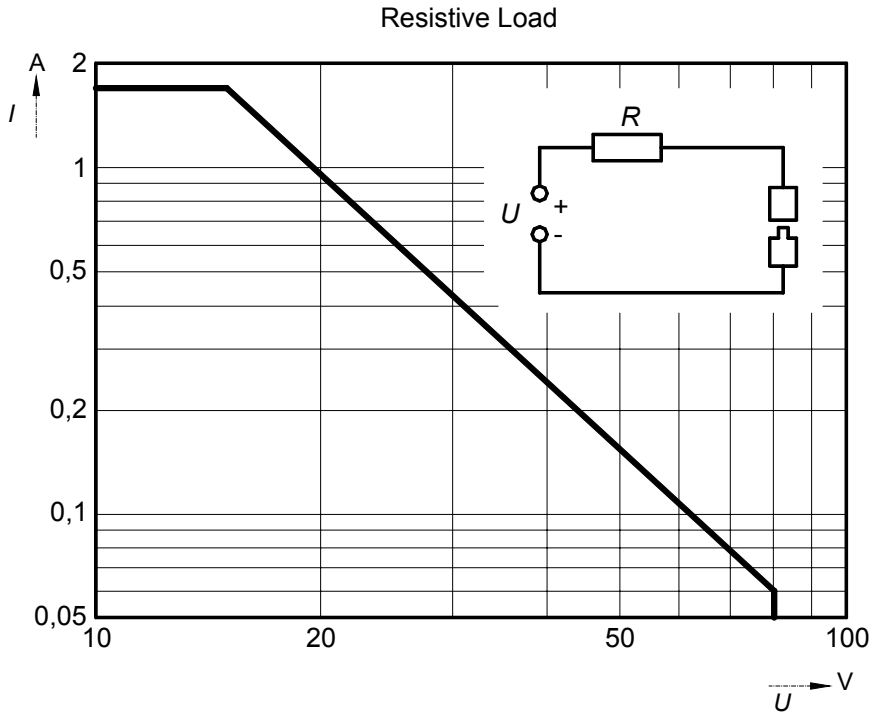


Figure 34 – Maximum allowable current *I* as a function of the maximum allowable voltage *U* measured in a purely resistive circuit in an OXYGEN RICH ENVIRONMENT (see 11.2.2)

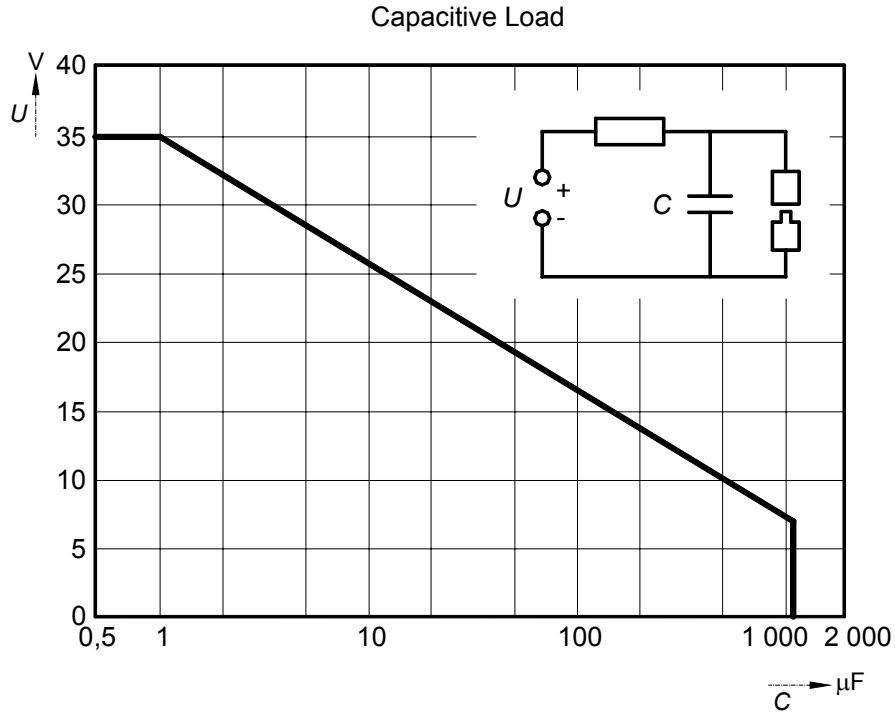


Figure 35 – Maximum allowable voltage *U* as a function of the capacitance *C* measured in a capacitive circuit used in an OXYGEN RICH ENVIRONMENT (see 11.2.2)

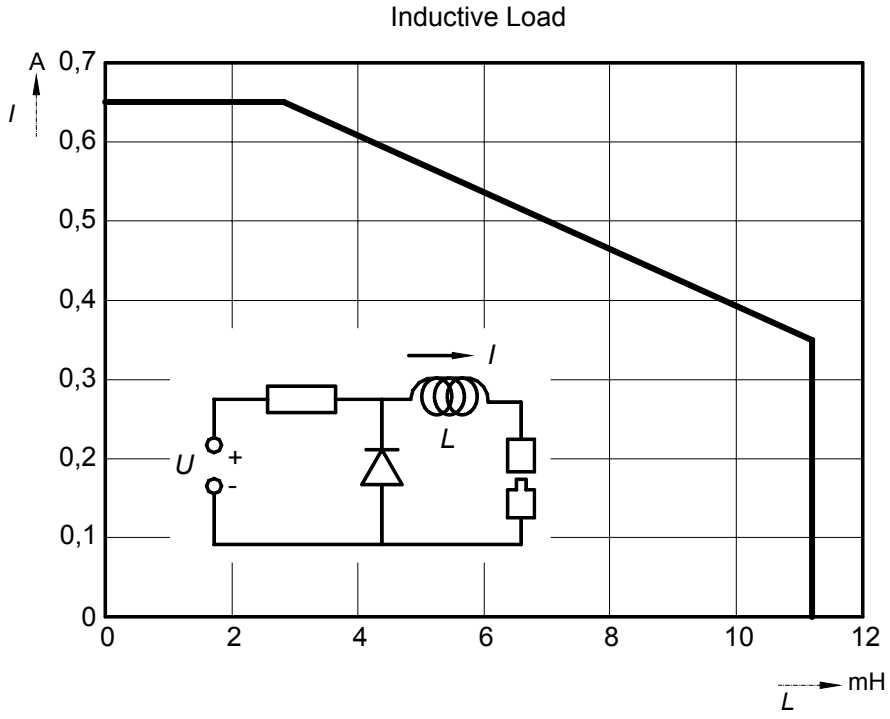


Figure 36 – Maximum allowable current *I* as a function of the inductance *L* measured in an inductive circuit in an OXYGEN RICH ENVIRONMENT (see 11.2.2)

11.2.3 SINGLE FAULT CONDITIONS related to OXYGEN RICH ENVIRONMENTS in conjunction with ME EQUIPMENT and ME SYSTEMS[150]

– Failure of a ventilation system constructed in accordance with 11.2.2 *b) 2)*.

– Failure of a barrier constructed in accordance with 11.2.2 *b) 3)*.

– Failure of a component that creates a source of ignition (as defined in 11.2.2 *a)*).[151]

– Failure of insulation (whether solid material or spacing) providing the equivalent of at least one MEANS OF PATIENT PROTECTION but less than two MEANS OF PATIENT PROTECTION (as described in 8.8 and 8.9) that could create a source of ignition (as defined in 11.2.2 *a)*).[152]

– Failure of a pneumatic component that results in leakage of oxygen-enriched gas.

11.3 *Constructional requirements for fire-proof ENCLOSURES OF ME EQUIPMENT[153]

This subclause provides an alternative means of compliance to selected abnormal conditions as identified in 13.1.1. In doing so, the following constructional requirements shall be met or specifically analyzed in the RISK MANAGEMENT FILE and if not met, specific justification shall also be given.

a) Insulated wire within the fire-proof ENCLOSURE shall have a flammability classification equivalent FV-1, or better, of IEC 60707, connectors, printed circuit boards and insulating material on which components are mounted shall have a flammability classification FV-2, or better, of IEC 60707.

Conformity is checked by inspection of data on materials, or by performing the FV tests specified in IEC 60707 on three samples of the relevant parts being tested. The samples may be any of the following:

1) *Complete parts;*

2) *Sections of a part, including the area with the least wall thickness and any ventilation openings;*

Components certified in accordance with IEC 60707.

b) The fire-proof ENCLOSURE shall meet the following requirements:

1) The bottom shall have no openings or, to the extent specified in Figure 38, shall be constructed with baffles as specified in Figure 37, or be made of metal, perforated as specified in Table 21, or be a metal screen with a mesh not exceeding 2 mm × 2 mm centre to centre and a wire diameter of at least 0,45 mm.

2) The sides shall have no openings within the area that is included within the inclined line C in Figure 38.

3) The ENCLOSURE, and any baffle or flame barrier, shall be made of metal (except magnesium) or of non-metallic materials having a flammability classification of FV 2 (or better) for TRANSPORTABLE ME EQUIPMENT and FV 0 (or better) for FIXED ME EQUIPMENT or STATIONARY ME EQUIPMENT in accordance with IEC 60707.

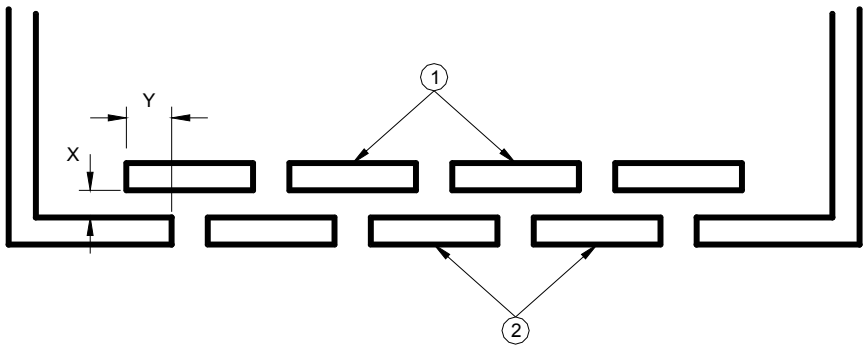
The ENCLOSURE, and any baffle or flame barrier, shall have adequate rigidity.

Conformity is checked by inspection. In case of doubt, the flammability classification of requirement b) 3) *is checked as in* a).

4136 **Table 21 – Acceptable perforation of the bottom of an ENCLOSURE**

Minimum thickness mm	Maximum diameter of holes mm	Minimum spacing of holes centre to centre mm
0,66	1,14	1,70 (233 holes/645 mm^2)
0,66	1,19	2,36
0,76	1.15	1,70
0,76	1,19	2,36
0,81	1,91	3,18 (72 holes/645 mm^2)
0,89	1,90	3,18
0,91	1,60	2,77
0,91	1,98	3,18
1,00	1,60	2,77
1,00	2,00	3,00

4137



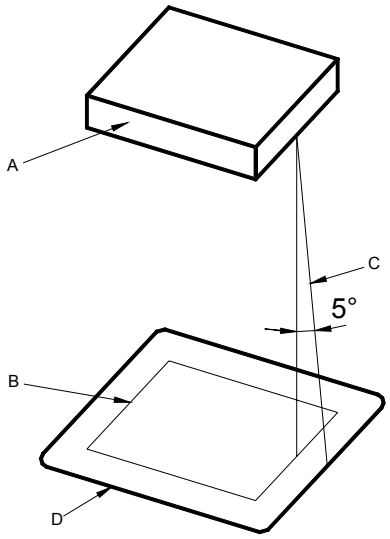
4138

Y = twice X but never less than 25 mm

(1) Baffle plates (may be below the bottom of the ENCLOSURE)

(2) Bottom of the ENCLOSURE

4139 **Figure 37 – Baffle**
4140 **(see 11.3)**



A Part or component of the ME EQUIPMENT that is considered to be a source of fire HAZARD. This consists of an entire component or part of the ME EQUIPMENT if it is not otherwise shielded, or the unshielded portion of a component that is partially shielded by its casing.

B Projection of the outline of A on the horizontal plane.

C Inclined line that traces out the minimum area of the bottom and sides to be constructed as specified in 11.3 *b) 1)* and 11.3 *b) 2)*. This line projects at a 5° angle from the vertical at every point around the perimeter of A and is oriented so as to trace out the maximum area.

D Minimum area of the bottom to be constructed as specified in 11.3 *b) 1)*.

Figure 38 – Area of the bottom of an ENCLOSURE as specified in 11.3 *b) 1)* (see 11.3)

11.4 *ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics.[154]

ME EQUIPMENT, ME SYSTEMS or their parts intended by the MANUFACTURER for use with flammable anaesthetics (CATEGORY AP) or flammable anaesthetics with oxidants (CATEGORY APG) shall meet the applicable requirements of Annex G.

11.5 *ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents

The MANUFACTURER'S RISK MANAGEMENT PROCESS shall address the possibility of fire and associated mitigations.

Compliance is determined by inspection of the RISK MANAGEMENT FILE

11.6 Overflow, spillage, leakage, ingress of liquids, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT

11.6.1 General

The construction of ME EQUIPMENT and ME SYSTEM shall ensure a sufficient degree of protection against HAZARDS caused by overflow, spillage, leakage, ingress of liquids, cleaning, disinfection and sterilization as well as compatibility with substances used with the ME EQUIPMENT.

11.6.2 Overflow in ME EQUIPMENT

If ME EQUIPMENT incorporates a reservoir or liquid storage chamber that is liable to be overfilled or to overflow in NORMAL USE, liquid overflowing from the reservoir or chamber shall not wet electrical SAFETY insulation that is liable to be adversely affected by such a liquid, nor shall a HAZARD be created. Unless restricted by a marking or by the instructions for use, no HAZARDS shall develop if TRANSPORTABLE ME EQUIPMENT is tilted through an angle of 15°.

Compliance is checked by filling the liquid reservoir completely and subsequently adding a further quantity equal to 15 % of the capacity of the reservoir, which is poured in steadily over a period of 1 min.

TRANSPORTABLE ME EQUIPMENT is subsequently tilted through an angle of 15° in the least favourable direction(s) (if necessary with refilling) starting from the position of NORMAL USE.

After these PROCEDURES, the ME EQUIPMENT shall show no signs of wetting of uninsulated electrical parts or electrical insulation of parts that may cause a HAZARD followed by the appropriate dielectric strength and LEAKAGE CURRENT tests.

11.6.3 *Spillage on ME EQUIPMENT and ME SYSTEM

ME EQUIPMENT and ME SYSTEMS requiring the handling of liquids in NORMAL USE shall be so constructed that spillage does not wet parts that may cause a HAZARD.

Compliance is checked by the following test:

The ME EQUIPMENT is positioned according to 5.4 a). *A quantity of normal tap water is poured steadily on a point on the top of the ME EQUIPMENT for approximately 15 s from a height not exceeding 5 cm.*

The location (point) shall be determined through the MANUFACTURER'S RISK MANAGEMENT PROCESS to identify the least favourable configuration during NORMAL USE.

After these PROCEDURES, the ME EQUIPMENT shall show no signs of bridging of insulation [or electrical components] that could cause a HAZARD in NORMAL CONDITION or in combination with a SINGLE FAULT CONDITION (based on a visual inspection) followed by the appropriate dielectric strength and LEAKAGE CURRENT tests.

The MANUFACTURER'S RISK MANAGEMENT PROCESS may require different test conditions.

After the test, the ME EQUIPMENT shall comply with all the requirements of this standard for NORMAL CONDITION.

11.6.4 *Leakage

See 13.2.7.

11.6.5 *Ingress of liquids and particulate matter into ME EQUIPMENT and ME SYSTEMS

ENCLOSURES of ME EQUIPMENT AND ME SYSTEMS designed to give a specified degree of protection against harmful ingress of water or particulate matter shall provide this protection in accordance with the classification of IEC 60529. See also 7.2.7.

Compliance is checked by the tests of IEC 60529 with the ME EQUIPMENT placed in the least favourable position of NORMAL USE (as defined in the instructions for use) and by inspection:

After these PROCEDURES, the ME EQUIPMENT shall show no signs of bridging of insulation [or electrical components] that could cause a HAZARD in NORMAL CONDITION or in combination with a SINGLE FAULT CONDITION (based on a visual inspection) followed by the appropriate dielectric strength and LEAKAGE CURRENT tests.[155]

11.6.6 Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS

For ME EQUIPMENT, ME SYSTEMS and their parts or ACCESSORIES that come in contact with the PATIENT in NORMAL USE, see 7.10.2.12.

ME EQUIPMENT, ME SYSTEMS and their parts, including APPLIED PARTS and parts into which PATIENTS may exhale, or ACCESSORIES shall be capable of withstanding without damage or deterioration of SAFETY provisions the cleaning or disinfection PROCESSES specified by the MANUFACTURER in the instructions for use. See also 7.10.2.12.

Where compliance with this standard could be affected by cleaning or disinfecting the ME EQUIPMENT, ME SYSTEM and their parts or ACCESSORIES, *they are cleaned or disinfected one time in accordance with the methods specified including any cooling or drying period. There shall be no appreciable signs of deterioration that could affect compliance with the requirements of this standard. After these PROCEDURES, the ME EQUIPMENT, ME EQUIPMENT parts or ACCESSORIES shall show no signs of deterioration that may cause a HAZARD (visual inspection) followed by the appropriate dielectric strength and LEAKAGE CURRENT tests.*[156]

The MANUFACTURER shall evaluate the effects of multiple cleanings/disinfections over the useful life of the product and assure that no HAZARD will occur. Compliance is determined by inspection of the MANUFACTURER'S RISK MANAGEMENT FILE.

11.6.7 Sterilization of ME EQUIPMENT and ME SYSTEMS

ME EQUIPMENT, ME SYSTEMS and their parts or ACCESSORIES intended to be sterilized shall be assessed and documented according to ISO 11134, ISO 11135 or ISO 11137 as appropriate. See also 7.10.2.12.

After these PROCEDURES, the ME EQUIPMENT, ME SYSTEM and their parts or ACCESSORIES shall show no signs of deterioration that may cause a HAZARD (visual inspection) followed by the appropriate dielectric strength and LEAKAGE CURRENT tests.

11.6.8 *Compatibility with substances used with the ME EQUIPMENT

When applicable, the MANUFACTURER shall address the RISKS associated with compatibility with substances used with the ME EQUIPMENT in the RISK MANAGEMENT PROCESS.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

11.7 Biocompatibility of ME EQUIPMENT and ME SYSTEMS

ME EQUIPMENT, ME SYSTEM and their parts, or ACCESSORIES intended to come into contact with biological tissues, cells or body fluids shall be assessed and documented according to the guidance and principles given in ISO 10993.

Compliance is checked by inspection of the information provided by the MANUFACTURER.

11.8 *Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT

11.8.1 THERMAL CUT-OUTS and OVER-CURRENT RELEASES

THERMAL CUT-OUTS and OVER-CURRENT RELEASES with automatic resetting shall not be used in ME EQUIPMENT if they may cause a HAZARD by such resetting.

Compliance is checked by a functional test.

11.8.2 Interruption and restoration of the power supply to ME EQUIPMENT and ME SYSTEM

ME EQUIPMENT shall be so designed that an interruption and restoration of the power supply shall not result in a HAZARD other than interruption of its intended function.

NOTE This may require testing at several durations and ME EQUIPMENT states.

Compliance is checked by interruption and restoration of relevant power supplies.

12. *ESSENTIAL PERFORMANCE, accuracy of controls and instruments and protection against hazardous outputs

12.1 *ESSENTIAL PERFORMANCE

The MANUFACTURER shall identify which performance characteristics of the ME EQUIPMENT or ME SYSTEM are ESSENTIAL PERFORMANCE characteristics and shall ensure that the RESIDUAL RISKS are acceptable.

NOTE ESSENTIAL PERFORMANCE requirements may be specified in legislation, regulations or particular standards.

Compliance is checked by assessment of the RISK MANAGEMENT FILE.

12.2 Accuracy of controls and instruments

When applicable, the MANUFACTURER shall address the RISKS associated with accuracy of controls and instruments in the RISK MANAGEMENT PROCESS.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

12.3 Protection against hazardous output

12.3.1 Use error

The MANUFACTURER shall address the RISK of use error, including those associated with identification, marking and documents (see Clause 7 and 16.2), in the RISK MANAGEMENT PROCESS.[157]

NOTE The RISKS of use error can be controlled through the application of a human factors engineering PROCESS. Such a PROCESS is detailed in a collateral standard, which is under development. IEC 60601-1-6 describes a PROCESS for the analysis, test and validation of human factors compatibility.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

12.3.2 Alarm systems

When applicable, the MANUFACTURER shall address the RISKS associated with the alarm systems in the RISK MANAGEMENT PROCESS.[158]

NOTE A collateral standard, IEC 60601-1-8, on general requirements and guidelines for the application of alarms is under development.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

12.3.3 *Intentional exceeding of SAFETY limits

When applicable, the MANUFACTURER shall address the RISKS associated with the intentional exceeding of SAFETY limits in the RISK MANAGEMENT PROCESS.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

12.3.4 *Indication of parameters relevant to SAFETY

When applicable, the MANUFACTURER shall address the RISKS associated with the indication of parameters that are relevant to SAFETY in the RISK MANAGEMENT PROCESS.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

12.3.5 Accidental selection of excessive output values

Where ME EQUIPMENT is a multi-purpose unit designed for providing both low-intensity and high-intensity outputs for different treatments, the MANUFACTURER shall address the RISK of accidental selection of the incorrect output value through appropriate steps to minimize the possibility of a high intensity output being selected accidentally e.g. interlocks in order to achieve deliberate action, separated output terminals.

Compliance is checked by inspection.

12.3.6 *Incorrect output

When applicable, the MANUFACTURER shall address the RISKS associated with incorrect output in the RISK MANAGEMENT PROCESS.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

12.3.7 Diagnostic or therapeutic radiation

12.3.7.1 Limits

For ME EQUIPMENT designed to produce radiation for diagnostic or therapeutic purposes, adequate provisions shall be made to protect PATIENTS, OPERATORS, other persons and sensitive devices in the vicinity, from unwanted or excessive radiation emitted by the ME EQUIPMENT.

NOTE Radiation from ME EQUIPMENT intended for application to PATIENTS for diagnostic or therapeutic purpose under medical supervision may exceed limits normally acceptable for the population as a whole.

As appropriate, particular standards shall specify requirements, limits and compliance tests to ensure radiation SAFETY.

12.3.7.2 Diagnostic X-ray equipment

See IEC 60601-1-3 and the relevant particular standards.

12.3.7.3 Radiotherapy equipment

When applicable, the MANUFACTURER shall address the RISKS associated with radiotherapy in the RISK MANAGEMENT PROCESS.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

12.3.8 Diagnostic or therapeutic acoustic pressure

When applicable, the MANUFACTURER shall address the RISKS associated with diagnostic or therapeutic acoustic pressure in the RISK MANAGEMENT PROCESS.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

13. *Abnormal operation and fault conditions

13.1 Specific hazardous situations

13.1.1 General

When applying the SINGLE FAULT CONDITIONS listed in 13.2, one at a time, none of the hazardous situations in 13.1.2 to 13.1.4 (inclusive) shall occur in ME EQUIPMENT.[159]

13.1.2 *Emissions, deformation of ENCLOSURE or exceeding maximum temperature

– Emission of flames, molten metal, poisonous or ignitable substance in hazardous quantities;

– Deformation of ENCLOSURES to such an extent that compliance with this standard is impaired;

– APPLIED PARTS exceeding the limits identified in Table 20 when measured as described in 11.1.3;[160]

– ME EQUIPMENT parts, which are not APPLIED PARTS, but are likely to be touched that exceed the limits in Table 19 when measured and adjusted as described in 11.1.3;

– Exceeding the limits for "other components and materials" identified in Table 18 times 1,5 minus 12,5 ºC. In all other cases the limits of Table 18 apply.[161] [162] [163]

Temperatures shall be measured using the method described in 11.1.3.

The SINGLE FAULT CONDITIONS in 13.2.6 and 13.2.12, with regard to the emission of flames, molten metal or ignitable substances, shall not be applied to parts and components where:

– The construction or the supply circuit limits the power dissipation in SINGLE FAULT CONDITION to less than 15 W or less or the energy dissipation to less than 900 J.

Compliance is determined by drawing 15 W from the supply circuit for 1 min. If, after 1 min. the supply circuit can not supply 15 W or greater, the circuit shall be considered to limit power dissipation to less than 15 W. The related design documentation shall also be reviewed.

OR

– They are completely contained within a fire-proof ENCLOSURE.

Compliance is determined by inspection and evaluation of the design documentation to assure that the ENCLOSURE is constructed in accordance with 11.3.[164]

NOTE The tests according to this subclause should be performed in the sequence indicated in Annex B. (B.23 to B.26 [inclusive]).[165] [166]

After the tests of this clause, THERMAL CUT-OUTS and OVER-CURRENT RELEASES shall be inspected to determine that their setting has not changed (by heating, vibration or other causes) sufficiently to affect their SAFETY function.

13.1.3 Exceeding LEAKAGE CURRENT or voltage limits

– Exceeding the limits for LEAKAGE CURRENT in SINGLE FAULT CONDITION as indicated in 8.7.3;

– Exceeding the voltage limits in case of A SINGLE FAULT CONDITION for the ACCESSIBLE PARTS indicated in 8.4.2.

13.1.4 Specific MECHANICAL HAZARDS

See 9.1 to 9.8 (inclusive).[167]

13.2 SINGLE FAULT CONDITIONS

13.2.1 General

During the application of the SINGLE FAULT CONDITIONS listed in 13.2.2 to 13.2.14 (inclusive), the NORMAL CONDITIONS identified in 8.1 *a)* shall also be applied in the least favourable combination.

13.2.2 Electrical SINGLE FAULT CONDITION

Requirements and tests relating to this SINGLE FAULT CONDITION are found in 8.1 *b)*.

13.2.3 Overloading of transformers in ME EQUIPMENT

Requirements and tests relating to this SINGLE FAULT CONDITION are found in Clause 15.5.

13.2.4 Failure of THERMOSTATS

Requirements and tests relating to this SINGLE FAULT CONDITION are found in 13.2.14 and 15.4.2 for overloading situations.

THERMOSTATS are short-circuited or interrupted, whichever is less favourable.

13.2.5 Failure of temperature limiting devices

Requirements and tests relating to this SINGLE FAULT CONDITION are found in 13.2.14 and 15.4.2 for overloading situations.

THERMOSTATS are short-circuited or interrupted, whichever is less favourable.

13.2.6 Short-circuiting of either constituent part of a DOUBLE INSULATION

Requirements and tests relating to this SINGLE FAULT CONDITION are found in 8.1 and 8.7.

13.2.7 Leakage of liquid

ME EQUIPMENT shall be so constructed that liquid that might escape in a SINGLE FAULT CONDITION does not result in an unacceptable RISK.

Since only small amounts of liquid will escape when they leak, sealed rechargeable batteries are exempted from this requirement.

Compliance is checked by the following test:

A RISK MANAGEMENT PROCESS shall be used to determine the appropriate test conditions for the ME EQUIPMENT.

After these PROCEDURES, the ME EQUIPMENT shall comply with all the requirements of this standard for SINGLE FAULT CONDITIONS.

13.2.8 Impairment of cooling that could result in a HAZARD

ME EQUIPMENT shall be so designed that it remains SINGLE FAULT SAFE during the failure of cooling systems to operate as intended

Contrary to possible statements in the instructions for use, impairments of cooling that may occur in practice are simulated, for example:

– *single ventilation fans are locked consecutively;*
– *ventilation through openings in top and sides is impaired by, covering of openings in the top of the ENCLOSURE or positioning of ME EQUIPMENT against walls;*
– *blocking of filters is simulated;*
– *the flow of a cooling agent is interrupted.*

Temperatures shall not exceed the limits set in 13.1.2.

Compliance is checked utilizing the test methods of 11.1, which are applied as far as possible.

13.2.9 Locking of moving parts

ME EQUIPMENT shall be so designed that it remains SINGLE FAULT SAFE when moving parts become jammed.

Moving parts are locked if ME EQUIPMENT:

- *has moving ACCESSIBLE PARTS liable to be jammed, or*
- *is liable to be operated while unattended (this includes ME EQUIPMENT that is automatically or remotely controlled), or*
- *has one or more motors with a locked rotor torque smaller than the full load torque.*

If ME EQUIPMENT has more than one moving part as described above, only one part at a time is locked. For further test requirements see 13.2.11.

13.2.10 *Interruption and short-circuiting of motor capacitors

ME EQUIPMENT shall be so designed that it remains SINGLE FAULT SAFE during the short circuit of motor capacitors.

Compliance is checked by performing the following test:

Motors with a capacitor in the circuit of an auxiliary winding are operated with a locked rotor, with the capacitor short-circuited or open-circuited in turn. Capacitor voltages shall be measured with one side disconnected (open circuit) and shall not exceed their RATED values.

The test with a short-circuited capacitor is not performed if the motor is provided with a capacitor complying with IEC 60252-1 and the ME EQUIPMENT is not intended for unattended use (including automatic or remote control).

For additional test requirements, see 13.2.11.

13.2.11 Additional test requirements for motor operated ME EQUIPMENT

[168]*For every test in the SINGLE FAULT CONDITION of 13.2.9 and 13.2.10, taking into account the exemptions stated in 13.1.2, motor-operated ME EQUIPMENT shall be operated starting from COLD CONDITION, at RATED voltage or at the upper limit of the RATED voltage range for the following periods of time:*

a) *30 s for:*
   - *HAND-HELD ME EQUIPMENT,*
   - *ME EQUIPMENT that has to be kept switched on by hand,*
   - *ME EQUIPMENT that has to be kept under physical load by hand.*

b) *5 min for other ME EQUIPMENT not intended for unattended use (this includes automated or remotely controlled ME EQUIPMENT that could operate when the OPERATOR is not present).*

c) *for the maximum period of a timer, if such a device terminates the operation, for ME EQUIPMENT not listed under* a) *or* b).

d) *as long as necessary to establish steady thermal conditions for all the remaining ME EQUIPMENT.*

Temperatures of windings are determined at the end of the specified test periods or at the instant of operation of fuses, THERMAL CUT-OUTS, motor protective devices and the like.

Temperatures are measured as specified in 11.1.3 d).

Temperatures shall not exceed the limits of Table 22.

Table 22 – Temperature limits of motor windings

Temperature in °C

Type of ME EQUIPMENT	Insulation class				
	Class A	Class B	Class E	Class F	Class H
ME EQUIPMENT provided with a timer and not intended for unattended use and ME EQUIPMENT to be operated for 30 s or 5 min	200	225	215	240	260
Other ME EQUIPMENT					
– if impedance-protected, maximum value	150	175	165	190	210
– if protected by protection devices that operate during the first hour, maximum value	200	225	215	240	260
– after the first hour, maximum value	175	200	190	215	235
– after the first hour, arithmetic average	150	175	165	190	210

13.2.12 Failures of components in ME EQUIPMENT used in conjunction with OXYGEN RICH ENVIRONMENTS

Requirements and tests relating to these SINGLE FAULT CONDITIONS are found in 11.2.2. [169]

13.2.13 Failure of mechanical parts that might cause a HAZARD

Requirements and tests relating to these SINGLE FAULT CONDITIONS are found in Clause 9 and 15.3.

13.2.14 *Overload

13.2.14.1 General

After the test of 13.2.14.2 to 13.2.14.4 (inclusive), ME EQUIPMENT, when cooled down to approximately room temperature, shall remain safe.

Compliance is determined by inspection of the ME EQUIPMENT or the appropriate tests (such as dielectric strength of motor insulation according to 15.2).

For insulation of thermoplastic materials that is relied upon as a MEANS OF PROTECTION (see 8.8), the ball-pressure test specified in 8.8.4.1 a) is carried out at a temperature 25 °C higher than the temperature of the insulation measured during the tests of 13.2.14.2 to 13.2.14.4 (inclusive).

13.2.14.2 ME EQUIPMENT with heating elements

a) *ME EQUIPMENT having heating elements is checked for compliance as follows:*

1) *for thermostatically controlled ME EQUIPMENT having heating elements, which is intended for built-in or for unattended operation, or which has a capacitor not protected by a fuse or the like connected in parallel with the contacts of the THERMOSTAT: by the tests of 13.2.14.2* b) *and 13.2.14.2* c);

2) *for ME EQUIPMENT having heating elements RATED for non-CONTINUOUS OPERATION: by the tests of 13.2.14.2* b) *and 13.2.14.2* c);

3) *for other ME EQUIPMENT having heating elements: by the test of 13.2.14.2* b).

If more than one of the tests is applicable to the same ME EQUIPMENT, these tests shall be performed consecutively.

If, in any of the tests, a non-SELF-RESETTING THERMAL CUT-OUT operates, a heating element or an intentionally weak part ruptures, or if the current is otherwise interrupted before steady conditions are established without the possibility of automatic restoration, the heating period is ended. However, if the interruption is due to the rupture of a heating

element or of an intentionally weak part, the test shall be repeated on a second sample. Open circuiting of a heating element or of an intentionally weak part in the second sample does not in itself entail a failure to comply. Both samples shall comply with the conditions specified in 13.1.2.

b) *ME EQUIPMENT having heating elements is tested under the conditions specified in 11.1, but without adequate heat discharge, the supply voltage being 90 % or 110 % of the RATED supply voltage, whichever is the least favourable.*

If a non-SELF-RESETTING THERMAL CUT-OUT operates, or if the current is otherwise interrupted without the possibility of automatic restoration before steady thermal conditions are established, the operating period is ended. If interruption of the current does not occur, ME EQUIPMENT shall be switched off as soon as steady state thermal conditions are established and shall be allowed to cool to approximately room temperature.

For ME EQUIPMENT RATED for non-CONTINUOUS OPERATION, the duration of the test shall be equal to the RATED operating time.

c) *Heating parts of ME EQUIPMENT are tested with the ME EQUIPMENT operated in NORMAL CONDITION, at a supply voltage 110 % of the RATED supply voltage and as specified in 11.1. The following test conditions shall be met:*[170]

1) *Any control that serves to limit the temperature in NORMAL CONDITION, except a THERMAL CUT-OUT, is disabled.*

2) *If the ME EQUIPMENT is provided with more than one control, they are disabled in turn.*

3) The ME EQUIPMENT is operated at the RATED DUTY CYCLE until THERMAL STABILITY is achieved, irrespective of the RATED operating time.

13.2.14.3 ME EQUIPMENT with motors

a) *ME EQUIPMENT having motors is checked for compliance as follows:*

1) *For the motor part of the ME EQUIPMENT, compliance is checked by the tests of 13.2.9 to 13.2.11 (inclusive), 13.2.14.3 b), 13.2.14.3 c) and 13.2.14.4, as applicable. For motors located in circuits with a voltage not exceeding 42,4 V peak a.c. or 60 V d.c. and where difficulty is experienced in obtaining accurate temperature measurements due to the small size or design of the motor, it is permitted to use the following test instead of temperature measurement in order to determine compliance with 13.2.10 and 13.2.11.*[171]

The motor is covered with a single layer of bleached cotton cheesecloth of approximately 40 g/m^2. There shall be no ignition of the cheesecloth during the test or at its conclusion.

2) *For ME EQUIPMENT, which also contains heating parts, the tests shall be performed at the prescribed voltage, with the motor part and the heating part operated simultaneously so as to produce the least favourable condition.*

3) *If more than one of the tests is applicable for the same ME EQUIPMENT, these tests are performed consecutively.*

b) *Motors are checked for running overload protection if they are:*

1) *intended to be remotely controlled or automatically controlled (by a single control device without redundant protection), or*

2) *liable to be operated continuously whilst unattended.*

Compliance is determined by operating the ME EQUIPMENT under normal load conditions at RATED voltage or at the maximum of the RATED voltage range, until steady thermal conditions are achieved (see 11.1.3).

The load is then increased so that the current is increased in appropriate steps, the supply voltage being maintained at its original value.

When steady thermal conditions are established, the load is again increased. The load is thus progressively increased in appropriate steps until the overload protection operates, or until no further temperature rise is noted.

The motor winding temperature is determined during each steady period and the maximum value recorded shall not exceed the value in Table 23.

Table 23 – Maximum motor winding steady-state temperature

Insulation class	A	B	E	F	H
Maximum temperature °C	140	165	155	180	200

If the load cannot be changed in appropriate steps in ME EQUIPMENT, the motor is removed from the ME EQUIPMENT in order to perform the test.

The running overload test for motors located in circuits with a voltage not exceeding 42,4 V peak a.c. or 60 V d.c. is carried out only if a possibility of an overload occurring is determined by inspection or by review of the design. The test need not be carried out, for example, where electronic drive circuits maintain a substantially constant drive current.

c) *ME EQUIPMENT with three-phase motors is operated with normal load, connected to a three-phase (SUPPLY MAINS) with one phase disconnected. Periods of operation shall be according to 13.2.11 .*

13.2.14.4 *ME EQUIPMENT RATED for non-CONTINUOUS OPERATION

ME EQUIPMENT rated for non-CONTINUOUS OPERATION other than:

– *HAND-HELD ME EQUIPMENT;*

– *ME EQUIPMENT that has to be kept switched on by hand;*

– *ME EQUIPMENT that has to be kept under physical load by hand;*

– *ME EQUIPMENT with a timer and a back-up timer system;*

is operated under normal load and at RATED voltage or at the upper limit of the RATED voltage range until steady thermal conditions are established (peak temperature does not increase by more than 5 °C in one hour), or until any protective device operates.

Motor winding temperatures are determined when steady thermal conditions are established or immediately before the operation of the protective device and shall not exceed the values specified in 13.2.11.

If in NORMAL USE a load-reducing device in the ME EQUIPMENT operates, the test is continued with the ME EQUIPMENT running idle.

14. *PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

14.1 *General

The requirements of this clause shall apply to PEMS.

NOTE This clause requires that a PROCESS be followed throughout the DEVELOPMENT LIFE-CYCLE and that a RECORD of that PROCESS be produced. The concepts of RISK MANAGEMENT and a DEVELOPMENT LIFE-CYCLE are the basis of such a PROCESS. However, because a RISK MANAGEMENT PROCESS is already required by this standard, this clause will define the minimum elements of the DEVELOPMENT LIFE-CYCLE and only the additional elements for the PEMS that must be considered as part of the RISK MANAGEMENT PROCESS (see 4.2).

Compliance is determined by application of the requirements found in 14.2 to 14.13 (inclusive), by inspection of the RISK MANAGEMENT FILE, and assessment of PROCESSES cited in this clause.

NOTE This assessment could be carried out by internal audit.

14.2 *Documentation

In addition to the RECORDS and documents required by ISO 14971, the documents produced from application of Clause 14 shall be maintained and shall form part of the RISK MANAGEMENT FILE; see Figure H3 as guidance.

The documents required by Clause 14 shall be reviewed, approved, issued and changed in accordance with a formal document control PROCEDURE.

14.3 *RISK MANAGEMENT Plan

The RISK MANAGEMENT plan required by ISO 14971, subclause 3.5 shall also include a reference to the PEMS VALIDATION plan (see 14.11).

14.4 *DEVELOPMENT LIFE-CYCLE

A DEVELOPMENT LIFE-CYCLE shall be documented for the PEMS.

NOTE An example of a DEVELOPMENT LIFE-CYCLE is given in Figure H2.

The DEVELOPMENT LIFE-CYCLE shall be defined in terms of a set of milestones.

At each milestone, the tasks to be completed and the VERIFICATION methods to be applied to those tasks shall be defined.

Each task shall be defined in terms of required inputs, activities and outputs.

Each milestone shall identify the RISK MANAGEMENT tasks that must be completed before that milestone.

The defined life-cycle shall be tailored for a specific development by making plans which detail tasks, milestones and schedules.[172]

The DEVELOPMENT LIFE-CYCLE shall include documentation requirements.

14.5 *Problem resolution[173]

Where appropriate, a documented system for problem resolution within and between all phases and tasks of the DEVELOPMENT LIFE-CYCLE shall be developed and maintained as a part of the quality RECORDS.

Depending on the type of product, the problem resolution system may:

– be documented as a part of the DEVELOPMENT LIFE-CYCLE;

– allow the reporting of potential or existing SAFETY or performance problems;

– include an assessment of each problem for associated RISKS;

– identify the criteria (SAFETY or performance) that must be met for the issue to be closed;

– identify the action to be taken to resolve each problem;

– identify PEMS VALIDATION methods for each action;

– identify the steps taken for VERIFICATION of continuing compliance.

14.6 RISK MANAGEMENT PROCESS

14.6.1 *Identification of known and foreseeable HAZARDS

When compiling the list of known or foreseeable HAZARDS, the MANUFACTURER shall consider those HAZARDS associated with software and hardware aspects of the PEMS including those associated with NETWORK/DATA COUPLING, components of third-party origin and legacy subsystems.[174]

NOTE 1 In addition to the material given in Annex D of ISO 14971, the list of possible causes for HAZARDS associated with PEMS should include:

– failure of the NETWORK/DATA COUPLING to provide the characteristics necessary for the PEMS to achieve its ESSENTIAL PERFORMANCE;

– undesired feedback [physical and data] (Possibilities include: unsolicited input, out of range or inconsistent input, and input originating from electromagnetic interference.);[175]

– unavailable data;

– lack of integrity of data;

– incorrect data;

– incorrect timing of data.

– unintended interactions within and among PESS;

– unknown aspects or quality of third-party software;

– unknown aspects or quality of third-party PESS;

– lack of data security, particularly vulnerability to tampering, unintended interaction with other programs and viruses.[176]

NOTE 2 It is recognized that not all the PROCESSES required by Clause 14 can be followed for components of third-party origin and legacy subsystems.

14.6.2 *RISK CONTROL

The following are additional requirements for PEMS. They supplement subclause 6.1 of ISO 14971.

Suitably validated tools and PROCEDURES shall be selected and identified to implement each RISK CONTROL measure. These tools and PROCEDURES shall be appropriate to assure that each RISK CONTROL measure satisfactorily reduces the identified RISK(S).

14.7 *Requirement Specification

For the PEMS and each of its subsystems (e.g. for a PESS) there shall be a documented requirement specification.

NOTE Example structures of a PEMS are given in H.1.

The requirement specification for a system or subsystem shall include and distinguish any ESSENTIAL PERFORMANCE and any RISK CONTROL measures implemented by that system or subsystem.[177]

14.8 *Architecture

For the PEMS and each of its subsystems, an architecture shall be specified that shall satisfy the requirement specification.

Where appropriate, to reduce the RISK, the architecture specification shall make use of:

a) HIGH-INTEGRITY COMPONENTS;

b) fail-safe functions;

c) redundancy;

d) diversity;

e) partitioning of functionality;

f) defensive design, e.g. limits on potentially hazardous effects by restricting the available output power or by introducing means to limit the travel of actuators.

The architecture specification shall take into consideration:

a) allocation of RISK CONTROL measures to subsystems and components of the PEMS;

NOTE Subsystems and components include sensors, actuators, PESS and interfaces.

b) failure modes of components and their effects;

c) common cause failures;

d) systematic failures;

e) test interval duration and diagnostic coverage;

f) maintainability;

g) protection from REASONABLY FORESEEABLE MISUSE;

h) the NETWORK/DATA COUPLING specification, if applicable.

14.9 *Design and implementation

Where appropriate, the design shall be decomposed into subsystems, each having both a design and test specification.

Descriptive data regarding the design environment shall be included in the RISK MANAGEMENT FILE.

NOTE See H.3 for examples of design environment elements.

14.10 *VERIFICATION

VERIFICATION shall be required for all functions that create RISKS and all functions that control RISKS.

A VERIFICATION plan shall be produced to show how these functions shall be verified for each DEVELOPMENT LIFE-CYCLE phase, as appropriate. The plan shall include:

– the selection and documentation of VERIFICATION strategies, activities, techniques, and the appropriate level of independence of the personnel performing the VERIFICATION;[178]

– the selection and utilization of VERIFICATION tools;

– coverage criteria for VERIFICATION.

NOTE Examples of methods and techniques are:

– walkthroughs;

– inspections;

– static analysis;

– dynamic analysis;

– white box testing;

black box testing;

– statistical testing.

The VERIFICATION shall be performed according to the VERIFICATION plan. The results of the VERIFICATION activities shall be documented.

14.11 *PEMS VALIDATION

[179]A PEMS VALIDATION plan shall include the validation of SAFETY, and shall require checks for unintended functioning of the PEMS.

The PEMS VALIDATION shall be performed according to the PEMS VALIDATION plan. The results of PEMS VALIDATION activities shall be documented.

Any person responsible for the PEMS VALIDATION shall be independent of the design team. The MANUFACTURER shall document the rationale for the level of independence.[180]

No member of a design team shall be responsible for the PEMS VALIDATION of their own design.

All professional relationships of the members of the PEMS VALIDATION team with members of the design team shall be documented in the RISK MANAGEMENT FILE.

A reference to the methods and results of the PEMS VALIDATION shall be included in the RISK MANAGEMENT FILE.

14.12 *Modification

If any or all of a design results from a modification of an earlier design then either all of this clause applies as if it were a new design or the continued validity of any previous design documentation shall be assessed under a documented modification/change PROCEDURE.[181]

14.13 *Connection of PEMS by NETWORK/DATA COUPLING to other equipment[182]

If the PEMS is intended to be connected by NETWORK/DATA COUPLING to other equipment that is outside the control of the PEMS MANUFACTURER, the technical description shall:

a) specify the characteristics of the NETWORK/DATA COUPLING necessary for the PEMS to achieve its INTENDED USE/INTENDED PURPOSE;

b) list the potential HAZARDS resulting from a failure of the NETWORK/DATA COUPLING to provide the specified characteristics;

c) instruct the RESPONSIBLE ORGANIZATION that:

- connection of the PEMS to a NETWORK/DATA COUPLING that includes other equipment could result in previously unidentified RISKS to PATIENTS, OPERATORS or third parties;
- that the RESPONSIBLE ORGANIZATION should identify, analyze, evaluate and control these RISKS;
- that subsequent changes to the NETWORK/DATA COUPLING could introduce new RISKS and require additional analysis; and
- that changes to the NETWORK/DATA COUPLING include:
  - changes in NETWORK/DATA COUPLING configuration
  - connection of additional items to the NETWORK/DATA COUPLING
  - disconnecting items from the NETWORK/DATA COUPLING
  - update of equipment connected to the NETWORK/DATA COUPLING
  - upgrade of equipment connected to the NETWORK/DATA COUPLING

15. Constructional requirements for ME EQUIPMENT[183]

15.1 *Arrangements of functions of ME EQUIPMENT

When applicable, the MANUFACTURER shall address the RISKS associated with the arrangement of functions of ME EQUIPMENT in the RISK MANAGEMENT PROCESS.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

15.2 Serviceability

Parts of ME EQUIPMENT subject to mechanical wear, electrical degradation or aging that are likely to result in a HAZARD shall be accessible for inspection and replacement.

Parts of ME EQUIPMENT that are likely to be replaced or adjusted shall be so located and secured as to permit inspection, servicing, replacement and adjustment without damage to, or interference with, adjacent parts or wiring.

Compliance is checked by inspection.

15.3 Mechanical strength

15.3.1 General

ME EQUIPMENT or its parts shall have adequate mechanical strength and shall not present an unacceptable RISK due to moulding stress or when subjected to mechanical stress caused by pushing, impact, dropping, and rough handling.[184]

Compliance is checked by application of the tests in Table 24.

Table 24 – Mechanical strength test matrix

ME EQUIPMENT type	Test
HAND-HELD	Drop (15.3.1.3)
	Push (15.3.1.1)
	Moulding stress relief (15.3.1.5)
PORTABLE	Drop (15.3.1.3)
	Impact (15.3.1.2)
	Push (15.3.1.1)
	Moulding stress relief (15.3.1.5)
MOBILE	Rough handling (15.3.1.4)
	Impact (15.3.1.2)
	Push (15.3.1.1)
	Moulding stress relief (15.3.1.5)
FIXED or STATIONARY	Impact (15.3.1.2)
	Moulding stress relief (15.3.1.5)
	Push (15.3.1.1)

15.3.1.1 *Push test

External parts of an ENCLOSURE are subject to a steady force of 250 N ± 10 N for a period of 5 s, applied by means of a suitable test TOOL providing contact over a circular plane surface 30 mm in diameter.[185]

There shall not be any damage resulting in an unacceptable RISK, including reduction of CREEPAGE DISTANCES and AIR CLEARANCES below those specified in 8.9.[186]

15.3.1.2 Impact test

Except for HAND-HELD ME EQUIPMENT and ME EQUIPMENT parts that are hand held during their NORMAL USE, ENCLOSURES and other external insulating parts, the deterioration of which could result in unacceptable RISK, are tested as indicated below.

A sample consisting of the complete ENCLOSURE, or a portion thereof representing the largest unreinforced area, is supported in its normal position. A solid smooth steel ball, approximately 50 mm in diameter and with a mass of 500 g ± 25 g, is permitted to fall freely from rest at a vertical distance of 1,3 m onto the sample.

To test vertical surfaces, the steel ball may be suspended by a cord and allowed to swing like a pendulum in order to apply a horizontal impact, dropping though a vertical distance of 1,3 m.

Cathode ray tubes are excluded (see 9.5.2).

After the test, any damage sustained shall produce no unacceptable RISK; in particular compliance with the requirements of Clause 8 and 11.6 shall be maintained. If, as a result of the preceding test, the integrity of SUPPLEMENTARY or REINFORCED INSULATION is in doubt, the relevant insulation only (not the rest of the ME EQUIPMENT) is subjected to a dielectric strength test as specified in 8.8.

Any damage or dents shall not have reduced CREEPAGE DISTANCES or AIR CLEARANCES below the values specified in 8.9. Small chips that do not adversely affect the protection against electric shock or moisture are to be ignored.

Cracks not visible to the naked eye and surface cracks in fibre reinforced mouldings and the like are to be ignored.

15.3.1.3 *Drop test

15.3.1.3.1 HAND-HELD ME EQUIPMENT

HAND-HELD ME EQUIPMENT and parts that are HAND-HELD during NORMAL USE shall not present an unacceptable RISK as a result of a free fall.

Compliance is checked by the following tests:

The sample to be tested, with any SAFE WORKING LOAD in place, is allowed to fall freely once from each of three different starting orientations encountered during NORMAL USE from the height the ME EQUIPMENT is used, or, if not defined by the MANUFACTURER, from a height of 1 m, whichever is greater, onto a 50 mm ± 5 mm thick hardwood board (for example, hardwood > 600 kg/m^3) lying flat on a concrete or a similar rigid base.

After the test, the HAND-HELD ME EQUIPMENT or HAND-HELD ME EQUIPMENT PARTS shall not present an unacceptable RISK. Unacceptable RISK to be determined by examination of the ME EQUIPMENT, the HAND-HELD parts, and relevant information from RISK MANAGEMENT FILE. In particular, compliance with the requirements of Clause 9 and 11.6 shall be maintained. If, as a result of the preceding test, the integrity of SUPPLEMENTARY or REINFORCED INSULATION is in doubt, the relevant insulation only (not the rest of the ME EQUIPMENT) is subjected to a dielectric strength test as specified in 8.8.3.

15.3.1.3.2 *PORTABLE ME EQUIPMENT

PORTABLE ME EQUIPMENT or PORTABLE ME EQUIPMENT parts shall withstand the stress caused by a freefall from the height indicated in Table 25 onto a hard surface.

Compliance is checked by the following test:

The sample to be tested, with the SAFE WORKING LOAD in place, is lifted to a height as indicated in Table 25 above a 50 mm ± 5 mm thick hardwood board (for example, > 600 kg/m^3) that lies flat on a concrete floor or a similar rigid base. The dimensions of the board shall be at least that of the sample tested. The sample is dropped three times from each orientation in which it may be placed during NORMAL USE.

Table 25 – Drop height

Mass (*m*) of PORTABLE ME EQUIPMENT or PORTABLE ME EQUIPMENT parts kg	Drop height cm
$m \leq 10$	5
$10 < m \leq 50$	3
$m > 50$	2

After the test, the PORTABLE ME EQUIPMENT or PORTABLE ME EQUIPMENT parts shall not present an unacceptable RISK. Unacceptable RISK to be determined by examination of the ME EQIUPMENT, its PORTABLE parts, and relevant information from RISK MANAGEMENT FILE. In particular, compliance with the requirements of Clause 9 and 11.6 shall be maintained. If, as a result of this test, the integrity of SUPPLEMENTARY or REINFORCED INSULATION is in doubt, the relevant insulation only (not the rest of the ME EQUIPMENT) shall be subjected to a dielectric strength test as specified in 8.8.3.

15.3.1.4 *Rough handling test

MOBILE ME EQUIPMENT or MOBILE ME EQUIPMENT parts shall withstand the stress caused by rough handling and movement and shall not present an unacceptable RISK.

Compliance is checked by the following tests:

a) *Ascending step shock*

The sample to be tested, with any SAFE WORKING LOAD in place, is pushed three times from each of the starting position attitudes encountered during NORMAL USE at a speed of 0,4 m/s ± 0,1 m/s against an ascending hardwood step obstruction with vertical face of 40 mm that is rigidly attached to an otherwise flat floor. The direction of movement is perpendicular to the face of the obstacle. The sample need not go over the 40 mm obstruction.

b) *Threshold*

MOBILE ME EQUIPMENT exceeding 45 kg with the MAXIMUM SAFE WORKING LOAD in place is tested as follows. The sample to be tested, in transport position with any SAFE WORKING LOAD in place and loaded as indicated in the ACCOMPANYING DOCUMENTS, is moved as in NORMAL USE ten times in forward direction over (up and down) a solid vertical plane obstruction with a rectangular cross-section, 20 mm high and 80 mm wide that is affixed flat on the floor. All wheels and castors shall impact the obstruction at a speed of 0,4 m/s ± 0,1 m/s for manual MOBILE equipment, or, for motor driven MOBILE equipment, the maximum speed capable of being maintained.[187]

It is unacceptable for equipment to be unable to go over (up) the obstruction (due to small wheel diameter, for example).

c) *Descending step shock*

The sample to be tested with any SAFE WORKING LOAD in place is pushed three times from each of the starting transport position as intended in NORMAL USE a speed of 0,4 m/s ± 0,1 m/s in order to fall over a vertical step having a height of 40 mm affixed flat on a rigid base (e.g. concrete). The direction of movement is perpendicular to the face of the descending step.

d) *Door frame shock*

The sample to be tested with any SAFE WORKING LOAD *in place is moved three times from each of the starting transport positions as intended in* NORMAL USE, *at a speed of 0,4 m/s ± 0,1 m/s, or, for motor driven* MOBILE *equipment, the maximum speed capable of being maintained, against a hardwood vertical obstacle having a width and thickness of 40 mm affixed to a vertical rigid support (e.g. concrete). The height of the vertical obstacle must be higher than the equipment contact point(s). The direction of movement is perpendicular to the face of the obstacle.*

After each test, the MOBILE ME EQUIPMENT *or* MOBILE ME EQUIPMENT *parts shall not present an unacceptable* RISK. *Unacceptable* RISK *to be determined by examination of the* ME EQIUPMENT, *its parts, and relevant information from* RISK MANAGEMENT FILE. *In particular, compliance with the requirements of Clause 9 and 11.6 shall be maintained. If, as a result of any test, the integrity of* SUPPLEMENTARY *or* REINFORCED INSULATION *is in doubt, the relevant insulation only (not the rest of the* ME EQUIPMENT*) is subjected to a dielectric strength test as specified in 8.8.3. See also 9.4.2.6.b).*

15.3.1.5 Mould stress relief

ENCLOSURES of moulded or formed thermoplastic materials shall be so constructed that any shrinkage or distortion of the material due to release of internal stresses caused by the moulding or forming operation does not result in an unacceptable RISK.

Compliance is checked by inspection of the construction and available data were appropriate or by the following test:

One sample consisting of the complete ME EQUIPMENT, *or of the* ENCLOSURE *together with any supporting framework, is placed in a circulating air oven at a temperature 10 °C higher than the maximum temperature observed on the* ENCLOSURE *during the test of 11.1.1, but not less than 70 °C, for a period of 7 h, then permitted to cool to room temperature.*

NOTE Relative humidity needs not be maintained at a specific value during this conditioning.

For large ME EQUIPMENT *where it is not practical to condition a complete* ENCLOSURE, *it is permitted to use a portion of the* ENCLOSURE *representative of the complete assembly with regard to thickness and shape, including any mechanical support members.*

There shall not be any damage resulting in an unacceptable RISK, *including reduction of* CREEPAGE DISTANCES *and* AIR CLEARANCES *below those specified in 8.9.*

15.3.2 *Environmental influences

a) The selection and treatment of materials used in the construction of ME EQUIPMENT shall take account of the INTENDED USE/INTENDED PURPOSE, the intended life and the conditions for transport and storage.

The ME EQUIPMENT shall be so designed and constructed that during its life, as designated by the MANUFACTURER in the ACCOMPANYING DOCUMENTS, any corrosion, ageing, mechanical wear, or degradation of biological materials due to the influence of bacteria, plants, animals and the like, shall not reduce its mechanical properties in a way that presents an unacceptable RISK.

b) Where this performance is achieved only by the replacement or servicing of some parts during the useful life of the ME EQUIPMENT, such parts shall be accessible to inspection and maintenance, and shall be listed in the ACCOMPANYING DOCUMENTS as parts to be replaced or serviced preventatively at stated intervals.

Compliance is checked by inspection:

– *of the* ME EQUIPMENT, *of the* ACCOMPANYING DOCUMENTS *and of the* MANUFACTURER'S *specifications of materials used and of the processing specifications for these materials;*

– *of the MANUFACTURER'S relevant tests and or calculations.*

15.4 ME EQUIPMENT components and general assembly

15.4.1 Construction of connectors

Design and construction of electrical, hydraulic, pneumatic and gas connection terminals and connectors of ME EQUIPMENT shall be such that incorrect connection of accessible connectors, removable without the use of a TOOL, shall be prevented where a HAZARD would otherwise exist.

a) Plugs for connection of PATIENT leads shall be so designed that they cannot be connected to other outlets on the same ME EQUIPMENT intended for other functions, unless it can be proven that no HAZARD can result.

b) Medical gas connections on ME EQUIPMENT for different gases to be operated in NORMAL USE shall not be interchangeable. See also 7.8 and ISO 407.

Compliance is checked by inspection, if possible by interchanging of connections, to establish the absence of a HAZARD.

15.4.2 Temperature and overload control devices

15.4.2.1 Application

a) THERMAL CUT-OUTS with a SAFETY function that have to be reset by a soldering operation that may affect the operating value shall not be fitted in ME EQUIPMENT.

b) In ME EQUIPMENT, where a failure of a THERMOSTAT could constitute a HAZARD an independent non-SELF-RESETTING THERMAL CUT-OUT shall additionally be provided. The temperature of operation of the additional device shall be outside that attainable at the extreme setting of the normal control device but shall be within the safe temperature limit for its intended function.

c) Loss of function of the ME EQUIPMENT caused by operation of a THERMAL CUT-OUT or OVER-CURRENT RELEASE shall not cause a HAZARD.

d) Capacitors or other spark-suppression devices of ME EQUIPMENT shall not be connected between the contacts of THERMAL CUT-OUTS.

Compliance is checked by inspection and, if applicable, by the following tests:

Verify compliance of Positive Temperature Coefficient devices (PTC's) with IEC 60730-1: 1999 clauses 15, 17, j15 and j17 as applicable.

THERMAL CUT-OUTS and OVER-CURRENT RELEASES shall be tested by operating the ME EQUIPMENT under the conditions described in Clause 13.

SELF-RESETTING THERMAL CUT-OUTS and self-resetting OVER-CURRENT RELEASES including circuits that perform equivalent functions (other than PTC's) shall be caused to operate 200 times unless approved to the appropriate IEC component standard.

Manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES shall be caused to operate 10 times, if they are not approved to the appropriate IEC component standard (see 4.3).

Thermal protection devices shall comply with the appropriate IEC component standards (see 4.3) or the MANUFACTURER shall provide adequate data to demonstrate the reliability of the component to perform its SAFETY related function.[188]

Thermal SAFETY devices may be tested separately from ME EQUIPMENT.

e) ME EQUIPMENT that incorporates a fluid filled container having heating facilities shall be provided with a SAFETY device to safeguard against overheating in the event of the heater

being switched on with the container empty. An unacceptable RISK shall not occur from overheating.

Compliance is checked by operating the relevant ME EQUIPMENT with an empty container until the SAFETY device activates.

f) ME EQUIPMENT that incorporates tubular heating elements shall have protection against overheating in both leads where a conductive connection to earth could result in overheating.[189]

Compliance is checked by inspection of the design documentation and the RISK MANAGEMENT FILE.

15.4.2.2 Temperature settings

a) Where means are provided for varying the temperature setting of THERMOSTATS in ME EQUIPMENT, the temperature setting shall be clearly indicated.

b) If THERMAL CUT-OUTS and OVER-CURRENT RELEASES can be replaced, the technical characteristics necessary for safe operation shall be marked on the component or elsewhere inside of the ME EQUIPMENT (see 7.3.4).

Compliance is checked by inspection.

15.4.3 *Batteries

15.4.3.1 Housing

In ME EQUIPMENT, housings containing batteries from which gases that are likely to cause a HAZARD can escape during charging or discharging shall be ventilated to minimize the RISK of accumulation and ignition.

Battery compartments of ME EQUIPMENT shall be designed to prevent the RISK of accidentally short-circuiting the battery where such short circuits could result in a HAZARD.

Compliance is checked by inspection and examination of the RISK MANAGEMENT FILE.

15.4.3.2 Connection

If a HAZARD might develop by the incorrect connection or replacement of a battery, ME EQUIPMENT shall be fitted with a means of preventing incorrect polarity of connection. See also 7.3.3 and 8.2.2.

Compliance is checked by inspection.

15.4.3.3 Protection against overcharging

Where overcharging of any battery of ME EQUIPMENT could result in an unacceptable RISK, the design shall prevent overcharging.

Compliance is determined by inspection of the design documentation.

15.4.3.4 Lithium batteries

Lithium batteries of ME EQUIPMENT shall comply with the requirements of IEC 60086-4 (see also 7.3.3).

Compliance is determined by inspection of the battery design documentation or by performance of the tests identified in IEC 60086-4.

15.4.3.5 *Excessive current and voltage protection

An INTERNAL ELECTRICAL POWER SOURCE in ME EQUIPMENT shall be provided with an appropriately RATED device for protection against fire HAZARD caused by excessive currents if the cross-sectional area and layout of the internal wiring or the rating of connected

components may give rise to the occurrence of a fire HAZARD in case of a short circuit. See also 8.11.5.

Compliance is checked by inspection for the presence of protective means and if necessary by inspection of the design data and the relevant contents of the RISK MANAGEMENT FILE

15.4.4 *Indicators

Unless it is otherwise apparent to the OPERATOR from the normal operating position, indicator lights shall be provided to indicate that ME EQUIPMENT is ready for NORMAL USE. The marking of 7.4.1 is not sufficient for this purpose.

If equipped with a stand-by state or a warm-up state whose duration exceeds 15 s, the ME EQUIPMENT shall be provided with an additional indicator light.

Indicator lights shall be provided on ME EQUIPMENT incorporating non-luminous heaters to indicate that the heaters are operational, if a HAZARD exists.

NOTE This does not apply to heated stylus-pens for recording purposes.

Indicator lights shall be provided on ME EQUIPMENT to indicate that an output exists where an inadvertent or prolonged operation of the output circuit could constitute a HAZARD.

Colours of indicator lights are described in 7.9.1.

In ME EQUIPMENT incorporating a means for charging an INTERNAL ELECTRICAL POWER SOURCE, the charging mode shall be visibly indicated to the OPERATOR.

Compliance is checked by inspection of the presence and function of indicating means visible from the position of NORMAL USE.

15.4.5 Pre-set controls

When applicable, the MANUFACTURER shall address the RISKS associated with pre-set controls in the RISK MANAGEMENT PROCESS.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

15.4.6 Actuating parts of controls of ME EQUIPMENT

15.4.6.1 Fixing, prevention of maladjustment

a) All actuating parts of ME EQUIPMENT shall be so secured that they cannot be pulled off or work loose during NORMAL USE.

b) Controls, the adjustment of which can present a HAZARD to the PATIENT or OPERATOR while ME EQUIPMENT is in use, shall be so secured that the indication of any scale always corresponds with the position of the control.

The indication in this case refers to “On” or “Off” position, scale markings or other indications of position.

c) Incorrect connection of the indicating device to the relevant component shall be prevented by an adequate construction, if it can be separated without the use of a TOOL.

Compliance is checked by inspection and manual tests. For rotating controls, the torques as shown in Table 26 are applied between the control knob and the shaft for not less than 2 s in each direction alternately. The test is repeated 10 times.

The knob shall not rotate with respect to the shaft.

If an axial pull is required in NORMAL USE, compliance is checked by applying for 1 min an axial force of 60 N for electrical components and 100 N for other components.

Table 26 – Test torques for rotating controls

Gripping diameter (*d*) of control knob mm [a)]	Torque Nm
$0 \leq d < 23$	1,0
$23 \leq d < 31$	2,0
$31 \leq d < 41$	3,0
$41 \leq d < 56$	4,0
$56 \leq d \leq 70$	5,0
$d > 70$	6,0

[a)] The gripping diameter (*d*) is the maximum width of a control knob regardless of its shape (e.g. control knob with pointer.

15.4.6.2 Limitation of movement

Stops of adequate mechanical strength shall be provided on rotating or movable parts of controls of ME EQUIPMENT, where necessary to prevent an unexpected change from maximum to minimum, or vice-versa, of the controlled parameter where this could produce a HAZARD.

Compliance is checked by inspection and manual tests. For rotating controls, the torques as shown in Table 26 are applied for not less than 2 s in each direction alternately. The test is repeated 10 times.

If an axial pull is likely to be applied to the rotating or movable parts of controls of ME EQUIPMENT in NORMAL USE, no unacceptable RISK shall develop.

Compliance is checked by applying for 1 min an axial force of 60 N for electrical components and 100 N for other components.[190]

15.4.7 Cord-connected HAND-HELD and foot-operated control devices (See also 8.10.4.)

15.4.7.1 Mechanical strength

a) HAND-HELD control devices of ME EQUIPMENT shall comply with the requirement and test of 15.3.1.3.1.

b) Foot-operated control devices of ME EQUIPMENT shall be able to support the weight of an adult human being.

Compliance is checked by application to the foot-operated control device, in its position of NORMAL USE, of an actuating force of 1 350 N for 1 min. The force is applied over an area of 625 mm^2. There shall be no damage to the device resulting in an unacceptable RISK.

15.4.7.2 Inadvertent operation of ME EQUIPMENT

HAND-HELD and foot-operated devices shall not cause unacceptable RISK by changing their control setting when inadvertently placed in an abnormal position.

Compliance is checked by turning the device in all possible abnormal positions and placing it as such on a supporting surface. There shall not be any inadvertent change of control setting resulting in an unacceptable RISK.

15.4.7.3 *Entry of liquids

a) Foot-operated control devices of ME EQUIPMENT shall be at least IPX1 according to IEC 60529.

Compliance is checked by the tests of IEC 60529.

b) In ME EQUIPMENT, ENCLOSURES of foot operated control devices that contain electrical circuits shall be RATED at least IPX6[191] according to IEC 60529 if they are intended for use (as defined in the instructions for use) in areas where liquids are likely to be found (such as emergency rooms). The likelihood shall be evaluated as part of the RISK MANAGEMENT PROCESS.[192]

Compliance is determined by inspection of the ACCOMPANYING DOCUMENTS, the RISK MANAGEMENT FILE and by performing the appropriate tests of IEC 60529.

15.4.8 Internal wiring of ME EQUIPMENT[193]

Aluminium wires of less than 16 mm^2 cross-section shall not be used in ME EQUIPMENT.

Compliance is checked by inspection.

15.4.9 Oil containers

a) Oil containers in PORTABLE ME EQUIPMENT shall be adequately sealed to prevent loss of oil in any position. The container design shall allow for the expansion of the oil.

b) Oil containers in MOBILE ME EQUIPMENT shall be sealed to prevent the loss of oil during transport but may be fitted with a pressure-release device that can operate during NORMAL USE.

c) Partially sealed oil-filled ME EQUIPMENT or ME EQUIPMENT parts shall be provided with means for checking the oil level.

Compliance is checked by inspection of the ME EQUIPMENT and the technical description, and by manual test.

15.5 *MAINS SUPPLY TRANSFORMERS of ME EQUIPMENT and transformers providing separation in accordance with 8.5

15.5.1 Overheating

15.5.1.1 *Transformers

Transformers of ME EQUIPMENT shall be protected against overheating in the event of short-circuit or overload of any output winding.

Compliance is checked by the tests of 15.5.1.2 and 15.5.1.3 as appropriate under the following conditions:

Each winding is tested, in turn, with the following parameters at the most adverse value:

– *primary voltage maintained between 90 % to 110 % of RATED voltage*

– *RATED input frequency*

– *loads on other windings between no load and their NORMAL USE load*

Short circuit or resistive load, as appropriate, is applied at the ends of the windings or at the first point that can be short circuited under SINGLE FAULT CONDITION.

During the tests, no winding shall open, no HAZARD shall occur, and the maximum temperatures of windings shall not exceed the values in Table 27. The transformer shall also pass a dielectric strength test (as described in 8.8) between primary and secondary windings and between primary and the transformer frame.[194] *The tests are carried out under the conditions specified in 11.1, either in the ME EQUIPMENT or under simulated conditions on the bench.*

Table 27 – Maximum allowable temperatures of transformer windings under overload and short-circuit conditions at 25 °C ambient temperature

Parts	Maximum temperature °C
Windings and core laminations in contact therewith, if the winding insulation is:	
– of Class A material	150
– of Class B material	175
– of Class E material	165
– of Class F material	190
– of Class H material	210

15.5.1.2 *Short-circuit test*

The output winding under test is short circuited. The unit is operated until the protective device operates or steady thermal condition is reached. For transformers not tested according to the 5X frequency and 5X voltage test of 15.5.2, the short circuit shall be applied directly across the output windings.

15.5.1.3 Overload test

Windings with more than one protective device may require multiple overload tests in order to fully evaluate worst-case NORMAL USE loading and fusing.

If the short circuit test is completed without operation of a protective device, the overload test is not required.

a) *This step is omitted if, based on a review of the provided protective devices and their performance data, the current at which the first protective device operates can be determined.*

The winding under test is loaded to its NORMAL USE load until THERMAL STABILITY is reached. The load is then progressively adjusted in appropriate steps to approach the minimum current at which the protective device operates. Each adjustment of the load shall be followed by a sufficient time to reach THERMAL STABILITY, and the load current shall be noted.

Following operation of a protective device, b) *shall be performed.*

b) *If the protective device that operated in* a) *is external to the transformer, it shall be shunted. The winding under test shall be loaded based on the type of protective device as follows:*

Fuse in accordance with IEC 60127-1: 30 minutes at the appropriate test current determined from Table 28.

Table 28 – Test current for transformers

Marked value of RATED current (I) of protecting fuse-link A	Ratio between test current and RATED current of the fuse-link
$I \leq 4$	2,1
$4 < I \leq 10$	1,9
$10 < I \leq 25$	1,75
$I > 25$	1,6

Fuses not in accordance with IEC 60127: 30 minutes at the current according to the characteristics supplied by the fuse manufacturer, specifically the 30 minute clearing-time current. If no 30 minute clearing-time current data is available, the test current from Table 28 shall be used until THERMAL STABILITY is achieved.

Other protective device: until THERMAL STABILITY at a current just below that which caused the device to operate in a).

This portion of the overload test is concluded at the specified time or when a second protective device opens.[195]

15.5.2 *Dielectric strength

The electrical insulation between the primary winding and other windings, screens and the core of a MAINS SUPPLY TRANSFORMER is presumed to have been investigated by the dielectric strength tests performed on the assembled ME EQUIPMENT as described in 8.8.3. The dielectric strength tests need not be repeated.

ME EQUIPMENT transformer windings shall have adequate insulation to prevent unacceptable RISKS caused by overheating as determined during the application of the RISK MANAGEMENT PROCESS.

The dielectric strength of the electrical insulation between turns and layers of each winding of a MAINS SUPPLY TRANSFORMER of ME EQUIPMENT shall be such that after the humidity preconditioning treatment (see 5.7) it passes the following tests:

a) *Transformers having any winding with a RATED voltage ≤ 500 V or RATED frequency ≤ 60 Hz are tested with a voltage across the winding of five times the RATED voltage or five times the upper limit of the RATED voltage range of that winding and a frequency not less than five times the RATED frequency*.

b) *Transformers having any winding with a RATED voltage exceeding 500 V or RATED frequency exceeding 60 Hz are tested with a voltage across that winding of twice the RATED voltage or twice the upper limit of the RATED voltage range of that winding and a frequency not less than twice the RATED frequency*.

In the two cases above, however, the stress on the turn and layer insulation of any winding of the transformer shall be such that the test voltage appearing at the winding with the highest RATED voltage does not exceed the test voltage specified in Table 3, for one MEANS OF PROTECTION, if the RATED voltage of such a winding is considered as REFERENCE VOLTAGE (U). *If this should occur, the test voltage on the primary winding shall be reduced accordingly. The test frequency may be adapted to produce in the core approximately the magnetic induction present in NORMAL USE.*

– *Three-phase transformers may be tested by means of a three-phase testing device or by three consecutive tests using a single-phase testing device.*

– *The value of the test voltage with respect to the core and to any screen between primary and secondary windings shall be in accordance with the specification of the relevant transformer. If the primary winding has an identified connection point for the neutral of the SUPPLY MAINS such a point shall be connected to the core (and screen if present) unless the core (and screen) are specified for connection to an unearthed part of the circuit. To simulate this, the core (and screen) are connected to a source with an appropriate voltage and frequency with respect to the identified connection point.*

If such a connection point has not been identified, each side of the primary winding in turn shall be connected to the core (and screen if present) unless the core (and screen) are specified for connection to an unearthed part of the circuit.

To simulate this, the core (and screen) shall be connected to a source with an appropriate voltage and frequency with respect to each side of the primary winding in turn.

– *During the test, all windings not intended for connection to the SUPPLY MAINS shall be left unloaded (open circuit). Windings intended to be earthed at a point or to be operated with*

a point nearly at earth potential shall have such a point connected to the core, unless the core is specified for connection to an unearthed part of the circuit.

To simulate this, the core is connected to a source with an appropriate voltage and frequency with respect to such windings.

– *Initially not more than half the prescribed voltage shall be applied, then, it shall be raised over a period of 10 s to the full value, which is then maintained for 1 min, after which the voltage shall be reduced gradually and switched off.*

– *Tests are not conducted at resonant frequencies.*

– *During the test, no flashover or breakdown of any part of the insulation shall occur. There shall be no detectable deterioration of the transformer after the test.*

Slight corona discharges are neglected, provided that they cease when the test voltage is temporarily dropped to a lower value, that this value is higher than the REFERENCE VOLTAGE (U) *and that the discharges do not provoke a drop in test voltage*.

15.5.3 *Construction of transformers used to provide separation as described in 8.5

Transformers of ME EQUIPMENT that form MEANS OF PROTECTION shall comply with IEC 61558-1: 1998, subclause 5.12.

Compliance is checked as specified in IEC 61558-1.[196]

16. *Requirements for ME SYSTEMS [197]

16.1 *General requirements for the ME SYSTEMS

After installation or subsequent modification, an ME SYSTEM shall not cause an unacceptable RISK.

Only HAZARDS arising from the interconnection of various equipment to constitute an ME SYSTEM shall be considered.

NOTE RESPONSIBLE ORGANIZATIONS are reminded that the assembly of ME SYSTEMS and modifications during their useful life require evaluation to the requirements of this standard

An ME SYSTEM shall provide:

– within the PATIENT ENVIRONMENT, the equivalent level of SAFETY as provided by ME EQUIPMENT complying with this standard; and

– outside the PATIENT ENVIRONMENT, the level of SAFETY appropriate for the equipment complying with their respective IEC or ISO SAFETY standards.

Tests shall be carried out:

– in NORMAL CONDITION unless otherwise specified, and

– under the operating conditions specified by the MANUFACTURER of the ME SYSTEM.

SAFETY tests that have already been carried out on individual equipment of the ME SYSTEM according to relevant standards shall not be repeated.

Compliance is considered to exist if the requirements of this standard are met.

Non-ME EQUIPMENT, when used in an ME SYSTEM, shall comply with IEC and ISO safety standards that are relevant to that equipment.

Equipment in which protection against electric shock relies only on BASIC INSULATION shall not be used in an ME SYSTEM.

Compliance is checked by inspection of appropriate documents or certificates.

16.2 *ACCOMPANYING DOCUMENTS of an ME SYSTEM

An ME SYSTEM, (including a modified ME SYSTEM), shall be accompanied by documents containing all the data necessary for safe and INTENDED USE/INTENDED PURPOSE, and an address to which the RESPONSIBLE ORGANIZATION can refer. The ACCOMPANYING DOCUMENTS shall be regarded as a part of the ME SYSTEM.

NOTE ACCOMPANYING DOCUMENTS may be provided electronically, e.g. electronic file format or CD-ROM, for an ME SYSTEM capable of displaying or printing those documents.

These documents shall include:

a) the ACCOMPANYING DOCUMENTS for each item of ME EQUIPMENT (see 7.10);

b) the ACCOMPANYING DOCUMENTS for each item of non-ME EQUIPMENT;

c) the following information:

– the specification of the ME SYSTEM, including the INTENDED USE/INTENDED PURPOSE and a listing of all of the items forming the ME SYSTEM;

– instructions for the installation, assembly and modification of the ME SYSTEM to ensure continued compliance with this standard;

– instructions for cleaning and, where applicable, disinfecting and sterilizing each item of equipment forming part of the ME SYSTEM (see 11.6.6 and 11.6.7);

- additional SAFETY measures that should be applied, during installation of the ME SYSTEM;
- which parts of the ME SYSTEM are suitable for use within the PATIENT ENVIRONMENT;
- additional measures that should be applied during preventive maintenance;
- if a MULTIPLE SOCKET-OUTLET is present and it is a separate item, a warning that it shall not be placed on the floor;
- a warning that an additional MULTIPLE SOCKET-OUTLET or extension cord shall not be connected to the ME SYSTEM;
- a warning not to connect items that are not specified as part of the ME SYSTEM;
- the maximum permitted load for any MULTIPLE SOCKET-OUTLET(S) used with the ME SYSTEM;
- an instruction that MULTIPLE SOCKET-OUTLETS provided with the ME SYSTEM shall only be used for supplying power to equipment that is intended to form part of the ME SYSTEM;
- an explanation of the RISKS of connecting non-ME EQUIPMENT, which has been supplied as a part of the ME SYSTEM, directly to the wall outlet when the non-ME EQUIPMENT is intended to be supplied via a MULTIPLE SOCKET-OUTLET with a separating transformer;
- an explanation of the RISKS of connecting any equipment, which has not been supplied as a part of the ME SYSTEM, to the MULTIPLE SOCKET-OUTLET;
- the permissible environmental conditions of use of the ME SYSTEM including conditions for transport and storage; and
- instructions to the OPERATOR not to touch parts referred to in 16.4 and the PATIENT simultaneously.

d) advice to the RESPONSIBLE ORGANIZATION:

- to carry out all cleaning, adjustment, sterilization and disinfection PROCEDURES specified therein; and
- that the assembly of ME SYSTEMS and modifications during their useful life require evaluation to the requirements of this standard.

Compliance is checked by inspection.

16.3 *Power supply

If ME EQUIPMENT is intended to receive its power from other equipment in an ME SYSTEM, the instructions for use shall specify such other equipment sufficiently to ensure compliance with the requirements of this standard (see 4.8.1, 5.5 *g)* and 7.10.2.3).

Compliance is checked by inspection.

16.4 ENCLOSURES

Parts of non-ME EQUIPMENT in the PATIENT ENVIRONMENT that may be contacted by the OPERATOR during routine maintenance, calibration, etc. after removal of covers, connectors, etc., without the use of a TOOL shall operate at a voltage not exceeding 42,5 V peak a.c. or 60 V d.c. or peak value supplied from a source that is separated from the SUPPLY MAINS by two MEANS OF OPERATOR PROTECTION (see 8.5.1).

Compliance is checked by inspection.

16.5 *SEPARATION DEVICES

When FUNCTIONAL CONNECTION between ME EQUIPMENT and other items of equipment of an ME SYSTEM or other systems can cause the allowable values of LEAKAGE CURRENT to be exceeded, then SAFETY measures incorporating a SEPARATION DEVICE shall be applied.

The SEPARATION DEVICE shall have the dielectric strength, CREEPAGE DISTANCES and AIR CLEARANCES required for one MEANS OF OPERATOR PROTECTION appropriate for the highest voltage occurring across the SEPARATION DEVICE during a fault condition.

The REFERENCE VOLTAGE (*U*) shall be the highest voltage across the SEPARATION DEVICE during a fault condition, but not less than the maximum MAINS VOLTAGE.

NOTE 1 For CLASS I equipment, potential differences can occur between the protective earth of the ME EQUIPMENT and the protective earth of other parts of the ME SYSTEM in the absence of a common protective earth.

NOTE 2 Situations that can require a SEPARATION DEVICE include FUNCTIONAL CONNECTIONS to an emergency calling system or a data processing system.

Compliance is checked by the tests in 8.8 and 8.9.

16.6 *LEAKAGE CURRENTS

16.6.1 Measurements

16.6.1.1 General conditions for ME SYSTEMS

a) *The TOUCH CURRENT, the PATIENT LEAKAGE CURRENT and the total EARTH LEAKAGE CURRENT of any MULTIPLE SOCKET-OUTLET are measured after the ME SYSTEM has been brought up to operating temperature as follows:*

The ME SYSTEM is operated:

– *For ME SYSTEMS intended for non-CONTINUOUS OPERATION;*

After operating in standby/quiescent mode until THERMAL STABILITY is reached, the ME SYSTEM is operated in NORMAL USE over consecutive cycles until THERMAL STABILITY is again achieved, or for seven hours, whichever is shorter. The "on" and "off" periods for each cycle shall be the RATED "on" and "off" periods;

– *For ME SYSTEMS intended for CONTINUOUS OPERATION;*

The ME SYSTEM is operated until THERMAL STABILITY is reached.

b) *The ME SYSTEM is connected to a supply with a voltage equal to the highest RATED MAINS VOLTAGE.*

NOTE Where examination of the circuit arrangement and the arrangement of components and material of the ME SYSTEM shows no possibility of any HAZARD, the number of tests may be reduced.

16.6.1.2 Connection of the ME SYSTEM to the measuring supply circuit

a) *The ME SYSTEM is tested after being assembled according to its ACCOMPANYING DOCUMENTS*.

b) *Measuring arrangement*

The reference earth of the measuring circuits shall be connected to mains earth If an isolating transformer is not used for LEAKAGE CURRENT measurements.

NOTE 1 It is recommended to position the measuring circuit as far as possible away from unscreened power supply leads and (unless specified otherwise in the following subclauses) to avoid placing the ME SYSTEM on or near a large earthed metal surface.

NOTE 2 However, external parts of APPLIED PARTS, including PATIENT cords (when present), should be placed on an insulating surface with a dielectric constant of approximately 1 (for example, expanded polystyrene) and approximately 200 mm above an earthed metal surface.

16.6.2 TOUCH CURRENT

In NORMAL CONDITION, the TOUCH CURRENT from or between parts of the ME SYSTEM within the PATIENT ENVIRONMENT shall not exceed 100 µA.

In the event of the interruption of any non-PERMANENTLY INSTALLED PROTECTIVE EARTH CONDUCTOR or the equivalent conductor of a MULTIPLE SOCKET-OUTLET or of an equipment, the TOUCH CURRENT from or between parts of an ME SYSTEM within the PATIENT ENVIRONMENT shall not exceed 500 µA.

NOTE For the purposes of this clause, the LEAKAGE CURRENT from accessible outer surfaces of equipment is also considered to be TOUCH CURRENT.

16.6.3 LEAKAGE CURRENT of MULTIPLE SOCKET-OUTLET

If the ME SYSTEM or part of the ME SYSTEM is supplied from a MULTIPLE SOCKET-OUTLET, then the current in the PROTECTIVE EARTH CONDUCTOR of the MULTIPLE SOCKET-OUTLET shall not exceed 500 µA.

16.6.4 *PATIENT LEAKAGE CURRENT

Where APPLIED PARTS are connected to elements of an ME SYSTEM, the PATIENT LEAKAGE CURRENT and total PATIENT LEAKAGE CURRENT in NORMAL CONDITION shall not exceed the values specified for ME EQUIPMENT, as given in Table 2 (see also 8.7.3).

Compliance with the requirements of 16.6.2 and 16.6.4 is checked by inspection and measurement of LEAKAGE CURRENTS using a measuring device as specified in 8.7.4.4.

16.7 *Protection against MECHANICAL HAZARDS

When an ME SYSTEM can cause an unacceptable RISK, the ME SYSTEM shall comply with the applicable requirements of Clause 9.

Compliance is checked by inspection or applicable tests.

16.8 Interruption of the power supply to parts of an ME SYSTEM

An ME SYSTEM shall be so designed that an interruption and restoration of the power to the ME SYSTEM as a whole, or any part of the ME SYSTEM, shall not result in a HAZARD other than interruption or cessation of its intended function.

Compliance is checked by interruption and restoration of relevant power connections one at a time and all connections simultaneously.

16.9 ME SYSTEM connections and wiring

16.9.1 Connection terminals and connectors

Design and construction of electrical, hydraulic, pneumatic and gas connection terminals and connectors shall be such that incorrect connection of accessible connectors, removable without the use of a TOOL, shall be prevented when a HAZARD can arise.

– Connectors shall comply with 15.4.1.

– Plugs for connection of PATIENT leads shall be so designed that they cannot be connected to other outlets of the same ME SYSTEM, which are likely to be located in the PATIENT ENVIRONMENT, unless it can be proved that no HAZARD can result.

Compliance is checked by inspection and, if possible, by interchanging connectors.

16.9.2 MAINS PARTS, components and layout

16.9.2.1 *MULTIPLE SOCKET-OUTLET

a) A MULTIPLE SOCKET-OUTLET shall:

– only allow connection by using a TOOL, or

– be of a type that cannot accept a MAINS PLUG (see IEC/TR3 60083), or

– be supplied via a separating transformer (see 16.9.2.1 *d)*).

Compliance is checked by inspection.

b) A MULTIPLE SOCKET-OUTLET:

– shall be marked with Symbol ISO 7000-0434 (see Table D1, Symbol 10) such that it is visible in NORMAL USE; and

– shall be marked either individually or in combinations, with the maximum allowed continuous output in amperes or volt-amperes, or

– shall be marked as to the specific equipment or equipment parts that may be safely attached. may be a separate item or an integral part of ME EQUIPMENT or non-ME EQUIPMENT.

NOTE Each outlet does not have to be marked.

Compliance is checked by inspection.

c) The MULTIPLE SOCKET-OUTLET shall comply with IEC 60884-1, and the following requirements:

– CREEPAGE DISTANCES and AIR CLEARANCES shall comply with 8.9.

– It shall be of CLASS I construction and the PROTECTIVE EARTH CONDUCTOR shall be connected to the earthing contacts in the output sockets.

– PROTECTIVE EARTH TERMINALS and PROTECTIVE EARTH CONNECTIONS shall comply with 8.6.

NOTE The total impedance of the protective earth path for an ME SYSTEM may be up to 0,4 Ω. It may be higher, if the conditions of 8.6.4 *b)* are satisfied.

– ENCLOSURES shall comply with 8.4.2 *d)*.

– MAINS TERMINAL DEVICES and wiring, if applicable, shall comply with 8.11.4.

– RATINGS of components shall not conflict with the conditions of use (see 4.6).

– Requirements for connections as described in 15.4.1 shall be fulfilled.

– Requirements for the POWER SUPPLY CORD as described in 8.11.3 shall be fulfilled.

d) If the MULTIPLE SOCKET-OUTLET is combined with a separating transformer, the following additional requirements apply:

– The separating transformer shall comply with the requirements of IEC 60989, except the requirements of maximum RATED output power 1 kVA and degree of protection IPX4 do not apply.

NOTE 1 This separating transformer does not require more than BASIC INSULATION and is not a MAINS SUPPLY TRANSFORMER.

NOTE 2 Limitation of output power is not explained in IEC 60989 and the RATED output power is defined by the fuse in the installation and by the used allowable power supply cable. However, the characteristics of the separating transformer shall be carefully selected, taking into account the variations in the load current of the ME SYSTEM to ensure that the voltage supplied to the various items of the ME SYSTEM remains within the limits specified for the equipment.

NOTE 3 Attention is drawn to the development of IEC 61558 which may replace 60989.

– The separating transformer assembly shall be of CLASS I construction.

– The degree of protection against ingress of water as given in IEC 60529 shall be specified.

– The separating transformer assembly shall be marked according to the requirements of 7.2 and 7.3 of this standard.

– The MULTIPLE SOCKET-OUTLET shall be permanently connected to the separating transformer or the socket-outlet of the separating transformer assembly shall be of a type that cannot accept MAINS PLUGS according to IEC/TR3 60083 (see Annex J).

Compliance is checked by inspection and as described in the relevant subclauses of this standard.

16.9.2.2 *PROTECTIVE EARTH CONNECTIONS in ME SYSTEMS

PROTECTIVE EARTH CONNECTIONS shall be made so that the removal of any single item of equipment in the ME SYSTEM will not interrupt the protective earthing of any other part of the ME SYSTEM, without at the same time disconnecting the electrical supply to that part.

Additional PROTECTIVE EARTH CONDUCTORS shall only be detachable by use of a TOOL.

Compliance is checked by inspection.

16.9.2.3 Protection of conductors

Conductors that connect different items of equipment within an ME SYSTEM shall be protected against mechanical damage.

Compliance is checked by inspection.

17. *Requirements for electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

The requirements for electromagnetic compatibility are found in IEC 60601-1-2.

18. *Requirements for protection of the NATURAL ENVIRONMENT

18.1 *Introduction to design of ME EQUIPMENT for life-cycle

Clause 18 contains requirements for the planning and the development of environmentally compatible products. Its objective is to achieve the best environmental compatibility possible, taking into account all stages of the product life-cycle, as well as technical aspects. This means the prevention of environment and health HAZARDS from harmful substances, saving raw materials and energy, the prevention of waste, as well as the minimization of the HAZARDS presented by unavoidable waste, taking into account the entire product life from the moment the product is manufactured until it is disposed of. The preconditions to enable this goal to be reached must be created during the product planning and development stages. Environmentally compatible product development is currently focussed on the avoidance of harmful substances and the recoverability of the products after their useful life.

In this clause, only environmental requirements for the design of ME EQUIPMENT are addressed. Environmental requirements for the production of ME EQUIPMENT only are covered by other standards.

This clause is product related and will complement the ISO 14000 series of environmental management standards.

This document contains only those environmental requirements for which methods of VERIFICATION can be established. These requirements do not replace national or international laws and regulations.

Environmental protection is one aspect of the overall RISK MANAGEMENT PROCESS.

The application of a Life-Cycle Assessment methodology can be used in the PROCESS of identifying the impact on the environment of the ME EQUIPMENT and parts thereof across its life-cycle.

18.2 Design for life-cycle

18.2.1 *Life-Cycle Assessment (LCA) of ME EQUIPMENT

A Life-Cycle Assessment (LCA) shall be considered for the entire ME EQUIPMENT, but LCAs shall be performed and documented during design of ME EQUIPMENT parts such as:

– DISPOSABLES
– consumables
– toxic material
– packaging
– parts with major impact on the NATURAL ENVIRONMENT
– parts that are referred to in this clause

In the LCA, consideration shall be given to the manufacturing phase, useful life and disposal.

Compliance is checked by inspection of the relevant design documents.

18.2.2 HAZARDOUS SUBSTANCES AND MATERIALS used in conjunction with ME EQUIPMENT

The technical description shall include the list of HAZARDOUS SUBSTANCES AND MATERIALS used for or by ME EQUIPMENT and their quantities.

For HAZARDOUS SUBSTANCES AND MATERIALS, see Annex L.

HAZARDOUS SUBSTANCES AND MATERIALS shall be marked with Symbol IEC 60417-xxx1Pr (see Table D1, Symbol 27). Where marking is not practical, the location of HAZARDOUS SUBSTANCES AND MATERIALS in ME EQUIPMENT shall be described in the list of HAZARDOUS SUBSTANCES AND MATERIALS.

Compliance is checked by inspection of the ME EQUIPMENT and the technical description.

18.2.3 *Packaging of ME EQUIPMENT

The MANUFACTURER shall identify the kinds and mass of packaging material(s) as well as the appropriate method for returning, RECYCLING or disposal of the materials. The MANUFACTURER also shall inform the receiver that local laws supersede this information. This information shall be provided to the receiver for the person responsible for the unpacking (see 18.2.9.3).

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

18.2.4 *Consumption during useful life

18.2.4.1 *Energy and materials to be consumed by ME EQUIPMENT[198]

The technical description shall provide relevant data for all kinds of energy and MATERIALS TO BE CONSUMED during the useful life.

Compliance is checked by inspection of the technical description.

18.2.4.2 *Energy consumption of ME EQUIPMENT[199]

The technical description shall provide data on energy consumption for active, standby and "quiescent" modes including assumptions made in the determination of such data.

If ME EQUIPMENT contains multiple levels of energy saving modes, these shall be listed in the instructions for use.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS

18.2.4.3 Electrical input power[200]

a) Marking on the outside of ME EQUIPMENT and data provided in the technical description shall include:

1) For ME EQUIPMENT intended for continuous use, the RATED input shall be given:

– in amperes or volt-amperes. If the power factor exceeds 0,9, the RATED input may be given in watts.

– for the upper and lower limits of the RATED voltage range or ranges. In the case of voltage range limits that do not differ by more than 10 % from the mean value, marking of the RATED input at the mean value of the range is sufficient.

If ME EQUIPMENT is designed for multiple RATED voltages, the corresponding RATED input shall be marked such that the different RATED input ratings are separated by a solidus (/), and the relation between RATED voltage and associated RATED input appears distinctly.

2) For ME EQUIPMENT where the rating includes both long-term and momentary current or volt-ampere ratings, both the long-term and the most relevant momentary volt-ampere rating shall be clearly identified and indicated.

3) For ME EQUIPMENT intended for non-continuous use, the RATED input shall be marked in average W for the mode of operation as specified by the MANUFACTURER.

4) For ME EQUIPMENT provided with power output connection to supply other ME EQUIPMENT or any equipment in an ME SYSTEM shall include the RATED output in the RATED input of the ME EQUIPMENT. The RATED output value shall also be marked adjacent to the output connection.

5) The technical description shall include the energy consumption per hour.

Compliance is checked by inspection of ME EQUIPMENT markings and the technical description.

b) The measured input of the ME EQUIPMENT or any equipment in an ME SYSTEM at RATED voltage and at operating settings specified by the MANUFACTURER shall not exceed the marked rating by more than 10 %.

Compliance is checked by measuring the energy consumption in the DUTY CYCLE or modes of operations of the ME EQUIPMENT under the following conditions:

– *ME EQUIPMENT or an ME SYSTEM is operated as specified in the instructions for use until the input has reached a stable value. Input is measured and compared with markings and the contents of the technical description.*

– *ME EQUIPMENT or an ME SYSTEM marked with one or more RATED voltage ranges is tested at both upper and lower limits of the range, unless each marking of RATED input is related to the mean value of the relevant voltage range, in which case the test is performed at a voltage equal to the mean value of that range.*

– *The steady state or average current shall be measured with a true r.m.s. reading instrument, for example, a thermal instrument.*

– *RATED input power, if expressed in volt-amperes, shall either be measured with a volt-ampere meter or be determined as the product of the steady state current (measured as described above) and the supply voltage.*[201]

18.2.4.4 *Water consumption by ME EQUIPMENT

Potable water for cooling purposes shall only be used in a closed recirculation system unless preference for using potable water in a non-recirculating system can be demonstrated (e.g. by a Life-Cycle Assessment).

If water is used for cleaning purposes in ME EQUIPMENT, the MANUFACTURER shall define the intended level of cleaning and measures to reduce water consumption.

The instructions for use shall indicate minimum settings on ME EQUIPMENT necessary to achieve the required level of cleaning.

Compliance is checked by inspection of relevant design documents and the instructions for use.

18.2.5 Emission during useful life from ME EQUIPMENT

18.2.5.1 *Air contamination

If air is used for cooling purposes in ME EQUIPMENT, the technical description shall include a list of HAZARDOUS SUBSTANCES AND MATERIALS and possible quantities in the emitted air.

Compliance is checked by inspection of the technical description and the RISK MANAGEMENT FILE.

18.2.5.2 *Gas emission

In the design of ME EQUIPMENT, the emission of methane, nitrogen oxide (NOX), carbon dioxide (CO_2) and other gases harmful to the NATURAL ENVIRONMENT shall be avoided. If not physically possible, the emission shall be reduced as far as practicable.

If these gases cannot be avoided for the INTENDED USE/INTENDED PURPOSE, the amount shall be reduced as far as reasonably possible.

Compliance is checked by inspection of the relevant design documents.

18.2.5.3 *Water emission

If water is used for cleaning purposes in ME EQUIPMENT, the technical description shall include a list of substances and possible quantities derived during the cleaning PROCESS in the water.

Compliance is checked by inspection of the technical description.

18.2.6 *Batteries and accumulators used in conjunction with ME EQUIPMENT

In the technical description, batteries and accumulators containing HAZARDOUS SUBSTANCES AND MATERIALS shall be identified.

The technical description shall have information concerning the type, mode of extraction, insertion and disposal of batteries and accumulators.

A recommendation shall be given not to dispose of batteries and accumulators containing HAZARDOUS SUBSTANCES AND MATERIALS into the NATURAL ENVIRONMENT and to follow local laws and regulations for disposal, if available.

Compliance is checked by inspection of the technical description.

18.2.7 *DISPOSABLES and MATERIALS TO BE CONSUMED by ME EQUIPMENT

a) The decision to design ME EQUIPMENT using MEDICAL DISPOSABLES shall require both a medical and an environmental justification using, for example, Life-Cycle Assessment.

b) The decision to design ME EQUIPMENT using MATERIALS TO BE CONSUMED or DISPOSABLES shall require both a technical and an environmental justification using, for example, Life-Cycle Assessment.

Compliance is checked by inspection of the relevant design documents.

c) MATERIALS TO BE CONSUMED, MEDICAL DISPOSABLES and DISPOSABLES shall be listed in the ACCOMPANYING DOCUMENTS.

For MATERIALS TO BE CONSUMED, MEDICAL DISPOSABLES and DISPOSABLES containing HAZARDOUS SUBSTANCES AND MATERIALS such as radioactive substances, heavy metals etc., or that can be infected or contaminated by tissue or body fluids resulting from application of the ME EQUIPMENT, PROCEDURES shall be provided in the ACCOMPANYING DOCUMENTS for a safe method of disposal.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

18.2.8 *Design for REUSE, RECYCLING and disposal of ME EQUIPMENT

The ME EQUIPMENT shall be designed so that it can be easily disassembled as far as is practicable.

For maintenance and repair of ME EQUIPMENT, the same principles shall be applied as for REUSE, RECYCLING and disposal.

The technical description shall either contain disassembly instructions or a statement that the MANUFACTURER will provide them on request.

These disassembly instructions shall include as far as applicable:

– Preferred dismantling positions;

– Indication of the position of the parts within the ME EQUIPMENT;

– Information on how plastic parts with a mass of more than 50 g can be separated into homogenous materials of the same composition;

– Recommendations about the correct disassembly order;

– Statements concerning the required TOOLS (preferably standard commercially available TOOLS) as well as information about disposal methods;

– Recommendations for any applicable engineering controls or personal protective equipment to be used during dismantling;

– Information on the types, quantities, and names of the HAZARDOUS SUBSTANCES AND MATERIALS;

– Information regarding the material content of the ME EQUIPMENT above sensible threshold(s) defined by the MANUFACTURER (That information shall include the mass (kg) or percentage of total mass of the ME EQUIPMENT.);

– Information on the markings, including the markings according to ISO 11469, for plastic parts with a mass of more than 50 g.

NOTE See the five categories *a* to *e* in Table K1.

Compliance is checked by inspection of the ME EQUIPMENT and the disassembly instructions.

18.2.9 REUSE, RECYCLING and disposal of ME EQUIPMENT

18.2.9.1 *REUSE

The MANUFACTURER shall either list those components or parts of ME EQUIPMENT:

– that are suitable for REUSE, or

– that should not be subject to REUSE.

The MANUFACTURER, in the design documentation, shall record the decision on the application of reusable or non-reusable components or parts of ME EQUIPMENT (e.g. based on the Life-Cycle Assessment, RISK MANAGEMENT, etc.).

The technical description shall either contain this list or a statement that the MANUFACTURER will provide it on request.

Documentation of components or parts of ME EQUIPMENT in this list shall include:

– identification;

– location;

– special instructions for removal and renewing for reintroduction into the market (if appropriate for components, parts or whole ME EQUIPMENT);

– restrictions for REUSE, if any.

Compliance is checked by inspection of the technical description and the design documentation.

18.2.9.2 *RECYCLING

The MANUFACTURER shall enable RECYCLING by the design of the ME EQUIPMENT and by having available on request the necessary information to the service provider for RECYCLING.

The technical description shall either contain this information or a statement that the MANUFACTURER will provide it on request.

This information to the service provider shall include for the parts subject to RECYCLING:

– identification;

– location;

– mass;

– HAZARDOUS SUBSTANCES AND MATERIALS that need special treatment;

and, if applicable:

– special removal and disposal instructions;

– if encapsulated or not; if so, identification of part/component/etc.;

– packaging considerations, e.g. sealed packaging;

– resistance to certain types of exposure, such as to chemicals, e.g. resistance to acids;

– additives such as flame retardants, stabilisers and softeners, if available;

– materials that may have transmuted in use;

– colouring information including liquid or powder lacquering, paint PROCESS, colour ingredients.

Compliance is checked by inspection of the technical description and the information to the service provider for RECYCLING.

5594 **18.2.9.3 *Disposal**

5595 The MANUFACTURER shall identify any HAZARDS (e.g. HAZARDOUS SUBSTANCES AND MATERIALS)
5596 associated with the disposal of waste products, residues, etc. and of the ME EQUIPMENT and
5597 ACCESSORIES at the end of their useful lives. If disposal could constitute an unacceptable
5598 RISK, the MANUFACTURER shall provide in the ACCOMPANYING DOCUMENTS advice on ways the
5599 RESPONSIBLE ORGANIZATION can reduce these RISKS to an acceptable level.

5600 *Compliance is checked by inspection of the RISK MANAGEMENT FILE and the ACCOMPANYING*
5601 *DOCUMENTS.*

Annex A
(Informative)
GENERAL GUIDANCE AND RATIONALE

A.1 General Guidance

The requirements for ME EQUIPMENT differ from those for other kinds of electrical equipment because of the particular relationship of ME EQUIPMENT to the PATIENT, the OPERATOR and the surroundings. The following aspects play an important role in this relationship:

a) The inability of PATIENT or OPERATOR to detect the presence of certain potential HAZARDS, such as ionizing or high-frequency radiation.

b) Absence of normal reactions of the PATIENT who may be ill, unconscious, anaesthetized, immobilized, etc.

c) Absence of normal protection to currents provided by the PATIENT'S skin, if this is penetrated or treated to obtain a low skin-resistance.

d) Support or replacement of vital body functions may depend on the reliability of ME EQUIPMENT.

e) The simultaneous connection to the PATIENT of more than one piece of ME EQUIPMENT.

f) Combination of high-power ME EQUIPMENT and sensitive low-signal ME EQUIPMENT often in *ad hoc* combinations.

g) The application of electrical circuits directly to the human body, either through contacts to the skin or through the insertion of probes into internal organs.

h) Conditions, particularly in operating theatres, which may present a combination of humidity, moisture or fire or explosion HAZARDS caused by air, oxygen or nitrous oxide.

If ME EQUIPMENT is combined with another electrical equipment and forms an ME SYSTEM, additional requirements apply. These are given in Clause 16. In some instances, reference to other parts of this standard is made. If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause may be applicable to ME SYSTEMS as well as to ME EQUIPMENT.[202]

A.1.1 SAFETY of ME EQUIPMENT

SAFETY of ME EQUIPMENT, as described in IEC/TR 60513, is part of the total SAFETY situation, comprising SAFETY of ME EQUIPMENT, SAFETY of the installation in medically used rooms of medical establishments and SAFETY of application.

SAFETY of ME EQUIPMENT is required for NORMAL USE and NORMAL CONDITION and for SINGLE FAULT CONDITIONS. Reliability of functioning is regarded as a SAFETY aspect for life supporting ME EQUIPMENT and where interruption of an examination or treatment is considered as a HAZARD for the PATIENT.

Adequate construction, lay-out and ACCOMPANYING DOCUMENTS that serve to prevent use errors are regarded as SAFETY aspects.

SAFETY precautions are considered acceptable if they provide adequate protection without an undesirable restriction of normal function.

Generally, it is presumed that ME EQUIPMENT is operated under the jurisdiction of qualified or licensed persons and that the OPERATOR has the skill required for a particular medical application and acts according to the instructions for use.

The total SAFETY of ME EQUIPMENT may consist of:[203]

– Inherent SAFETY by design.

– Protective measures are incorporated into the ME EQUIPMENT or additional protective measures, such as the use of shields or protective clothing, is called for.

– Information for SAFETY, such as restriction in the instructions for use concerning transport, mounting or positioning, connection, putting into service, operation and the position of the OPERATOR and his/her assistants in relation to the ME EQUIPMENT during use.

Generally, SAFETY measures are presumed to be applied in the order as described here. They may be attained by sound engineering (which includes knowledge of methods of production and environmental conditions during manufacture, transport, storage and use), by application of redundancy or by protective devices of a mechanical or electrical nature.

A.1.2 Guidance to the third edition

In this edition, a number of clauses and subclauses from the second edition have been deleted, e.g. when the clause or subclause was indicated as “Not used.” However, those clauses or subclauses form the second edition that stated “No general requirement” have been retained so that particular or collateral standards may refer to them. The statement, “No general requirement”, has been replaced with a reference to the RISK MANAGEMENT PROCESS because the “general requirement” is that, in the absence of a particular or collateral standard, these issues must be dealt with through the application of RISK MANAGEMENT.

While preparing the third edition, basic safety standards and ISO/IEC guides have been taken into consideration to the extent possible consistent with the particular relationship of ME EQUIPMENT to the PATIENT, the OPERATOR and the surroundings.

The format of the third edition has been aligned with the basic requirements of Part 2 of the ISO/IEC Directives. All the section except Section 1 of the second edition has been converted into major clauses. This change was implemented because sections are no longer allowed under the drafting rules and the new number will allow future changes to modify a clause without effecting the number of other parts of the standard.

The normative references have been moved from Appendix L of the second edition to Clause 2. Informative references are listed in the Bibliography.

The definitions in Clause 3 have been rearranged into a single alphabetical listing as organizing the definitions by category was becoming increasingly more difficult and the result less intuitive. The index of defined terms has been expanded to identify each page where a term is used in the body of the standard. Several new defined terms have been introduced in support of new or expanded requirements.

A general requirement for a RISK MANAGEMENT PROCESS has been introduced in 4.2.

Clause 8 has been extensively restructured to bring together in one section the requirements relating to electrical SAFETY. The requirements in Clause 8 have been reviewed against the SAFETY requirements for information technology (IT) equipment in IEC 60950-1 and harmonized where appropriate given the particular relationship of ME EQUIPMENT to the PATIENT, the OPERATOR and the surroundings.

Clause 9 on protection against mechanical HAZARDS has been substantially revised to deal with a wide range of the potential HAZARDS that ME EQUIPMENT could pose to the OPERATOR or PATIENT. Requirements relating to the mechanical strength of the ME EQUIPMENT when subjected to the stresses caused by pushing, impact, dropping, and rough handling are in 15.3.

The standard now deals with “use errors” in 12.3.1 as opposed to “user or human errors.”

Section SIX of the second edition on protection against the HAZARDS of ignition of flammable anaesthetic mixtures has been moved to a normative annex. While this annex was originally

intended to be informative because the use of such anaesthetics is extremely rare, comments from National Committees indicated that some MANUFACTURERs might still want to offer ME EQUIPMENT for such applications.

The surface temperature limit for APPLIED PARTS in subclause 11.1.2.2 has been increased from 41 °C to 43 °C. However, the MANUFACTURER must disclose in the ACCOMPANYING DOCUMENTS if the surface temperature of an APPLIED PART exceeds 41 °C.

The requirements for ME EQUIPMENT incorporating PROGRAMMABLE ELECTRONIC SUBSYSTEMS was moved from subclause 52.1 of the second edition to a new Clause 14. The requirements of IEC 60601-1-4 have been incorporated into the body of this standard.

The requirements for ME SYSTEMS now appear in a new Clause 16. The requirements of IEC 60601-1-1 have been incorporated into this clause.

A new Clause 18 was added dealing with concerns about the impact of ME EQUIPMENT on the NATURAL ENVIRONMENT.

A.2 Clause 1 – Scope, object and related standards

Subclause 1.1 – *Scope

The scope of this standard is established by the reference to the definitions of ME EQUIPMENT and ME SYSTEMS. This is to clearly define the scope of this standard as compared with requirements for other types of electrical equipment.

Laboratory equipment within the scope of IEC 61010-1 is not covered by this standard except when a MANUFACTURER incorporates such laboratory equipment into an ME SYSTEM.

This standard does not apply to any other electrical equipment unless it falls under the definition of ME EQUIPMENT or ME SYSTEMS.

This standard does not apply to active implantable medical devices covered by the ISO 14708 series except where the ISO 14708 series requires compliance with IEC 60601-1.

Subclause 1.3 – *Particular standards

A particular standard may state:

– clauses of this standard that apply without amendment;

– clauses or subclauses (or parts of them) of this standard that do not apply;

– clauses or subclauses (or parts of them) of this standard that are replaced by a clause or a subclause in a particular standard;

– any additional clauses or subclauses.

A particular standard may contain:

a) requirements that result in an increased degree of SAFETY;

b) requirements that may be less stringent than the requirements in this standard, if the latter cannot be maintained because of, for example, the power output of ME EQUIPMENT;

c) requirements concerning performance, reliability, interfaces, etc.;

d) accuracy of working data;

e) extension and limitation of environmental conditions.

A.3 Clause 3 – Terminology and definitions)

Subclause 3.8 – APPLIED PART

Parts that contact PATIENTS can present greater HAZARDS than other parts of the ENCLOSURE, and these APPLIED PARTS are therefore subject to more stringent requirements, for example, for temperature limits and (according to classification B/BF/CF) for LEAKAGE CURRENT.

NOTE Other ACCESSIBLE PARTS of the ENCLOSURES of ME EQUIPMENT are subject to tests that are more demanding than those for ENCLOSURES of other kinds of equipment, because the PATIENT may touch them, or the OPERATOR may touch them and the PATIENT simultaneously.

In order to determine which requirements apply, it is necessary to distinguish between APPLIED PARTS and parts that are simply considered as the ENCLOSURE.

Thus, typically:

– An infrared therapy lamp does not have an APPLIED PART because it does not need to be brought into direct contact with the PATIENT.

– The only part of an X-ray table that is an APPLIED PART is the top on which the PATIENT lies.

– Likewise, in an MRI scanner, the only APPLIED PART is the table supporting the PATIENT.

However, a part that unintentionally comes into contact with an unconscious, anaesthetized or incapacitated PATIENT may present the same RISKS as an APPLIED PART that necessarily has to contact the PATIENT. On the other hand, a part that an active PATIENT may reach out and touch may present no more RISK to that PATIENT than to an OPERATOR.

The definition in the first and second editions of this standard failed to address this problem. The second amendment to the second edition extended the definition to include parts that can be brought into contact with the PATIENT, but the new definition continued to cause difficulties.

In this edition, subclause 4.4 requires the RISK MANAGEMENT PROCESS to identify which parts other than APPLIED PARTS as defined shall be subject to the same requirements as APPLIED PARTS. These can include parts of non-ME EQUIPMENT in an ME SYSTEM.

Particular standards should specifically identify the APPLIED PART(S) in particular types of ME EQUIPMENT.

In order to assess which parts are APPLIED PARTS and PATIENT CONNECTIONS, the following PROCESS is employed in the order shown:

a) Determine whether the ME EQUIPMENT has an APPLIED PART and if it has, identify the extent of the APPLIED PART (these decisions being based on non-electrical considerations).

b) If there is no APPLIED PART, there are no PATIENT CONNECTION(S).

c) If there is an APPLIED PART, there may be one or more PATIENT CONNECTION(S). Even if the APPLIED PART has no accessible conductive parts, foil applied in accordance with 8.7.4.7 is regarded as one PATIENT CONNECTION.

d) Where a conductive part of the APPLIED PART is not in direct contact with the PATIENT, but is not isolated and current can flow through such a part to or from the PATIENT, it is to be treated as an individual PATIENT CONNECTION.

NOTE Relevant separation requirements are those that relate to MEANS OF PATIENT PROTECTION.

An APPLIED PART may include one or more functions. Each function may include one or more PATIENT CONNECTIONS. A PATIENT CONNECTION may be an electrode that is intended to carry current; or the electrical connection may be incidental to the purpose, for example with an intra-vascular fluid line or a PATIENT support.

See also the rationale for 3.79.

Figure A1 to Figure A5 provide examples of the way in which APPLIED PARTS and PATIENT CONNECTIONS are identified in order to apply the requirements for PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT in various ME EQUIPMENT and ME SYSTEMS.

Figure A1 shows an ECG monitor in which:

The ME EQUIPMENT includes the ECG monitor, the PATIENT cable and the electrodes.

– The APPLIED PART includes the electrodes and those parts of the PATIENT cable that need to physically contact the PATIENT in NORMAL USE.

– Application of RISK MANAGEMENT may identify that other parts of the PATIENT cable have to be treated as APPLIED PARTS because of the likelihood of contacting the PATIENT.

– The PATIENT CONNECTIONS consist of the ECG electrodes, which are all part of the same function of the APPLIED PART.

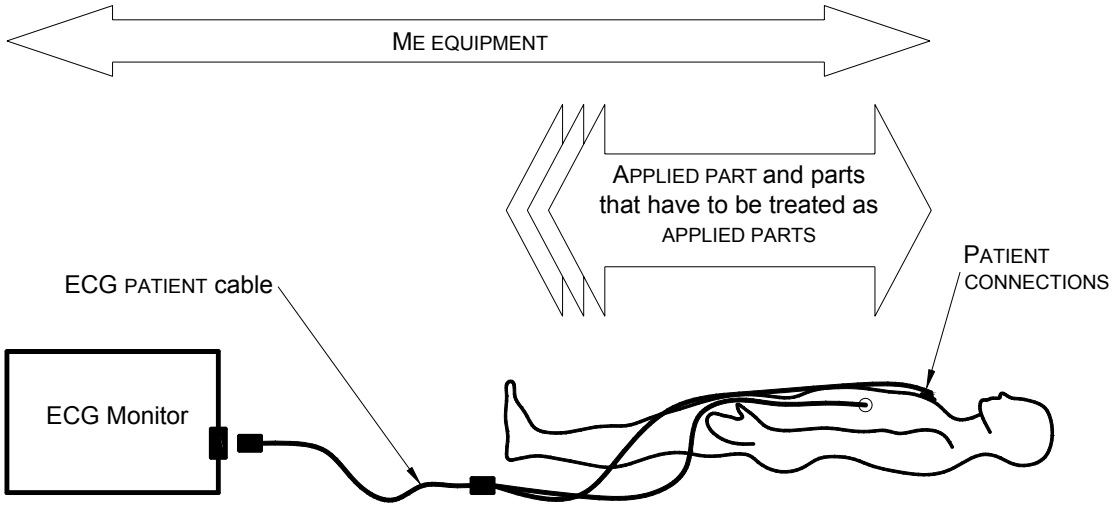


Figure A1 – Identification of ME EQUIPMENT, APPLIED PARTS and PATIENT CONNECTIONS in an ECG monitor

Figure A2 shows a PATIENT monitor with ECG and invasive pressure monitoring facilities. In this example:

– The ME EQUIPMENT includes the ECG monitor; the ECG PATIENT cable and its electrodes; and the pressure transducer and its fluid filled line.

– The APPLIED PART(s) include the ECG electrodes and those parts of the PATIENT cable that need to physically contact the PATIENT in NORMAL USE; and the fluid filled pressure monitoring line.

– Application of RISK MANAGEMENT may identify that other parts of the ECG PATIENT cable or the pressure transducer that have to be treated as APPLIED PARTS because of the likelihood of contacting the PATIENT.

– The ECG PATIENT CONNECTIONS consist of the ECG electrodes.

– The pressure monitoring PATIENT CONNECTION consists of the electrically conducting fluid in the pressure line. For the measurement of PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT, an electrode is placed in the electrically conducting fluid and treated as a single PATIENT CONNECTION.

– If the PATIENT CONNECTIONS associated with the ECG function are not electrically separated from the PATIENT CONNECTION associated with the pressure monitoring function, these are treated as two functions of the same APPLIED PART.

– If the PATIENT CONNECTIONS associated with the ECG function are electrically separated from the PATIENT CONNECTION associated with the pressure monitoring function, these are treated as separate APPLIED PARTS.

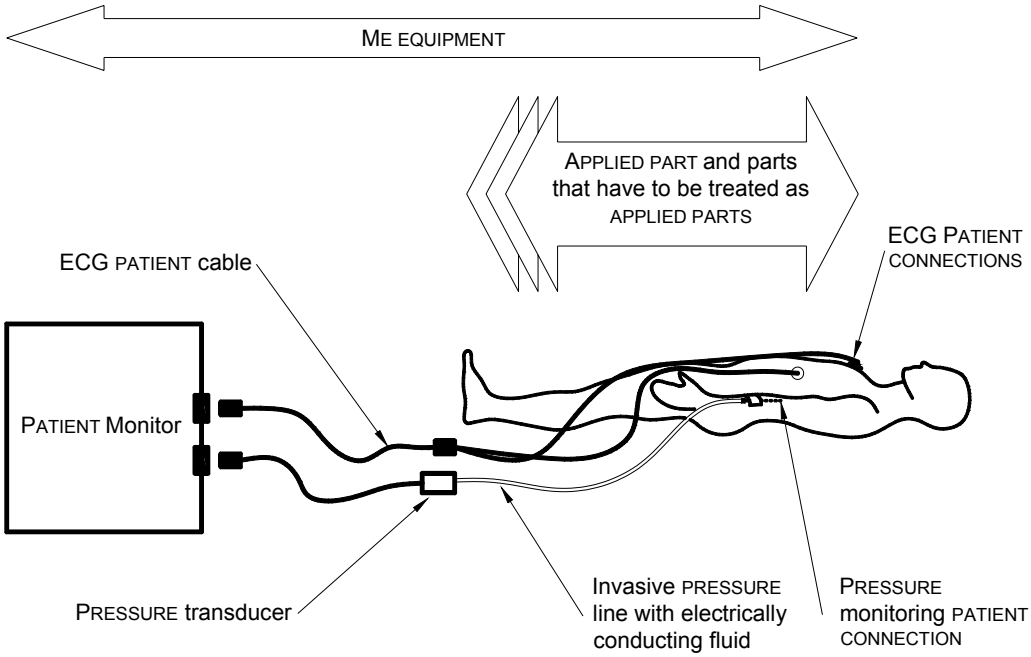


Figure A2 – Identification of ME EQUIPMENT, APPLIED PARTS and PATIENT CONNECTIONS in a PATIENT monitor with invasive pressure monitoring facilities

Figure A3 shows an X-ray ME SYSTEM in which:

– The ME SYSTEM includes the X-ray tube assembly, the X-ray table and the wall stand, which are all items of ME EQUIPMENT.

– Other parts of the ME SYSTEM such as the X-ray generator and OPERATOR console are not shown.

– The APPLIED PART(s) include the top of the table and the front of the wall stand, as these parts need to physically contact the PATIENT in NORMAL USE.

– The application of RISK MANAGEMENT may identify that some parts of the tube assembly and some other parts of the table and the wall stand have to treated as APPLIED PARTS because of the likelihood of contacting the PATIENT.

– The PATIENT CONNECTIONS consist of the conductive parts of these APPLIED PARTS that electrically contact the PATIENT.

– The MANUFACTURER may specify that the table and the wall stand are different functions of the same APPLIED PART.

– Alternatively, the MANUFACTURER may specify that the table and the wall stand are different APPLIED PARTS.

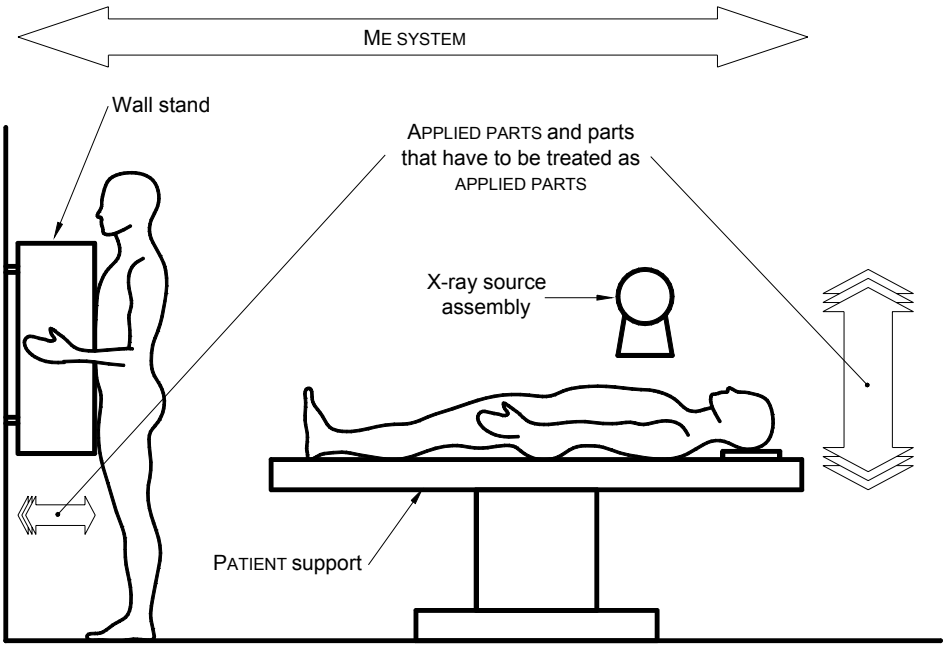


Figure A3 – Identification of APPLIED PARTS and PATIENT CONNECTIONS in an X-ray ME SYSTEM

Figure A4 shows a transcutaneous electronic nerve stimulator (TENS) that is intended to be worn on the PATIENT's belt and connected to electrodes applied to the PATIENT's upper arm. In this case:

– The ME EQUIPMENT includes the TENS stimulator, the electrode cable and the electrodes.

– The APPLIED PART includes the electrodes and those parts of the electrode leads that physically need to contact the PATIENT in NORMAL USE.

– The application of RISK MANAGEMENT may identify that the case of the stimulator and its belt clip also have to treated as APPLIED PARTS because of the likelihood of contacting the PATIENT.

– The PATIENT CONNECTIONS consist of the electrodes, which are all part of the same function of this APPLIED PART.

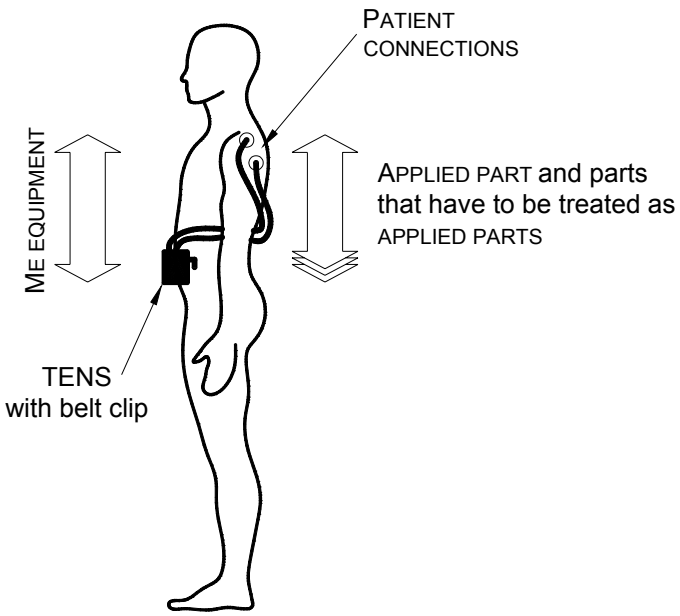


Figure A4 – Identification of ME EQUIPMENT, APPLIED PARTS and PATIENT CONNECTIONS in a transcutaneous electronic nerve stimulator (TENS) intended to be worn on the PATIENT's belt and connected to electrodes applied to the PATIENT's upper arm

Figure A5 shows an ECG processing ME EQUIPMENT / ME SYSTEM in which:

– The ME SYSTEM includes the ECG module, PATIENT cable and electrodes, and the personal computer and any of its accessories (not shown).

– The MANUFACTURER may choose to specify one of the following situations:

  - The ECG module and its PATIENT cable and electrodes are an item of ME EQUIPMENT; and the personal computer is not an item of ME EQUIPMENT. This would be an ME SYSTEM.
  - The ECG module and its PATIENT cable and electrodes are one item of ME EQUIPMENT; and the personal computer is a separate item of ME EQUIPMENT. This would also be an ME SYSTEM.
  - The ECG module and its PATIENT cable and electrodes together with the personal computer is a single item of ME EQUIPMENT and not an ME SYSTEM.

– The APPLIED PART includes the electrodes and those parts of the PATIENT cable that need to physically contact the PATIENT in NORMAL USE.

– Application of RISK MANAGEMENT may identify that other parts of the PATIENT cable have to be treated as APPLIED PARTS because of the likelihood of contacting the PATIENT.

– The PATIENT CONNECTIONS consist of the ECG electrodes, which are all part of the same function of the APPLIED PART.

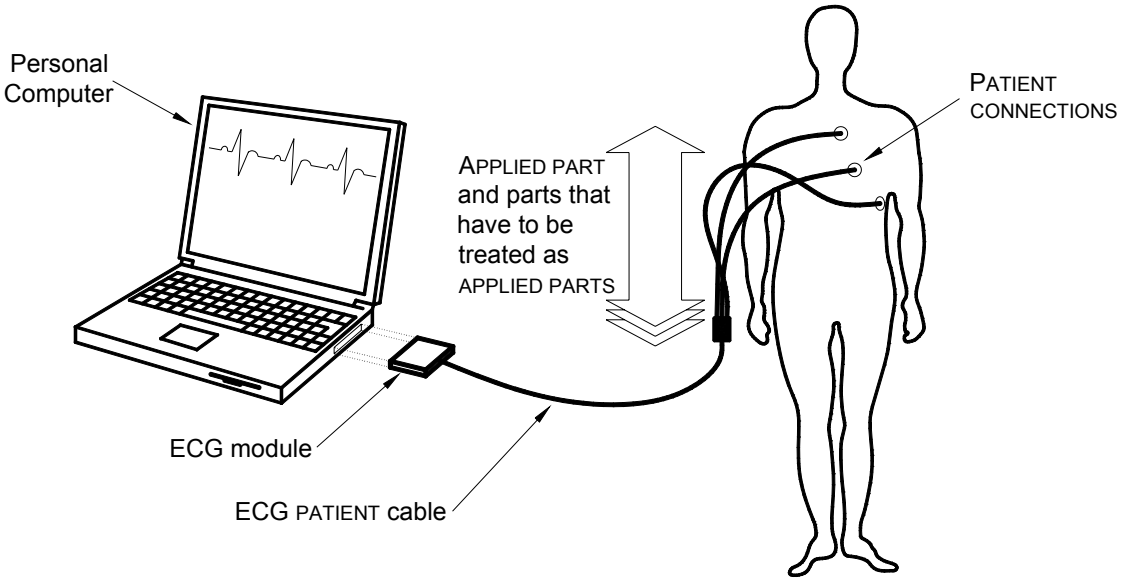


Figure A5 – Identification of ME EQUIPMENT or ME SYSTEM, APPLIED PARTS and PATIENT CONNECTIONS in a personal computer with an ECG module

Subclause 3.9 – *BASIC INSULATION

This definition does not include insulation used exclusively for functional purposes.

Subclause 3.16 – *CONTINUOUS OPERATION

While the terms CONTINUOUS OPERATION or non-CONTINUOUS OPERATION are used with regard to the ME EQUIPMENT, parts of the ME EQUIPMENT may be RATED differently. For example, an electrosurgical generator may be RATED for CONTINUOUS OPERATION while the APPLIED PART is RATED for non-CONTINUOUS OPERATION.

Subclause 3.18 – *DEFIBRILLATION-PROOF APPLIED PART

A DEFIBRILLATION-PROOF APPLIED PART is protected only against discharges of defibrillators designed in accordance with IEC 60601-2-4. Higher voltage defibrillators could damage DEFIBRILLATION-PROOF APPLIED PARTS.

Subclause 3.19 – *DETACHABLE POWER SUPPLY CORD

Cord sets are covered by IEC 60320-1.

Subclause 3.21 – *DIRECT CARDIAC APPLICATION

A distinction is made between use of APPLIED PARTS that may come in direct contact with the PATIENT'S heart and all other circumstances of contact, because ventricular fibrillation can be caused by a much smaller current, if it flows through a small contact area where a wire or catheter makes direct contact with the heart, than if it flows through any other point of contact on or in the PATIENT'S body.

Subclause 3.23 – *DOUBLE INSULATION

BASIC INSULATION and SUPPLEMENTARY INSULATION can, if required, be tested separately.

Subclause 3.26 – *ENCLOSURE

The ENCLOSURE of ME EQUIPMENT or ME EQUIPMENT parts includes all ACCESSIBLE PARTS, accessible shafts, knobs, grips, cables, connectors and the like. This includes any ACCESSIBLE PARTS of external connections between other separate parts.

Subclause 3.28 – *ESSENTIAL PERFORMANCE

It is recognized that separating "SAFETY" and "performance" is somewhat inappropriate in addressing the HAZARDS that result from inadequate design of ME EQUIPMENT. Many particular standards in the IEC 60601-2-xx series address a range of ESSENTIAL PERFORMANCE requirements that cannot be directly evaluated by the RESPONSIBLE ORGANIZATION without applying such standards.

ESSENTIAL PERFORMANCE, sometimes referred to as functional SAFETY, is most easily understood by considering whether its absence would result in an unacceptable RISK. Examples are:

– Accuracy of a life-supporting function or correct administration of a drug by a syringe pump where inaccuracy/incorrect administration would cause an unacceptable RISK of HARM to the PATIENT;

– The ability of an electrocardiograph/monitor to recover from the effects of the discharge of a defibrillator where the failure to recover could lead to an incorrect response by the medical staff that would present an unacceptable RISK of HARM to the PATIENT;

– Correct operation of an alarm in an intensive care or operating room monitoring system where an incorrect/missing alarm could lead to an incorrect response by the medical staff that would present an unacceptable RISK of HARM to the PATIENT

– Correct diagnostic information from ME EQUIPMENT that is likely to be relied upon to determine treatment, where incorrect information could lead to an inappropriate treatment that would present an unacceptable RISK of HARM to the PATIENT;

An additional example of ESSENTIAL PERFORMANCE is performance of ME EQUIPMENT required for a PROCEDURE associated with a known RISK to the PATIENT, where a failure of the ME EQUIPMENT to perform correctly would necessitate a repetition of this PROCEDURE thus invalidating the original RISK/benefit assessment.

Subclause 3.33 – *FUNCTIONAL CONNECTION

In the definition of an ME SYSTEM, the FUNCTIONAL CONNECTION is included to allow non-ME EQUIPMENT to supply power to ME EQUIPMENT. This power supply is restricted by the requirements in Clause 16 (see 16.3).

The phrase "or otherwise" may include mechanical, optical or wireless connections for example.

Subclause 3.35 – *FUNCTIONAL EARTH TERMINAL

In ME EQUIPMENT functional earth connections may be made by means of a FUNCTIONAL EARTH TERMINAL that is accessible to the OPERATOR. Alternatively this standard also allows a functional earth connection for CLASS II ME EQUIPMENT via a green and yellow conductor in a POWER SUPPLY CORD. In this case the parts concerned cannot be ACCESSIBLE PARTS (see 8.6.9) and have to be insulated from ACCESSIBLE PARTS.

Subclause 3.38 – *HARM

The definition of HARM is based on the definition in ISO 14971 modified to include animals. This change was made since the scope of the IEC 60601-1 includes the SAFETY of animals.

Subclause 3.49 – *MAINS PART

A definition of MAINS PART is needed to identify the parts to which certain requirements apply. The definition given in the first and second editions of this standard depended on another defined term, "CONDUCTIVE CONNECTION". During the development of this edition, a difficulty with the definition of "CONDUCTIVE CONNECTION" became apparent and the requirements were revised so the defined term was no longer needed. This necessitated a new definition of MAINS PART focussing on the MEANS OF PROTECTION that separate the MAINS PART from other parts.

Subclause 3.50 – *MAINS PLUG

A definition of MAINS PLUG is needed to identify the plug to which certain requirements apply. The words "mains plug" without a definition would also cover other connectors within ME EQUIPMENT that carry MAINS VOLTAGE.

Subclause 3.56 – *MAXIMUM MAINS VOLTAGE

Several requirements and tests of this standard relate to the possibility that an unintended voltage originating from an external source becomes connected to the PATIENT or to certain parts of the ME EQUIPMENT. The actual magnitude of such a voltage is unknown but it is assumed to be related to the voltage of the SUPPLY MAINS in the location where the ME EQUIPMENT is used. See also the Rationale for 8.5.3 *a).*

In the early stages of preparing this edition, a defined term "REFERENCE SUPPLY VOLTAGE" was introduced to avoid repetition of extensive wording. During the review of the National Committees' comments on an early draft, it became apparent that there was some confusion between the defined term "REFERENCE SUPPLY VOLTAGE" and the undefined term "reference voltage" which is used in relation to the requirements for dielectric strength, CREEPAGE DISTANCES and AIR CLEARANCES.

In order the clarify the requirements, the term "REFERENCE SUPPLY VOLTAGE" has been replaced by MAXIMUM MAINS VOLTAGE and "REFERENCE VOLTAGE" has been made a defined term.

Subclause 3.57 – *MAXIMUM PERMISSIBLE WORKING PRESSURE

The MAXIMUM PERMISSIBLE WORKING PRESSURE is decided by a competent person, taking into account the original design specification, the MANUFACTURER'S rating, the current condition of the vessel and the circumstances of use.

In some countries, the figure may be reduced from time to time.

Subclause 3.58 – *MEANS OF PROTECTION (MOP)

One guiding principle in the development of the third edition of this standard was to make it less prescriptive than the second edition, especially clauses 17 and 20 of the second edition. The concept of MEANS OF PROTECTION was conceived as a generic one that could cover a number of things such as PROTECTIVE EARTH CONNECTIONS, BASIC INSULATION, SUPPLEMENTARY INSULATION, impedances, etc; and that might also be expanded to include other things which serve in the same capacity but have not yet been envisioned or are not yet practical. This concept, with the general requirement for ME EQUIPMENT to have two MEANS OF PROTECTION, fitted in well with the single fault philosophy, which all agreed was to be retained in the third edition. It enables a consistent approach to carry through a design effort without getting bogged down in the wordy prescriptive subclauses.

The concept also fitted in well when it was decided to differentiate protection of PATIENTS from protection of OPERATORS.

National Committee comments during the development of this edition suggested that the concept should be extended to apply to protection against HAZARDS other than electric shock. However it was decided that such a change would not be justified by the benefits.

Subclause 3.59 – *MEANS OF PATIENT PROTECTION (MOOP)

See the Rationale for 8.5.1.

Subclause 3.60 – *MEANS OF OPERATOR PROTECTION (MOOP)

See the Rationale for 8.5.1.

Subclause 3.64 – *MEDICAL ELECTRICAL SYSTEM (HEREINAFTER ME SYSTEM)

Rationale for permitting the use of a MULTIPLE SOCKET-OUTLET in an ME SYSTEM.

To minimize the impairment of the SAFETY level of this standard, the connection of MULTIPLE SOCKET-OUTLET to the SUPPLY MAINS is subject to certain conditions. An additional subclause 16.9.2.1, requires that MULTIPLE SOCKET-OUTLETS are constructed to comply with the requirements applying to ME EQUIPMENT from this standard.

Subclause 3.66 – *MODEL OR TYPE REFERENCE

The MODEL OR TYPE REFERENCE is intended to establish its relationship to commercial and technical publications, to ACCOMPANYING DOCUMENTS and between separable parts of ME EQUIPMENT. It is also important for identifying of ME EQUIPMENT or ACCESSORIES in case of a SAFETY alert or other required field action.

Subclause 3.67 – *MULTIPLE SOCKET-OUTLET (MSO)

The definition is derived from IEC 60884-1.

MULTIPLE SOCKET-OUTLETS are sometimes necessary and offer advantages and disadvantages, which have to be investigated in order to establish a balance. MULTIPLE SOCKET-OUTLETS may be necessary for the following reasons:

– to minimize the number of POWER SUPPLY CORDS lying on the floor;

– to allow all the equipment necessary for proper treatment or diagnosis to be used despite an insufficient number of FIXED mains socket-outlets;

– to improve mobility having all equipment on one trolley;

– to reduce potential differences within the protective earth wiring to below those that occur in some FIXED installations.

The use of MULTIPLE SOCKET-OUTLETS should be avoided as far as possible for the following reasons:

– combined EARTH LEAKAGE CURRENTS may result in

  - excessive EARTH LEAKAGE CURRENT in NORMAL CONDITION,
  - excessive TOUCH CURRENT in the SINGLE FAULT CONDITION of the broken PROTECTIVE earth conductor of the MULTIPLE SOCKET-OUTLET supply cable;

– availability of the SUPPLY MAINS depends on the reliability of a single FIXED mains socket-outlet;

– a complete interruption of electrical supply is possible and may require a long set-up time to reactivate the complete ME SYSTEM;

– only one PROTECTIVE EARTH CONNECTION to the electrical installation is provided; this is less reliable than when each part of the ME SYSTEM is directly earthed;

– the protective earth resistance is increased.

The optimum solution is, obviously, to install an adequate number of FIXED mains socket-outlets according to appropriate installation rules.

Subclause 3.69 – *NETWORK/DATA COUPLING

The definition of NETWORK/DATA COUPLING has been written so as not to be restricted to any particular technology, such as electronic transmission along wires. The definition allows for wireless electromagnetic transmission, infra-red, optical, etc., as well as any future technology.

Subclause 3.76 – *OXYGEN RICH ENVIRONMENT

At a 25 % oxygen concentration, the increase in the burning rate of a paper strip is only moderate (30 %) (per NFPA 99, *Standard for Health Care Facilities*). In NFPA 99, 23,5 % is defined to be oxygen enriched atmosphere that requires protective measures, but it allows this value also for oxygen chambers at pressures of more than 200 kPa. NASA allows concentrations of 25,9 % in their space shuttles (NFPA 53). UL 2601-1 uses 25 % as threshold value. A sample of epoxy circuit board material burns incompletely at 20,9 % and 25,9 % (burning length of 3 and 8,3 cm) but completely at 30 % according to Rimanosky, E.M. *et al*., ASTM STP 1267.[204]

Subclause 3.78 – *PATIENT AUXILIARY CURRENT

PATIENT AUXILIARY CURRENT is a current that is necessary for:

– the ME EQUIPMENT to perform its function, e.g. electrical impedance imaging, monitoring of respiration by impedance changes;

– monitoring the correct operation of the ME EQUIPMENT, e.g. contact impedance of electrodes with the PATIENT;

– the functioning of the ME EQUIPMENT,

or that is incidental to the functioning of the ME EQUIPMENT. An example is the bias current of an amplifier for physiological signals.

PATIENT AUXILIARY CURRENT may have a function, but not a physiological function, or it may have no function.

Subclause 3.79 – *PATIENT CONNECTION

One of the potential HAZARDS associated with the application of PATIENT CONNECTIONS is the fact that LEAKAGE CURRENT may flow through the PATIENT via the PATIENT CONNECTIONS. Particular limits are placed on the magnitude of these currents, both in the NORMAL CONDITION and in various fault conditions.

NOTE The current that flows through the PATIENT between various parts PATIENT CONNECTIONS is known as PATIENT AUXILIARY CURRENT. The LEAKAGE CURRENT that flows through the PATIENT to earth is known as PATIENT LEAKAGE CURRENT.

The definition of PATIENT CONNECTION is intended to ensure the identification of each individual part of the APPLIED PART between which current may flow as PATIENT AUXILIARY CURRENT, and from which PATIENT LEAKAGE CURRENT may flow into an earthed PATIENT.

In some cases it will be necessary to carry out PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT measurements to determine which parts of the APPLIED PARTS are individual PATIENT CONNECTIONS.

PATIENT CONNECTIONS are not always accessible to touch. Any conductive parts of the APPLIED PART that come into electrical contact with the PATIENT, or which are prevented from doing so only by insulation or air gaps that do not comply with the relevant dielectric strength tests or AIR CLEARANCE and CREEPAGE DISTANCE requirements specified in this standard, are PATIENT CONNECTIONS. See also the rationale for 3.8.

Examples include the following:

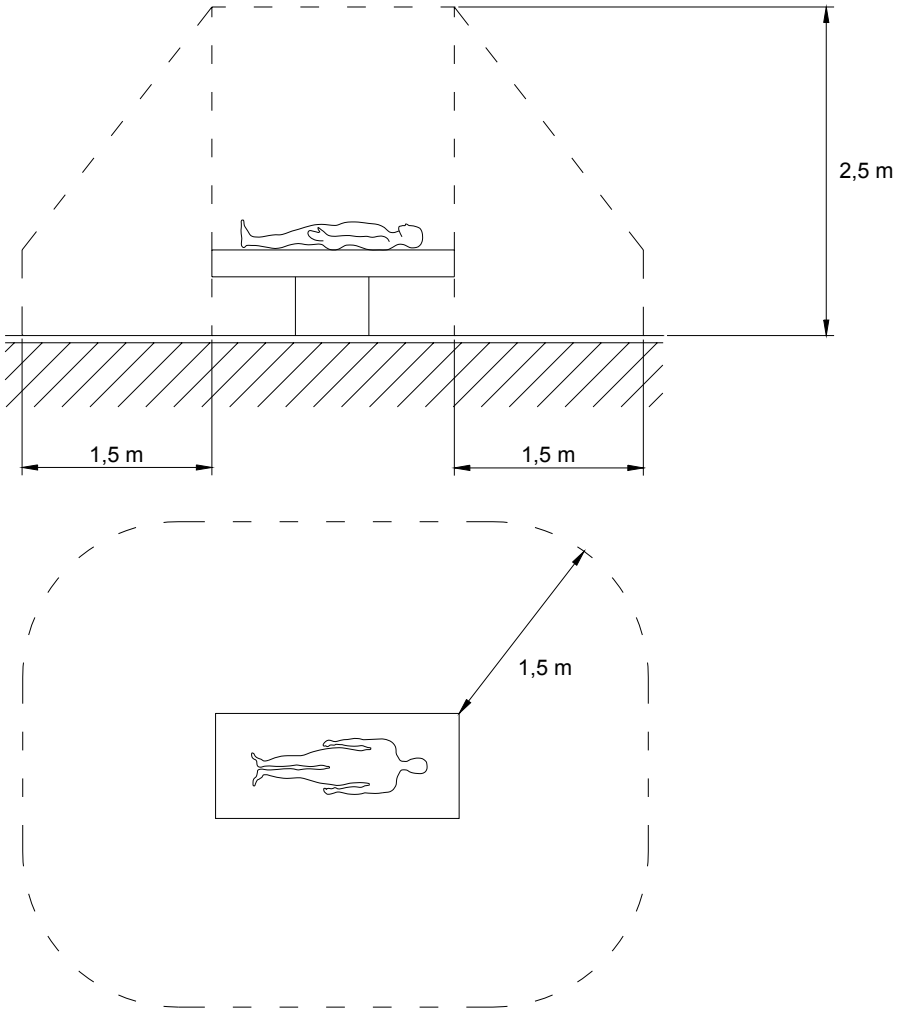
– A table top supporting a PATIENT is an APPLIED PART. Sheets do not provide adequate insulation and the conductive parts of the table top would therefore be classified as PATIENT CONNECTIONS.

– The administration set or needle of an infusion controller is an APPLIED PART. Conductive parts of the controller separated from the (potentially conducting) fluid column by inadequate insulation would be PATIENT CONNECTIONS.

Where an APPLIED PART has a surface of insulating material, 8.7.4.7 *d)* specifies that it is tested using foil or saline solution. This is then considered as a PATIENT CONNECTION.

Subclause 3.80 – *PATIENT ENVIRONMENT

It is difficult to apply unique dimensions to the volume in which diagnosis, monitoring or treatment occurs. The dimensions for the PATIENT ENVIRONMENT given in Figure A6 have been justified in practice.



NOTE The dimensions in the figure show minimum extending of the PATIENT ENVIRONMENT in a free surrounding.

Figure A6 – Example of PATIENT ENVIRONMENT

Subclause 3.102 – *REFERENCE VOLTAGE (U)

This definition is based on the second paragraph of subclause 20.3 of the second edition.

Subclause 3.103 – *REINFORCED INSULATION

The term “insulation system” does not imply that the insulation must be one homogeneous piece. It may comprise several layers that cannot be tested separately as SUPPLEMENTARY or BASIC INSULATION.

Subclause 3.110 – *RISK CONTROL[205]

For the purpose of RISK CONTROL it is important to identify all initiating causes of HAZARDS that influence the output behaviour of a certain function. SAFETY measures can only be introduced against causes or root causes.

To determine the impact of a particular HAZARD for the response of a system, it is important to understand the principal Input-Output-behaviour of ME EQUIPMENT/ME SYSTEM.

As one possible example this can be described by a Functional Analysis determining the "Input-output-relation" of a system. Only the most significant functions should be explicitly addressed inside the system’s boundary (see Figure A7).

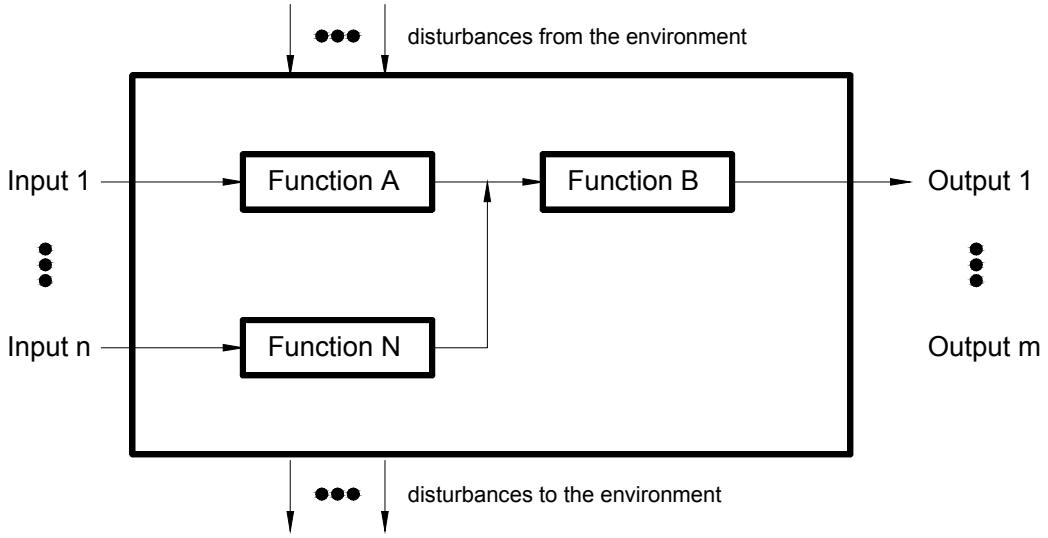


Figure A7 – Schematic representation of the Input-output-relation of a system

It is possible to zoom into the ME EQUIPMENT or ME SYSTEM to identify more details of a particular functionality. Disturbances from the environment can be evaluated as additional unintended inputs (e.g. EMI, moisture, vibrations, etc.) to the ME EQUIPMENT or ME SYSTEM. In the same way the ME EQUIPMENT or ME SYSTEM itself may disturb the environment with unintended side-effects. These can be described as disturbances from the ME EQUIPMENT or ME SYSTEM as outputs to the environment.

Adverse effects to PATIENTS, OPERATORS or third parties are only associated with the intended or unintended outputs of ME EQUIPMENT or an ME SYSTEM. All technical events (fault conditions, component failure, breakage of material) are always causes or root causes. Use errors are causes that are associated with inputs.

Subclause 3.117 – *SECONDARY CIRCUIT

This definition is based on the definition of the same term in IEC 60950-1 and identifies circuits that are subject to lower transient overvoltages than the MAINS PART and therefore have lower value for dielectric strength test voltages and AIR CLEARANCES.

Subclause 3.119 – *SEPARATION DEVICE

Assembly of equipment into an ME SYSTEM may involve connections that transfer power or signals. In both cases the same separation requirements are needed.

Subclause 3.122 – *SIGNAL INPUT/OUTPUT PART

If a SIGNAL INPUT/OUTPUT PART carries electrical signals, or if it carries non-electrical signals but nevertheless introduces an electrical connection to the other equipment (e.g. through an optical fibre cable with a metal sheath), appropriate separation from other circuits can be necessary to satisfy the requirements of this standard. Alternatively a SIGNAL INPUT/OUTPUT PART may have no electrical connections, in which case it will automatically satisfy the requirements for electrical SAFETY.

Subclause 3.128 – *SUPPLY MAINS

An external d.c. power source (e.g. in an ambulance) is considered as a SUPPLY MAINS. ME EQUIPMENT specified for connection to such a power source has to satisfy all requirements for mains powered ME EQUIPMENT. In the past, some ME EQUIPMENT specified for such a power source has had a direct connection between the ENCLOSURE and one side of the supply, presumed to be at earth potential. In the event of interruption of the connection to this side of the supply, the ENCLOSURE of such ME EQUIPMENT assumes the supply potential and would therefore exceed the specified limit for TOUCH CURRENT. The first and second editions of this standard were intended to exclude such an arrangement, but this was not always understood by users of the standard. This rationale has been added to clarify the requirement.

Subclause 3.140 – *TYPE B APPLIED PART

TYPE B APPLIED PARTS provide the lowest degree of PATIENT protection of all the types of APPLIED PART and are not suitable for DIRECT CARDIAC APPLICATION.

The PATIENT CONNECTION(S) of a TYPE B APPLIED PART may be:

– PROTECTIVELY EARTHED;

– connected to earth but not PROTECTIVELY EARTHED; or

– floating, but not isolated from earth to the degree that would be required for a TYPE BF APPLIED PART.[206]

Subclause 3.141 – *TYPE BF APPLIED PART

TYPE BF APPLIED PARTS provide a degree of PATIENT protection higher than provided by TYPE B APPLIED PARTS. This is achieved by isolating the PATIENT CONNECTIONS from earthed parts and other ACCESSIBLE PARTS of the ME EQUIPMENT, thus limiting the magnitude of current that would flow through the PATIENT in the event that an unintended voltage originating from an external source is connected to the PATIENT, and thereby applied between the PATIENT CONNECTIONS PART and earth. However, TYPE BF APPLIED PARTS are not suitable for DIRECT CARDIAC APPLICATION.

Subclause 3.142 – *TYPE CF APPLIED PART

TYPE CF APPLIED PARTS provide the highest degree of PATIENT protection. This is achieved by increased isolation of the PATIENT CONNECTION from earthed parts and other ACCESSIBLE PARTS of the ME EQUIPMENT, further limiting the magnitude of possible current flow through the PATIENT. TYPE CF APPLIED PARTS are suitable for DIRECT CARDIAC APPLICATION insofar as PATIENT LEAKAGE CURRENT is concerned, though they may be unsuitable in other respects, such as sterility or biocompatibility.

A.4 Clause 4 – General requirements

Subclause 4.2 – *RISK MANAGEMENT PROCESS for ME EDUIPMENT or ME SYSTEMS

A change introduced in the third edition of this standard is that, in specifying minimum SAFETY requirements, provision is made for assessing the adequacy of the design PROCESS where this provides an appropriate alternative to the application of laboratory testing with specific pass/fail criteria, (e.g. in assessing the SAFETY of new technologies such as programmable electronic systems). Application of this principle leads to the introduction of a general requirement to carry out a RISK MANAGEMENT PROCESS as part of demonstrating compliance with this standard.

The MANUFACTURER should make judgements relating to SAFETY of ME EQUIPMENT, including the acceptability of RISKS, taking into account the generally accepted state of the art, in order to determine the likely suitability of ME EQUIPMENT to be placed on the market for its INTENDED USE/INTENDED PURPOSE. ISO 14971 specifies a PROCEDURE for the MANUFACTURER to identify HAZARDS associated with a medical device and its accessories; to estimate and evaluate the RISKS associated with those HAZARDS; to control those RISKS, and to monitor the effectiveness of that control.

The MANUFACTURER of ME SYSTEMS should make the above judgements on a system level, i.e. he should assess RISKS resulting from the fact that individual system components have been integrated into one system. This assessment should include all aspects of the information exchanged between the system components. If system components are used that may cause RISKS in the system, the RISKS associated with these components need to be assessed in addition. While many individual clauses of this standard have been specifically identified as applicable only to ME EQUIPMENT indicating that the detailed requirements they contain are not intended to be applied to non-ME EQUIPMENT parts of ME SYSTEMS, they frequently address at the same time general principles of SAFETY that need to be considered when applying RISK MANAGEMENT to ME SYSTEMS.

Subclause 4.3 – *Equivalent SAFETY for to ME EQUIPMENT or ME SYSTEMS

This subclause allows alternative means of achieving equivalent SAFETY to be used. This is important as it permits a MANUFACTURER to use innovative solutions that might be safer or have other benefits, e.g. cost or performance.

Subclause 4.4 – *ME EQUIPMENT or ME SYSTEMS parts that contact the PATIENT

A part that unintentionally comes into contact with an unconscious, anaesthetized or incapacitated PATIENT may present the same RISKS as an APPLIED PART that necessarily has to contact the PATIENT. On the other hand, a part that an active PATIENT may reach out and touch may present no more RISK to that PATIENT than to an OPERATOR.

The definition of APPLIED PART in the first and second editions of this standard failed to address this problem. The second amendment to the second edition extended the definition to include parts that can be brought into contact with the PATIENT, but the new definition continued to cause difficulties.

Since this standard now requires a RISK MANAGEMENT PROCESS to be followed, it is appropriate to use this PROCESS to establish whether such parts should be subject to the requirements for APPLIED PARTS or not.

The exclusion of marking requirements reflects the majority view of the National Committees that responded to an enquiry on the subject during the development of this edition. It would be confusing to OPERATORS if parts that are not intended to be APPLIED PARTS were marked like APPLIED PARTS.

Subclause 4.5 – *NORMAL CONDITION and SINGLE FAULT CONDITION for ME EQUIPMENT

SINGLE FAULT SAFE is a concept that flows from the single fault philosophy described in ISO/TR 60513. SINGLE FAULT SAFE is a characteristic of ME EQUIPMENT that assures freedom from unacceptable RISK throughout its useful life. The useful life can be affected by many factors. For the purpose of this standard, it can be taken to be the period during which the ME EQUIPMENT continues to provide a level of SAFETY comparable to that achieved by complying with this standard.

In the ACCOMPANYING DOCUMENTS, the MANUFACTURER should provide information to allow the RESPONSIBLE ORGANIZATION to assess when the ME EQUIPMENT is approaching the end if its useful life. Information regarding useful life could be presented in the form of the tests to be performed as part of preventive maintenance, time (in terms of years of service), number of uses, or in other ways that allow the RESPONSIBLE ORGANIZATION to make an appropriate determination. The need for such information and the appropriate way to present it should be addressed as part of the RISK MANAGEMENT PROCESS.

As stated in 4.5, ME EQUIPMENT is required to remain safe in SINGLE FAULT CONDITION. Thus one fault of a single protective means is allowed.

The probability of simultaneous occurrence of two single faults is considered small enough to be negligible.

This condition can only be relied upon if either:

a) the probability of a single fault is small, because of sufficient design reserve, or the presence of a double protection prevents the development of a first single fault, or

b) a single fault causes operation of a SAFETY device (e.g. a fuse, OVER-CURRENT RELEASE, SAFETY catch, etc.) that prevents occurrence of a HAZARD, or

c) a single fault is discovered by an unmistakable and clearly discernible signal that becomes obvious to the OPERATOR, or

d) a single fault is discovered and remedied by periodic inspection and maintenance that is prescribed in the instructions for use. There is a finite probability that a second fault can arise before the next scheduled inspection and maintenance cycle. As with case *a)* above, for the probability of this double fault condition to be negligible, the probability of each fault has to be low. This means that the frequency of inspection and maintenance has to be high compared to the expected frequency of occurrence of the fault. The longer the time that one SINGLE FAULT CONDITION remains present before being detected and rectified, the greater the probability that a second fault will arise. Therefore, the MANUFACTURER may need to explicitly consider the detection time in relation to the occurrence of a possible second fault as part of RISK ANALYSIS.

Non-exclusive examples of the categories *a) to d)* are:

– REINFORCED or DOUBLE INSULATION;

– CLASS I ME EQUIPMENT in case of a fault in BASIC INSULATION;

– Abnormal indications of displays, defect in a redundant suspension cord causing excessive noise or friction;

– Deterioration of a flexible PROTECTIVE EARTH CONNECTION that is moved in NORMAL USE.

Capacitors (X1 and X2) complying with IEC 60384-14, which are connected between parts of opposite polarity of the MAINS PART, are exempted from this requirement. Thus, failure of such capacitors need not be simulated.

For information concerning X1 and X2, see IEC 60384-14: 1993, subclause 1.5.3.

Subclause 4.8 – *Power supply

An alternating voltage is considered in practice to be sinusoidal if any instantaneous value of the waveform concerned differs from the instantaneous value of the ideal waveform at the same moment by no more than ± 5 % of the peak value of the ideal waveform, unless stated otherwise.

A polyphase voltage system is considered to be symmetrical if neither the magnitude of its negative sequence components nor the magnitude of its zero sequence components exceeds 2 % of the magnitude of its positive sequence components.

A polyphase supply system is considered to be symmetrical if, when supplied from a symmetrical voltage system, the resulting current system is symmetrical. That is, the magnitude of neither the negative sequence current components nor the zero sequence current components exceeds 5 % of the magnitude of the positive sequence current components.

Because of the wide range of ME EQUIPMENT covered in this standard, it is not possible to specify the permissible effects on performance of each particular type of ME EQUIPMENT due to MAINS VOLTAGE and frequency fluctuations.

In this standard such effects are covered in a number of SAFETY tests.

According to Fortescue's theorem any unbalanced polyphase system can be resolved in three balanced systems of phases:

– a system of so-called positive sequence components of equal magnitude and phase angle, but having the opposite phase sequence as the original system;

– a system of so-called negative sequence components of equal magnitude and phase angle, but having the same phase sequence as the original system;

– a system of so-called zero sequence components of equal magnitude, no mutual phase angle (in phase) and no phase sequence (stationary vectors). Systems without a neutral conductor cannot have zero sequence current components.

The zero sequence current can be determined as the sum of the three phase currents divided by three.

Thus the neutral current is three times the zero sequence current.

Literature: – Elements of Power Systems Analysis
W.D. Stevenson, jr.

– Modern Power Systems
Neuenswonder
page 183, Measurement of Zero Sequence.

A.5 Clause 5 – *General requirements for tests for ME EQUIPMENT

In ME EQUIPMENT there may be many pieces of insulation, components (electrical and mechanical) and constructional features in which a failure would not produce a HAZARD to PATIENT, OPERATOR or surroundings, even though causing a deterioration in or a failure of performance of ME EQUIPMENT.

Subclause 5.1 – *Tests

The RISK MANAGEMENT PROCESS identifies the SAFETY measures that are necessary to ensure that the ME EQUIPMENT is safe.

Unless otherwise specified in this standard, tests shall not be repeated. This applies particularly to the dielectric strength tests, which are performed only at the MANUFACTURER'S site or in test laboratories.

In order to ensure that every individually produced item of ME EQUIPMENT conforms to this standard, the MANUFACTURER or installer should carry out such measures during manufacture or installation assembly as to ensure that each item satisfies all requirements even if it is not completely tested individually during manufacture or installation.

Such measures may take the form of:

a) production methods (to ensure good manufacturing output and constant quality) where such quality would be related to SAFETY;

b) production tests (routine tests) performed on every produced item;

c) production tests performed on a production sample where results would justify a sufficient confidence level.

Production tests may not be identical with type tests, but may be adapted to manufacturing conditions and possibly invoking less RISK for the quality of the insulation or other characteristics important for SAFETY.

Production tests would, of course, be restricted to settings (possibly derived from type tests) that would provoke the worst case situation.

Depending upon the nature of ME EQUIPMENT, production methods or tests may concern critical insulation of the MAINS PART, of the PATIENT CONNECTIONS and the insulation or the separation between these parts.

Suggested test parameters could be LEAKAGE CURRENT and dielectric strength.

Where applicable, the continuity of protective earthing may be a major test parameter.

Subclause 5.2 – *Number of samples

The type test sample or samples shall be representative of the units intended for the RESPONSIBLE ORGANIZATION.

Subclause 5.7 – *Humidity preconditioning treatment

According to IEC 60529, the ENCLOSURE of ME EQUIPMENT that is RATED IPX8 prevents, under stated conditions, the entry of an amount of water where its presence could cause a HAZARD.

The test condition as well as the acceptable amount and location of water are to be defined in particular standards. If no ingress of water is tolerated (sealed ENCLOSURES) the application of the humidity preconditioning treatment is inappropriate.

Parts sensitive to humidity, normally used in controlled environments and which do not influence SAFETY, need not be subjected to this test. Examples are: high-density storage media in computer-based systems, disc and tape drives, etc.

To prevent condensation when ME EQUIPMENT is placed in the humidity cabinet, the temperature of such a cabinet must be equal to or slightly lower than the temperature of the ME EQUIPMENT when it is introduced. To avoid the need for a temperature stabilization system for the air in the room outside the cabinet, the cabinet air temperature during the treatment is adapted to that of the outside air within the limits of the range of +20 °C to +32 °C and then "stabilized" at the initial value. Although the effect of the cabinet temperature on the degree of absorption of humidity is recognized, it is felt that the reproducibility of test results is not impaired substantially and the cost-reducing effect is considerable.

Subclause 5.9 – *Determination of ACCESSIBLE PARTS

Except in special cases, such as PATIENT supports and waterbeds, contact with ME EQUIPMENT is supposed to be made with:

– one hand, simulated for LEAKAGE CURRENT measurements by a metal foil of 10 cm x 20 cm (or less if the total ME EQUIPMENT is smaller);

– one finger, straight or bent in a natural position, simulated by a test finger provided with a stop plate;

– an edge or slit that can be pulled outwards allowing subsequent entry of a finger, simulated by a combination of test hook and test finger.

A.6 Clause 6 – *Classification of ME EQUIPMENT and ME SYSTEMS

ME EQUIPMENT may have a multiple classification.

Subclause 6.2 – *Protection against electric shock

The term “Class III equipment” is used in some other standards to identify equipment that is powered from a Safety Extra-Low Voltage (SELV) mains supply system. The term Class III equipment is not formally used in this standard. The SAFETY of Class III equipment is critically dependent on the installation and on other Class III equipment connected thereto. These factors are outside the control of the OPERATOR and this is considered to be unacceptable for ME EQUIPMENT. Additionally, limitation of voltage is not sufficient to ensure SAFETY of the PATIENT. For these reasons, this standard does not recognize Class III construction.

Subclause 6.6 – *Mode of operation

CONTINUOUS OPERATION and non-CONTINUOUS OPERATION cover the range of operating modes of virtually all equipment. ME EQUIPMENT that remains plugged into the SUPPLY MAINS continuously but is operated intermittently should be RATED for non-CONTINUOUS OPERATION, have the appropriate indication of on/off times in the ACCOMPANYING DOCUMENTS and markings on the ME EQUIPMENT (see 7.2.9).

A.7 Clause 7 – ME EQUIPMENT identification, marking and documents

Subclause 7.1.3 – *Durability of markings

The rubbing test is performed with distilled water, methylated spirit and isopropyl alcohol.

Methylated spirits – a flammable petroleum distillate that boils lower than kerosene and is suitable for use as a solvent and thinner especially for paints and varnishes.

Isopropyl alcohol is defined in the European Pharmacopoeia as a reagent in the following terms: C_3H_8O (MW60.1) – Propanol. Isopropyl alcohol. A clear colourless liquid with a characteristic odour, mixable with water and with alcohol. It has a relative density of 0,785 at 20 °C, boiling-point 82,5 °C at 101,3 kPa.

Subclause 7.2.2 – *Identification

This subclause is intended to apply to any detachable component when misidentification could present a HAZARD or impact ESSENTIAL PERFORMANCE. For examples, normal consumables would probably need to be identified, but a cosmetic cover would not need to be identified.

Although a MODEL OR TYPE REFERENCE usually denotes a certain performance specification, it may possibly not denote the exact construction, including the applied components and materials. If this is required, the MODEL OR TYPE REFERENCE may have to be supplemented by a serial number. The serial number may also be used for other purposes.

Indication of a manufacturing series only may not be sufficient if local requirements require individual identification.

Subclause 7.2.3 – *ACCESSORIES and MEDICAL DISPOSABLES

RESPONSIBLE ORGANIZATIONS and OPERATORS need to be able to identify ACCESSORIES in order to know which ones can be used without impairing SAFETY or ESSENTIAL PERFORMANCE. A MODEL OR TYPE REFERENCE alone is not sufficient, because different MANUFACTURERS might use the same number. The name marked on the ACCESSORY may be that of the ME EQUIPMENT MANUFACTURER or a different name.

Subclause 7.2.8 – *APPLIED PARTS

According to the second edition of this standard, the marking could be either on the APPLIED PART itself or adjacent to the connection point. Neither location is satisfactory in all cases. Where a conductor that is not separated from PATIENT CONNECTIONS extends up to the point inside ME EQUIPMENT where an isolation barrier exists, a TYPE BF or TYPE CF marking on the APPLIED PART itself could mislead the RESPONSIBLE ORGANIZATION and/or the OPERATOR into believing that isolation is built into the APPLIED PART itself. If, on the other hand, the classification depends on the particular APPLIED PART in use, a single marking on the connection point would be inaccurate and multiple marking would be confusing.

Subclause 7.2.10 – *Fuses

For fuses in accordance with IEC 60127-1, the marking of the type and rating should be in accordance thereto. When appropriate the marking should also include the breaking capacity. Examples of marking: T 315L or T 315mAL, F 1,25H or F 1,25AH.

Subclause 7.3.4 – *Fuses, THERMAL CUT-OUTS and OVER-CURRENT RELEASES

For fuses in accordance with IEC 60127-1, the marking of the type and rating should be in accordance thereto. When appropriate the marking should also include the breaking capacity. Examples of marking: T 315L or T 315mAL, F 1,25H or F 1,25AH.

Subclause 7.9 – *Indicator lights and controls

For colours of indicator lights see also IEC 60073.

Subclause 7.10.1 – *General (see also Table C4)

It is important that ME EQUIPMENT or an ME SYSTEM is not unintentionally used in an application for which it is not intended by its MANUFACTURER.

Subclause 7.10.2.1 – *General

RESPONSIBLE ORGANIZATIONS and OPERATORS must frequently deal with many different types of ME EQUIPMENT. Because of the complexity of modern ME EQUIPMENT, the instructions for use are an important part of the ME EQUIPMENT. Some commonality in the structure for the instructions for use may aid OPERATORS quickly and easily find needed material. However, because of the diversity of ME EQUIPMENT covered by this standard, no one format will be equally applicable to all ME EQUIPMENT. Therefore, the MANUFACTURER is encouraged, but not required, to use the sequence of topics in 7.10.2.2 to 7.10.2.15 as an outline when developing the instructions for use.

The subject of languages used in markings and in ACCOMPANYING DOCUMENTS cannot be solved by IEC. Even a requirement that identifications and ACCOMPANYING DOCUMENTS have to be in the national languages cannot be upheld world-wide.

Subclause 7.10.2.2 – *Warning and SAFETY notices

For CLASS I ME EQUIPMENT, where operation from either a SUPPLY MAINS or an INTERNAL ELECTRICAL POWER SOURCE is specified, the instructions for use should state that the INTERNAL ELECTRICAL POWER SOURCE shall be used if the integrity of the PROTECTIVE EARTH CONDUCTOR or the protective earthing system in the installation is in doubt.

Subclause 7.10.2.6 – *Installation

The instructions for use may contain a statement saying that the MANUFACTURER, assembler, installer or importer considers himself responsible for the effect on SAFETY, reliability and performance of the ME EQUIPMENT or ME SYSTEM only if:

– Appropriately trained personnel carry out assembly operations, extensions, readjustments, modifications or repairs,

– The electrical installation of the relevant room complies with the appropriate requirements, and

– The ME EQUIPMENT OR ME SYSTEM is used in accordance with the instructions for use.

[207]**Subclause 7.10.2.7 – *Isolation from the SUPPLY MAINS**

A plug and socket provide suitable means for isolation from the SUPPLY MAINS to satisfy 8.11.1 *a),* but they would not be suitable if they were not readily accessible when needed.

Subclause 7.10.3.1 – *General

According to the INTENDED USE/INTENDED PURPOSE of ME EQUIPMENT, the MANUFACTURER should specify the permissible environmental conditions for which a HAZARD is not induced. Environmental conditions such as the following shall be considered:

– the effect of humidity

– the effect of temperature

– the effect of atmospheric pressure

– the effect of shock and vibration

– the effect of ultra-violet radiation

– the effect of the temperature of the water for water cooled ME EQUIPMENT

– the effect of pollution.

Accuracy and precision are not possible to define in this standard. These concepts have to be addressed in particular standards.

The second edition of IEC 60601-1 specified the following range of environmental conditions for transport and storage of ME EQUIPMENT unless otherwise specified by the MANUFACTURER:

– an ambient temperature range of - 40 °C to + 70 °C

– a relative humidity range of 10 % to 100 %, including condensation

– an atmospheric pressure range of 50 kPa to 106 kPa

Amendment 2 to the second edition replaced the above list with a requirement that the MANUFACTURER must state the permissible storage and transport conditions. However, in the absence of other information, the above list may serve as a useful starting point in determining the permissible limits.

A.8 Clause 8 – *Protection against electrical HAZARDS FROM ME EQUIPMENT

The fundamental principle for protection against electric shock is that the voltage or current between any ACCESSIBLE PART and any other ACCESSIBLE PART or earth shall be low enough not

to present a HAZARD, in all relevant circumstances including NORMAL CONDITION and SINGLE FAULT CONDITION.

Requirements for achieving protection have been formulated in various ways in IEC basic safety standards, in previous editions of this standard, and in other IEC product standards.

In order for the fundamental principle to be satisfied:

a) parts that are "LIVE" (as defined in the second edition of this standard) [2)] or "hazardous live" (as defined in some other standards) have to be inaccessible (but see below regarding problems in identifying what is "LIVE") and

b) ACCESSIBLE PARTS have to be not "LIVE" / hazardous live.

These two requirements are in principle equivalent but some standards state both of them.

These requirements in turn imply that:

c) ACCESSIBLE PARTS have to be separated from certain internal live parts: in general two separate MEANS OF PROTECTION are necessary, one to provide separation in NORMAL CONDITION and a second to maintain SAFETY in SINGLE FAULT CONDITION, and

d) LEAKAGE CURRENTS (and possibly also voltages and energies) have to be below acceptable limits.

Most standards include explicit requirements covering each of these aspects of providing protection. For example the 1st and 2nd editions of this standard dealt with *a)* in Clause 16, with *b)* and *d)* in Clause 19 and with *c)* in Clauses 17, 18 and 20.

Requirement *a)* has typically been formulated as a requirement for the provision of ENCLOSURES or barriers to prevent contact with internal hazardous live parts. However it can alternatively be formulated in terms of the determination of which parts are accessible. Anyway the adequacy of ENCLOSURES or barriers is determined by use of the relevant test fingers and probes.

Application of the above approach to ME EQUIPMENT has presented some difficulties. The limits for voltage and current depend on how, if at all, the part(s) concerned can be connected to a PATIENT, e.g. directly to the heart, directly to other parts of the body, or indirectly via the OPERATOR. This has led to difficulties in identifying which parts are "LIVE" parts.

The definition of "LIVE" in the second edition of this standard refers to the allowable LEAKAGE CURRENT. The definition is therefore difficult to apply to internal parts for which no particular LEAKAGE CURRENT limits are specified.

Certain parts could be regarded as "LIVE" (within the definition of the second edition of this standard) for some purposes and at the same time as not "LIVE" for other purposes. For example an internal part that can source a current of, say, 200 μA has to be separated from all ACCESSIBLE PARTS, including PATIENT CONNECTIONS in NORMAL CONDITION.

The separation from PATIENT CONNECTIONS of TYPE CF APPLIED PARTS has to remain effective in SINGLE FAULT CONDITION, because a current of 200 μA from these is not permissible. The same part can however become connected to other ACCESSIBLE PARTS and PATIENT CONNECTIONS in SINGLE FAULT CONDITION.

Thus two MEANS OF PROTECTION (DOUBLE INSULATION or REINFORCED INSULATION) would be needed between such a part and the PATIENT CONNECTIONS of TYPE CF APPLIED PARTS, but a

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[2)] The term "LIVE" was defined in the second edition of this standard as, "State of a part which, when connection is made to that part, can cause a current exceeding the allowable LEAKAGE CURRENT (specified in Sub-clause 19.3) for the part concerned to flow from that part to earth or form that part to an ACCESSIBLE PART of the same ERQUIPMENT.

single MEANS OF PROTECTION (such as BASIC INSULATION alone) would be acceptable between such a part and other ACCESSIBLE PART.

Furthermore, requirements that specify the necessary separation between parts that are accessible and parts that are "LIVE" do not easily take account of parts that are not "LIVE" but can become "LIVE," such as the parts of a floating circuit that become "LIVE" when a connection is made to another part of the same circuit.

Consider, for example, the simple situation shown in Figure A8.

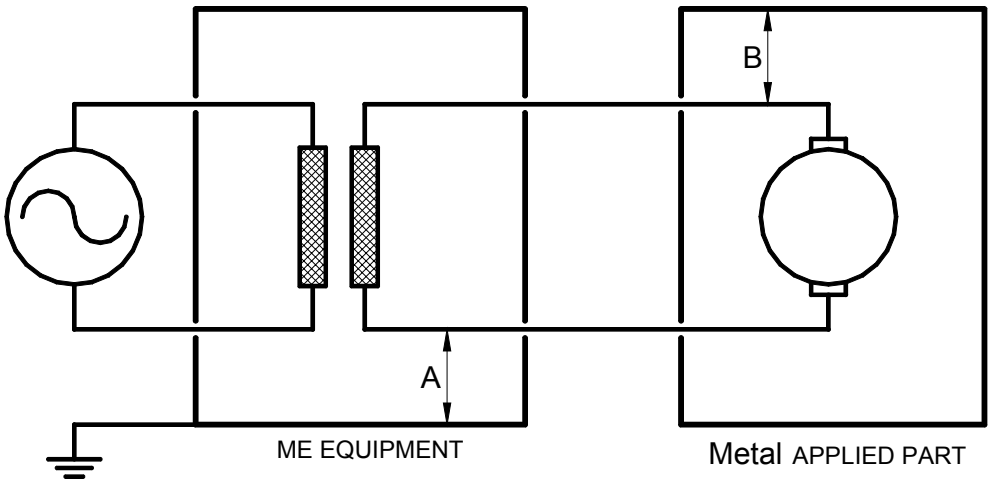


Figure A8 – Floating circuit

The APPLIED PART has a metal ENCLOSURE that is not PROTECTIVELY EARTHED. If there is a direct connection at point A, then the other end of the SECONDARY CIRCUIT is "LIVE," and even the first edition of this standard would have required DOUBLE INSULATION or REINFORCED INSULATION at point B.

If, instead, there is a direct connection at point B, the first edition would have required only BASIC INSULATION at point A; but this was dealt with in the second edition by adding subclause 20.2 B-e, which requires DOUBLE INSULATION or REINFORCED INSULATION at point A.

If however there is some insulation at both points A and B, then no part of the SECONDARY CIRCUIT is "LIVE" according to the definition in the second edition, so the second edition of this standard specifies no requirements for that insulation, which can therefore be minimal. The German National Committee of IEC discovered this problem in 1993, unfortunately just too late for it to be dealt with in the second (and final) amendment to the second edition of this standard. The approach adopted in this edition is intended to overcome this problem.

The formulation proposed for the third edition of this standard is to specify:

1) how to determine which parts are to be regarded as ACCESSIBLE PARTS (by inspection and where necessary by the use of appropriate test probes and fingers);

2) the permissible limits for voltage/current/energy in NORMAL CONDITION and relevant SINGLE FAULT CONDITIONS; these limits depend on the possible circumstances of connection to a PATIENT or to an OPERATOR;

3) that NORMAL CONDITION includes short-circuit of any insulation, AIR CLEARANCE or CREEPAGE DISTANCE or impedance which does not comply with specified requirements for the relevant REFERENCE VOLTAGE (U), and open-circuit of any earth connection which does not comply with the requirements for PROTECTIVE EARTH CONNECTIONS; and

4) that SINGLE FAULT CONDITIONS include short-circuit of any insulation, AIR CLEARANCE or CREEPAGE DISTANCE which does comply with specified requirements for the relevant REFERENCE VOLTAGE (*U*), short-circuit of any relevant component, and open-circuit of any earth connection which does comply with the requirements for PROTECTIVE EARTH CONNECTIONS.

This approach avoids the need to include explicit separate requirements for particular protective means, as specified in existing IEC standards. Arguably it could avoid even a general requirement for two MEANS OF PROTECTION, as presently proposed, but the Working Group considered that such a requirement is desirable.

Where requirements from the second edition that used the defined term "LIVE" have been retained, they have been re-phrased so as not to use this term.

Generally, protection is obtained by a combination of:

– limitation of voltage or energy, or protective earthing (see Clauses 8.4);

– enclosing or guarding of energized circuits (see 5.9);

– insulation of adequate quality and construction (see 8.5).

The dielectric strength requirements are included to check the quality of the insulation material used at different places in the ME EQUIPMENT.

Subclause 8.1 – Fundamental rule of protection against electric shock

***Subclause 8.1* a)**

Insulation not complying with 8.8, spacing less than specified in 8.9, etc. are not MEANS OF PROTECTION, but they may nevertheless influence the voltages or LEAKAGE CURRENTS appearing on ACCESSIBLE PARTS. Measurements may therefore need to be made with such parts intact or bypassed, whichever is the worse case.

As there are in general no integrity requirements for signal connections, interruption of a functional earth connection has to be considered as a NORMAL CONDITION.

***Subclause 8.1* b)**

LEAKAGE CURRENTS are not generally measured in the SINGLE FAULT CONDITION of breakdown of BASIC INSULATION in CLASS I EQUIPMENT because either the LEAKAGE CURRENTS in this case flow only during the time before a fuse or OVER-CURRENT RELEASE operates or the use of an isolated power supply limits the LEAKAGE CURRENTS to safe values. Exceptionally, LEAKAGE CURRENTS are measured during short-circuiting of BASIC INSULATION in cases where there are doubts concerning the effectiveness of PROTECTIVE EARTH CONNECTIONS inside the ME EQUIPMENT (see 8.6.4 *b)*)

With regard to the presence of the MAXIMUM MAINS VOLTAGE on an unearthed ACCESSIBLE PART, see the rationales for 8.5.2.2 and 8.7.4.7 d).

If ME EQUIPMENT were configured as shown in Figure A9, interruption of the connection would result in excessive TOUCH CURRENT. This situation is therefore one of the SINGLE FAULT CONDITIONS that may need to be investigated.

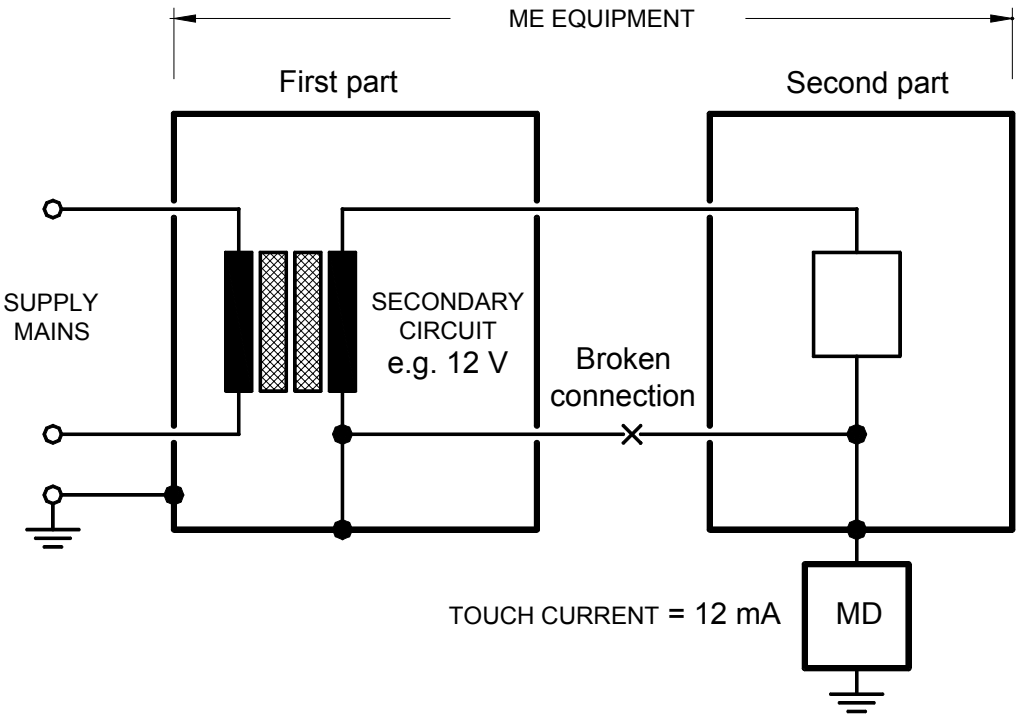


Figure A9 – Interruption of a power-carrying conductor between ME EQUIPMENT parts in separate ENCLOSURES

Subclause 8.3 – Classification of APPLIED PARTS

***Subclause 8.3* a)**

ME EQUIPMENT intended for DIRECT CARDIAC APPLICATION having one or more TYPE CF APPLIED PARTS may have one or more additional TYPE B APPLIED PARTS or TYPE BF APPLIED PARTS that may be applied simultaneously (see also 7.2.8).

Similarly ME EQUIPMENT may have a mixture of TYPE B APPLIED PARTS and TYPE BF APPLIED PARTS.

***Subclause 8.3* b)**

Most particular standards developed for kinds of ME EQUIPMENT that have PATIENT electrodes require the APPLIED PARTS to be TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS. For similar kinds of ME EQUIPMENT for which no particular standards are available, it is better to include such a requirement in this standard than to allow such APPLIED PARTS to be TYPE B APPLIED PARTS. The TYPE B APPLIED PART classification is mainly used, in practice, for PATIENT supporting ME EQUIPMENT such as X-ray tables, not for PATIENT electrodes.

***Subclause 8.3* d)**

Parts identified according to 4.4 as needing to be subject to the requirements for APPLIED PARTS (except for marking) will typically contact PATIENTS less frequently than APPLIED PARTS, so the benefits of electrical separation from earth would be less. However in some cases the RISK MANAGEMENT PROCESS may identify a need for such parts to satisfy the requirements for TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS. This requirement reflects the majority view of the National Committees that responded to an inquiry on this subject during the preparation of this edition.

Subclause 8.4.1 – *PATIENT CONNECTIONS INTENDED TO deliver current

This standard does not specify any limits for currents that are intended to produce a physiological effect in the PATIENT, but particular standards may do so. Any other currents flowing between PATIENT CONNECTIONS are subject to the specified limits for PATIENT AUXILIARY CURRENT.

Subclause 8.4.2 – ACCESSIBLE PARTS including APPLIED PARTS

***Subclause 8.4.2* b)**

It is presumed that TOUCH CURRENT can reach the PATIENT by chance contact through various paths, including a path via the OPERATOR. The limits for TOUCH CURRENT therefore apply to all ACCESSIBLE PARTS except PATIENT CONNECTIONS, which are covered by 8.4.2 a), and parts that satisfy the conditions specified in 8.4.2 c).

***Subclause 8.4.2* c)**

There is little or no justification for the difference in the second edition between the cases where there is a cover that is removable without a TOOL and where there is no cover. The limit values have been harmonized with IEC 60950-1: 2001 because Information Technology (IT) equipment is commonly used in ME SYSTEMS, and the values in IEC 60950-1 are not much different from those in the second edition of this standard. (60 V dc is the same, and 42.4 V peak is not much different from 25 V r.m.s.).

***Subclause 8.4.2* d)**

As well as parts that are determined to be ACCESSIBLE PARTS in accordance with 5.9, electrical contact with internal parts is supposed to be made with:

– a pencil or pen, held in a hand, simulated by a guided test pin;

– a necklace or similar pendant, simulated by a metal rod suspended over openings in a top cover;

– a screwdriver for adjustment of a preset control by the OPERATOR, simulated by an inserted metal rod.

Subclause 8.4.3 – *ME EQUIPMENT intended to be connected to a power source by a plug

The 45 μC limit is the same as that specified in IEC 60335-1, which is based on IEC 60479-1. It is comparable (though not exactly equivalent) to the 100 nF limit specified in the second edition of this standard. With regard to SAFETY there is no reason to specify a more stringent limit between the line and earth pins, as in the second edition.

Subclause 8.4.4 – *Internal capacitive circuits

The limit has been changed from the 2 mJ specified in the second edition of this standard to the same value as specified in the previous subclause, because whatever is safe for an OPERATOR, or even a PATIENT, who touches the pins of a MAINS PLUG is also safe for someone who opens an ACCESS COVER to gain access to the inside of ME EQUIPMENT.

Subclause 8.5.1 – *MEANS OF PROTECTION

This requirement may be fulfilled by one of the following methods:

1) PATIENT CONNECTIONS and other ACCESSIBLE PARTS are separated from parts different from earth potential by BASIC INSULATION only, but PROTECTIVELY EARTHED and have such a low internal impedance to earth that LEAKAGE CURRENTS do not exceed the allowable values in NORMAL CONDITION and SINGLE FAULT CONDITION.

2) PATIENT CONNECTIONS and other ACCESSIBLE PARTS are separated from parts different from earth potential by a PROTECTIVELY EARTHED metal part, which may be a fully enclosing metal screen.

3) PATIENT CONNECTIONS and other ACCESSIBLE PARTS are separated from parts different from earth potential by DOUBLE or REINFORCED INSULATION.

4) Impedances of components prevent the flow to PATIENT CONNECTIONS and other ACCESSIBLE PARTS of LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS exceeding the allowable values.

A survey of insulation paths is found in Annex M.

Previous editions of this standard also recognized the possibility of achieving separation by use of a PROTECTIVELY EARTHED intermediate circuit. However it is in general not possible for the whole of a circuit to be connected with very low impedance to the PROTECTIVE EARTH TERMINAL. Also, if one part of a circuit is earthed, other parts of the circuit are then different from earth potential, so have to be further separated from PATIENT CONNECTIONS and other ACCESSIBLE PARTS.

Air may form part or all of the BASIC INSULATION or SUPPLEMENTARY INSULATION.

In general DOUBLE INSULATION is preferable to REINFORCED INSULATION.

The first edition of this standard specified numerous pairs of parts between which separation was required, but the list was incomplete. It was expanded in the second edition but still remained incomplete, for example with regard to the situation illustrated in Figure A8.

Discussion in the working group at an early stage of the development of the third edition established that test houses actually have to identify the various circuits inside ME EQUIPMENT and the various points at which separation may be needed. This third edition therefore specifies this PROCEDURE explicitly.

The distinction between MEANS OF OPERATOR PROTECTION and MEANS OF PATIENT PROTECTION was introduced in response to concerns that the requirements of previous editions of this standard for insulation testing, CREEPAGE DISTANCES and AIR CLEARANCES were too stringent.

Many ME SYSTEMS incorporate equipment complying with IEC 60950-1. Also many kinds of ME EQUIPMENT incorporate parts, such as power supplies, that have been primarily designed for use in equipment complying with IEC 60950-1. This led some experts and National Committees to propose that the requirements of this standard be harmonized with IEC 60950-1 as far as possible.

However the test voltages and the minimum values of CREEPAGE DISTANCES and AIR CLEARANCES specified in IEC 60950-1 are derived from IEC 60664-1 and are based on assumptions about possible overvoltages in mains and other circuits, particularly the frequency of occurrence of various levels of overvoltage. According to the understanding of the working group experts who revised the corresponding requirements of this standard, compliance with the requirements of IEC 60664-1 or IEC 60950-1 leaves a RISK that transient insulation breakdown may occur with a frequency up to about once per year.

The probability that an OPERATOR will be in contact with a relevant part and with earth at the moment when breakdown occurs is low, so the RESIDUAL RISK is acceptable for ME EQUIPMENT, just as it is for IT equipment. However the probability that a PATIENT will be in contact with an APPLIED PART and with earth is significantly higher. The working group therefore decided that a larger margin of SAFETY should be applied where PATIENT SAFETY is concerned. However there was no reliable basis for deciding what additional margin might be applied to the values from IEC 60664-1, so the same values that were specified in the second edition of this standard have been retained for MEANS OF PATIENT PROTECTION.

For MEANS OF OPERATOR PROTECTION this revision of the standard allows the MANUFACTURER three options (see Figure A10). One option is to apply the requirements of IEC 60950-1 and to

identify the appropriate installation category and pollution degree. Alternatively, the MANUFACTURER can apply the values in the tables, which have been derived from IEC 60950-1 on the basis of reasonable assumptions about the installation category and pollution degree. The third option is to treat the MEANS OF OPERATOR PROTECTION as if it were a MEANS OF PATIENT PROTECTION.

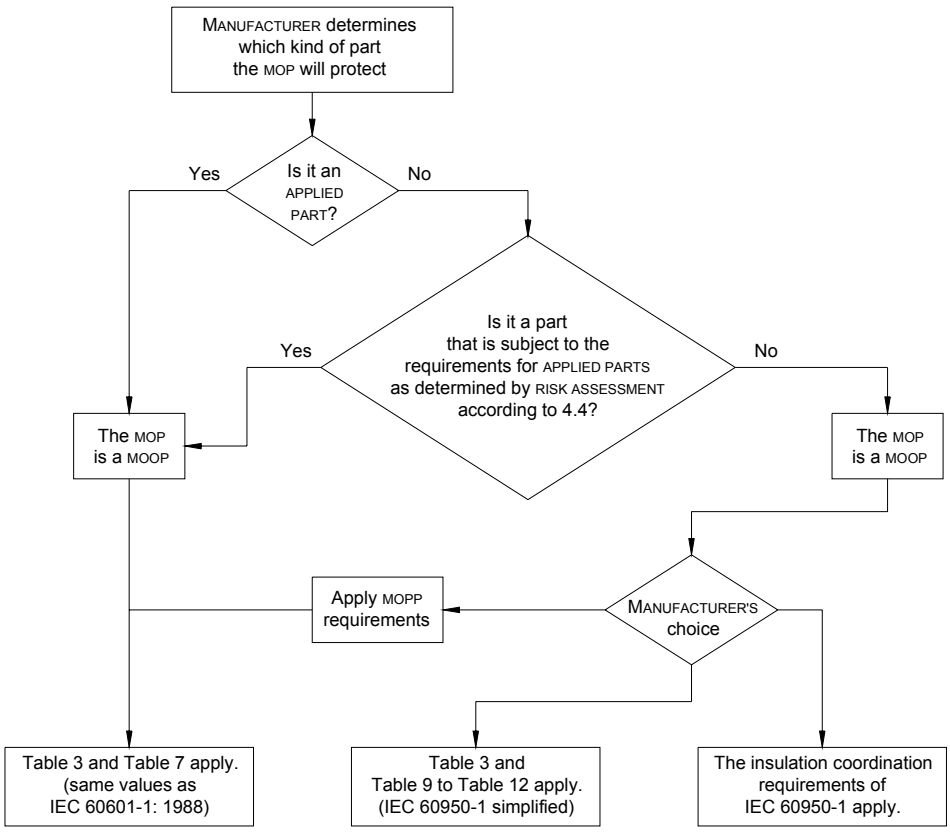


Figure A10 – Identification of MEANS OF PATIENT PROTECTION and MEANS OF OPERATOR PROTECTION

Subclause 8.5.2.1 – *F-TYPE APPLIED PARTS

The essential feature of an F-TYPE APPLIED PART is its separation from other parts. This subclause specifies and quantifies the necessary degree of separation.

The 500 V r.m.s. limit for protective devices was already specified in the first edition of this standard. The original rationale is not known, but this voltage corresponds to the highest RATED voltage specified in 4.8.

Subclause 8.5.2.2 – *Type B APPLIED PARTS

This requirement addresses the possibility that an unintended voltage originating from an external source becomes connected to a part of the ME EQUIPMENT. In the absence of appropriate separation between such a part and PATIENT CONNECTIONS, an excessive PATIENT LEAKAGE CURRENT could result.

According to subclause 17 *c)* of the second edition of this standard, this requirement applied to all APPLIED PARTS, but in many cases it no longer applies:

– For F-TYPE APPLIED PARTS, the isolation required by 8.5.2.1 also covers this situation (but TYPE BF APPLIED PARTS require an additional test, as explained in the rationale to 8.7.4.7 d)).

– The RISK cannot arise if either the ME EQUIPMENT part concerned or the PATIENT CONNECTIONS of a TYPE B APPLIED PART are PROTECTIVELY EARTHED. (Failure of the PROTECTIVE EARTH CONNECTION together with the appearance of the unintended voltage would be a double fault condition.)

– If the ME EQUIPMENT part concerned is physically contiguous with the APPLIED PART (for example a dental handpiece) the requirement does not apply if the RISK of contact with a source of voltage or LEAKAGE CURRENT above permitted limits is acceptably low.

Subclause 8.5.2.3 – *PATIENT leads

There are two sets of circumstances to guard against:

– firstly, for TYPE BF APPLIED PARTS and TYPE CF APPLIED PARTS, there should be no possibility of an accidental PATIENT-to-earth connection via any lead that may become detached from the ME EQUIPMENT; even for a TYPE B APPLIED PART an unwanted connection to earth may have an adverse effect on the operation of the ME EQUIPMENT;

– secondly, for all types of APPLIED PART, there should be no possibility of connecting the PATIENT accidentally to parts of ME EQUIPMENT or other conductive parts in the vicinity from which a current in excess of the allowable LEAKAGE CURRENT could flow.

An extreme case of the latter HAZARD would be a direct connection to the SUPPLY MAINS, resulting from insertion of the connector into a mains outlet or into the socket end of a DETACHABLE POWER SUPPLY CORD. It is essential to prevent this from occurring.

With certain combinations of PATIENT and MAINS CONNECTORS it will be possible to plug the PATIENT connector inadvertently into the mains socket.

This possibility cannot reasonably be removed by dimensional requirements as to do so would make single-pole connectors excessively large. Such an incident is rendered safe by the requirement for the PATIENT connector to be protected by insulation having a CREEPAGE DISTANCE of at least 1,0 mm and a dielectric strength of at least 1 500 V. The latter on its own would not suffice as 1 500 V protection could easily be achieved by thin plastic foil that would not stand up to daily wear or to being pushed, possibly repeatedly, into a mains socket. For this reason also it can be seen that the insulation should be durable and rigid.

The wording of this requirement was modified from that in the second edition of this standard to avoid use of the phrases “conductive connection”, which was eliminated as a defined term and “remote from the PATIENT. Both changes were a direct result of National Committee comments during the preparation of this edition.

According to the rationale in the second edition of this standard, the test in which the test finger is applied with a force of 10 N was intended “to check the strength of the insulating material”. This has now been supplemented by an explicit cross reference to 8.8.4.1.

In response to an enquiry , one National Committee stated that this test is “a mechanical test of the protective cover over the pin”; suggesting that the test was intended to apply specifically to one particular kind of connector design, in which the contact is surrounded by a movable sheath designed to allow contact with the correct mating connector but not with other parts.

During the development of the third edition of this standard, the question arose whether this test should be restricted to single-pole connectors, as in the second edition of this standard, or should apply to multi-pole connectors as well. Some multi-pole connectors are of similar shape to single-pole connectors and could similarly be inserted into a MAINS CONNECTOR, so

the same considerations of adequacy of insulation apply equally. On the other hand, typical kinds of multi-pole connectors that are in common use cannot be inserted into a MAINS CONNECTOR, but would fail this test if they were subject to it, because the test finger can easily touch their contacts, even without the application of a 10 N force. .

A further enquiry to the National Committees yielded a range of responses, with reasonable consensus on some questions but no consensus as to whether this test should apply to all connectors or should be restricted to single-pole connectors.

This test should certainly apply to a multi-pole connector that is of such shape and size that it could be inserted into a mains socket. In this case, the RISK is the same as with a single-pole connector.

Another reason for applying this test to some multi-pole connectors is that the test with the flat plate does not exhaustively assess the possibility of contact with conductive parts in the vicinity from which a current in excess of the allowable LEAKAGE CURRENT could flow. Almost any kind of connector, if detached from the ME EQUIPMENT or dropped, could possibly make contact with something besides the intended mating connector, but the RISK depends on the shape of the connector and the circumstances. In most cases the RISK is low. For example a typical “D” connector is likely to make contact with an earthed object only momentarily, whereas a straight pin may make contact for a prolonged period. However even prolonged contact with a metal object can cause a HAZARD only if it occurs in combination with a fault or abnormal situation that allows an excessive current to flow through the PATIENT. The RISK is in all cases much less than the RISK if the connector can make contact with a mains socket. The requirements of this standard should be formulated in relation to the RISK. The standard should minimise RISK to the PATIENT, while allowing MANUFACTURERS a reasonable range of choice of connectors.

“Any connector” should be understood to include multiple contact connectors, several connectors and connectors in series.

The dimension of 100 mm diameter is not in the least important and merely serves to indicate the scale of the flat surface. Any sheet of conductive material larger than this would be suitable.

Subclause 8.5.3 – *MAXIMUM MAINS VOLTAGE

Several requirements and tests of this standard relate to the possibility that an unintended voltage originating from an external source becomes connected to the PATIENT or to certain parts of the ME EQUIPMENT. The actual magnitude of such a voltage is unknown; but according to the second edition of this standard it was taken to be the highest RATED MAINS VOLTAGE, or for polyphase equipment the phase to neutral supply voltage. These values reflected a reasonable worst-case assumption that the actual unintended external voltage is unlikely to exceed the voltage of the SUPPLY MAINS in the location where the ME EQUIPMENT is used, and that ME EQUIPMENT is unlikely to be used in a location where the SUPPLY MAINS has a voltage higher than its highest RATED MAINS VOLTAGE. For INTERNALLY POWERED ME EQUIPMENT the value specified was (and remains) 250 V, because this is the highest commonly-encountered phase-to-neutral voltage in locations where ME EQUIPMENT is used.

In early drafts of this edition, the corresponding wording only referred to a.c. SUPPLY MAINS. This mistake was pointed out during the comment period. Discussion of this comment confirmed that the requirements should not depend on whether the SUPPLY MAINS is ac or dc, but revealed a further anomaly. If ME EQUIPMENT is specified for connection to ELV SUPPLY MAINS (for example 12 V in an ambulance) but not to any higher voltage SUPPLY MAINS, the external voltage assumed for test purposes would be only the ELV. Such ME EQUIPMENT could however be used in locations where a higher voltage SUPPLY MAINS is also installed. The wording has therefore been revised to remove this anomaly.

If ME EQUIPMENT has a highest RATED supply voltage less than 100 V, it will necessarily be used in a special location where that supply is available, and we do not know what other

supplies may also be present. Therefore the external voltage assumed for relevant tests is 250 V, as for INTERNALLY POWERED EQUIPMENT.

However ME EQUIPMENT having a highest RATED MAINS VOLTAGE of around 115 V is unlikely to be used in locations having higher voltage SUPPLY MAINS, so the external voltage assumed for relevant tests is equal to the highest RATED MAINS VOLTAGE, as in the second edition of this standard.

Subclause 8.5.4 – *REFERENCE VOLTAGE

The dielectric strength test voltages specified in Table 3 are appropriate for insulation that is normally subjected to a continuous REFERENCE VOLTAGE (*U*) and to transient overvoltages.

For insulation between two isolated parts or between an isolated part and an earthed part, the REFERENCE VOLTAGE (*U*) may in some cases be equal to the arithmetic sum of the highest voltages between any two points within both parts.

For DEFIBRILLATION-PROOF APPLIED PARTS, a test voltage deduced on the basis of a REFERENCE VOLTAGE (*U*) equal to the defibrillation peak voltage would be far too high for insulation that in NORMAL USE is exposed only occasionally to voltage impulses, normally shorter than 10 s and without additional overvoltage.

The special test described in 8.5.5 is considered to ensure sufficient protection against exposure to defibrillation pulses, no separate dielectric strength test being necessary.

Subclause 8.5.5 – *DEFIBRILLATION-PROOF APPLIED PARTS

One or the other of the defibrillation paddles may, by virtue of its clinical application, be connected to earth or at least referenced to earth.

When a defibrillator is used on the PATIENT, a HIGH VOLTAGE can thus be impressed either between one part of the ME EQUIPMENT and another, or between such parts collectively and earth. Therefore ACCESSIBLE PARTS should either be adequately isolated from PATIENT CONNECTIONS or, if the insulation of the PATIENT CONNECTIONS is protected by voltage-limiting devices, be PROTECTIVELY EARTHED.

Also, although SAFETY is not likely to be endangered, even in the case of incorrect use, in the absence of a particular standard it should generally be expected that APPLIED PART marked as DEFIBRILLATION-PROOF can be subjected to defibrillation voltages without any adverse effect on subsequent use of the ME EQUIPMENT in health care.

The tests ensure:

a) that any ACCESSIBLE PARTS of ME EQUIPMENT, PATIENT cables, cable connectors, etc. that are not PROTECTIVELY EARTHED will not deliver a hazardous level of charge or energy due to flashover of defibrillation voltage; and

b) that the ME EQUIPMENT will continue to function (at least with regard to ESSENTIAL PERFORMANCE) after exposure to defibrillation voltage.

The requirement and the test PROCEDURE refer to "any necessary time" stated in the ACCOMPANYING DOCUMENTS. There is no requirement for the ACCOMPANYING DOCUMENTS to include a statement of a recovery time, but if there is no statement the ME EQUIPMENT has to recover and deliver its ESSENTIAL PERFORMANCE immediately.

NORMAL USE includes the situation that a PATIENT is defibrillated while connected to the ME EQUIPMENT and, at the same time, the OPERATOR or another person is in contact with the ENCLOSURE. The possibility of this occurring at the same time as the SINGLE FAULT CONDITION of a defective PROTECTIVE EARTH CONNECTION is very unlikely and is therefore disregarded. However, interruption of functional earth connections is more probable, and is therefore required for these tests.

The SEVERITY of electric shock that a person receives when touching ACCESSIBLE PARTS during the discharge of a defibrillator is limited to a value (corresponding to a charge of 100 μC) which can be felt and which may be unpleasant, but which is not dangerous.

SIGNAL INPUT/OUTPUT PARTS are included, as signal lines to remote ME EQUIPMENT could otherwise carry energies that might be hazardous.

The test circuits of Figure 9 and Figure 10 of this standard are designed to simplify the test by integrating the voltage appearing across the test resistance (R_1).

The value of the inductance L in the test circuits of Figure 9 and Figure 10 is chosen to provide a shorter than normal rise time in order to test adequately the incorporated protective means.

Rationale for impulse test voltage

When a defibrillation voltage is applied to the thorax of a PATIENT, via externally applied paddles (or defibrillation electrodes), the body tissue of the PATIENT in the vicinity of the paddles and between the paddles becomes a voltage dividing system.

The voltage distribution can be gauged roughly using three-dimensional field theory but is modified by local tissue conductivity that is far from uniform.

If the electrode of another item of ME EQUIPMENT is applied to the PATIENT, roughly within the compass of the defibrillator paddles, the voltage to which such an electrode is subjected depends on its position but will generally be less than the on-load defibrillation voltage.

Unfortunately it is not possible to say how much less as the electrode in question may be placed anywhere in this area, including immediately adjacent to one of the defibrillator paddles. In the absence of a relevant particular standard, it must therefore be required that such an electrode and the ME EQUIPMENT to which it is connected will be able to withstand the full defibrillation voltage, and this must be the no-load voltage as one of the defibrillator paddles may not be making good contact with the PATIENT.

This standard therefore specifies 5 kV as the appropriate value in the absence of a relevant particular standard

Subclause 8.6 – *Protective earthing, functional earthing and potential equalization of ME EQUIPMENT

Generally, metal ACCESSIBLE PARTS of ME CLASS I EQUIPMENT shall be connected permanently and with sufficiently low impedance to the PROTECTIVE EARTH TERMINAL.

However, CLASS I ME EQUIPMENT may contain ACCESSIBLE PARTS that are so separated from the MAINS PART that, in NORMAL CONDITION and SINGLE FAULT CONDITION of the insulation of the MAINS PART or of the protective earthing, the LEAKAGE CURRENT from these ACCESSIBLE PARTS to earth does not exceed the value of Table 2 (see 8.7).

In this case, these ACCESSIBLE PARTS need not be connected to a PROTECTIVE EARTH TERMINAL but they may be connected to, for example, a FUNCTIONAL EARTH TERMINAL, or they may be left floating.

The separation of ACCESSIBLE PARTS from the MAINS PART may be obtained by DOUBLE INSULATION, by metallic screening or by a PROTECTIVELY EARTHED metal ACCESSIBLE PART, separating the ACCESSIBLE PARTS completely from the MAINS PART.

Metal parts behind a decorative cover that does not comply with the mechanical strength test are regarded as ACCESSIBLE PARTS.

Subclause 8.6.1 – *Applicability of requirements

PROTECTIVE EARTH CONNECTIONS that are only relevant to the SAFETY of OPERATORS are allowed to comply either with the requirements of this standard or with those of IEC 60950-1, but the latter alternative is not allowed for PROTECTIVE EARTH CONNECTIONS that are relevant to the SAFETY of both OPERATORS and PATIENTS.

Subclause 8.6.2 – *PROTECTIVE EARTH TERMINAL

These requirements are intended to ensure a reliable connection between the ME EQUIPMENT and the protective earthing system of the electrical installation.

Subclause 8.6.4 – *Impedance and current-carrying capability

Connections to moving parts, whether made by sliding contacts, by flexible wires or by any other means, may be more susceptible than ordinary FIXED connections to deterioration during the useful life of the ME EQUIPMENT. Therefore, they are not acceptable as PROTECTIVE EARTH CONNECTIONS unless their reliability is demonstrated.

***Subclause 8.6.4* a)**

PROTECTIVE EARTH CONNECTIONS can only perform their protective function if they are able to carry the fault current resulting from a failure in BASIC INSULATION.

Such a current is assumed to have sufficient amplitude to cause operation of protective devices in the electrical installation (fuses, circuit-breakers, earth leakage circuit-breakers and the like) in a reasonably short time.

It is therefore necessary to check both the impedance and the current-carrying capability of PROTECTIVE EARTH CONNECTIONS.

The minimum time required for the test current is intended to reveal any overheating of parts of the connection due to thin wiring or a bad contact. Such a “weak spot” may not be discovered by resistance measurement alone.

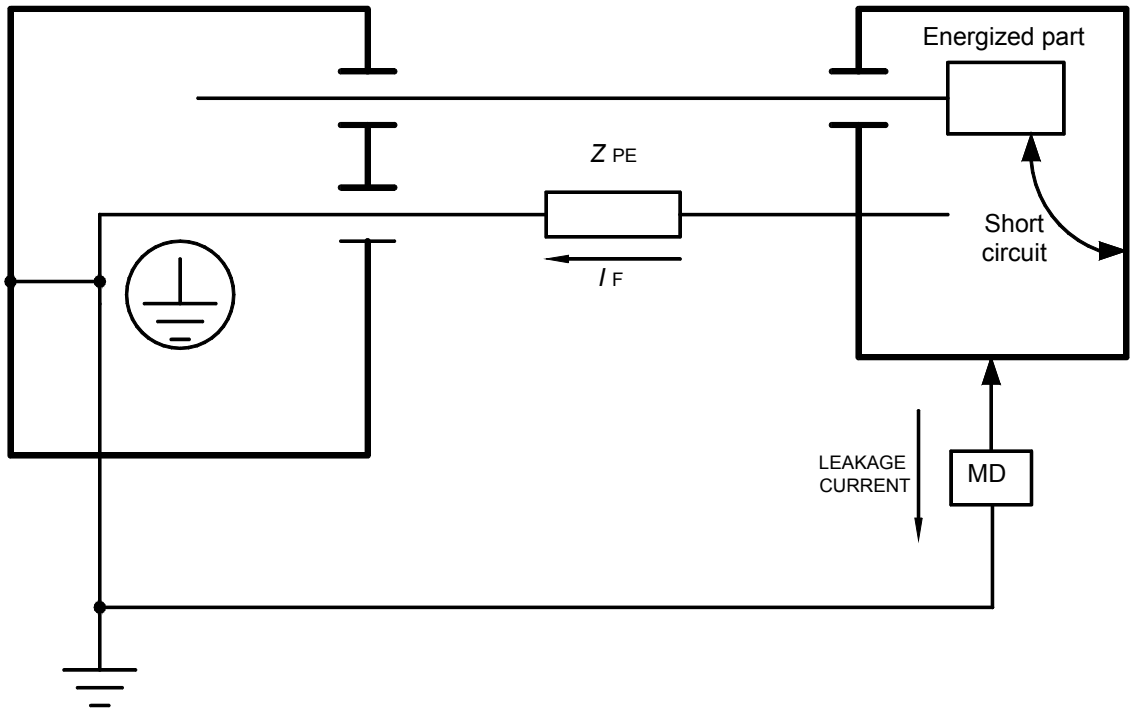
PROTECTIVE EARTH CONNECTIONS may have zones of higher impedance, for example due to oxidation of materials. Use of a current source with an unlimited voltage could prevent detection of such zones because of their ability to flash through. The impedance is therefore determined first, using a limited voltage.

If this voltage is sufficient to drive the specified test current through the total impedance, then this one test also serves to demonstrate the current-carrying capability of the connection. Otherwise an additional test is necessary, either using a higher voltage or by assessing the cross-sectional area of the connection by inspection.

***Subclause 8.6.4* b)**

The fault current may be limited to a relatively low value, because of inherent impedance or the characteristic of the power source, for example where the power system is not connected to earth or connected to it via a high impedance (see Figure A11).

In such cases the cross-section of the PROTECTIVE EARTH CONNECTION may be determined primarily by mechanical considerations.



6930

Legend

Z_{PE} = Impedance of PROTECTIVE EARTH CONNECTION in ohms (exceeding the limit specified in 8.6.4 *a)*).

I_F = Maximum continuous prospective fault current in amperes in the PROTECTIVE EARTH CONNECTION caused by a single failure of the insulation to earth.

MD Measuring device according to 8.7.4.4 (resistance = 1 kΩ).

NOTE The figure shows ME EQUIPMENT having a main ENCLOSURE and a remote part in a separate ENCLOSURE, as an example of a situation where the impedance of a PROTECTIVE EARTH CONNECTION may exceed the limit specified in 8.6.4 *a)*: however this situation may also exist in ME EQUIPMENT having a single ENCLOSURE.

6931 **Figure A11 – Allowable protective earth impedance where the fault current is limited**

6932 **Subclause 8.6.7 – *POTENTIAL EQUALIZATION CONDUCTOR**

6933 Medically used rooms in most countries have no facilities for the use of detachable POTENTIAL
6934 EQUALIZATION CONDUCTORS. This standard therefore does not require any means to be
6935 provided for the connection of a POTENTIAL EQUALIZATION CONDUCTOR to the ME EQUIPMENT. If
6936 however the ME EQUIPMENT does have such means, for use in locations where POTENTIAL
6937 EQUALIZATION CONDUCTORS are used, the appropriate requirements have to be satisfied.

6938 **Subclause 8.6.9 – *CLASS II ME EQUIPMENT**

6939 This requirement allows a CLASS II ME EQUIPMENT to have a connection to protective earth for
6940 functional reasons only. Green/yellow is required to avoid confusion in installation. The
6941 allowance does not degrade the degree of protection against electric shock.

6942 **Subclause 8.7.2 – *SINGLE FAULT CONDITIONS**

6943 Short circuiting of one part of DOUBLE INSULATION would be likely to increase LEAKAGE CURRENT
6944 by a factor of the order of 2. In some cases the test could be difficult to carry out and, as the
6945 allowable values for SINGLE FAULT CONDITION are five times those for NORMAL CONDITION, the
6946 test would not provide useful information.

Subclause 8.7.3 – Allowable values – and Table 2

The value of electric current flowing in the human or animal body that may cause a certain degree of stimulation varies from individual to individual, according to the way in which the connection to the body is made and according to the frequency of the current applied and its duration.

Currents of low frequency flowing directly into or through the heart considerably increase the danger of ventricular fibrillation. For currents of medium or high frequency, the RISK of electric shock is less or negligible, but the RISK of burning remains.

The sensitivity of the human or animal body to electric currents, depending upon the degree and nature of contact with the ME EQUIPMENT, leads to a system of classification reflecting the degree and quality of protection provided by the APPLIED PARTS (classified as TYPE B APPLIED PARTS, TYPE BF APPLIED PARTS and TYPE CF APPLIED PARTS). TYPE B APPLIED PARTS and TYPE BF APPLIED PARTS are generally suitable for applications involving external or internal contact with the PATIENT, excluding the heart. TYPE CF APPLIED PARTS are suitable for DIRECT CARDIAC APPLICATIONS with regard to LEAKAGE CURRENT.

In conjunction with this classification, the requirements for allowable LEAKAGE CURRENT have been formulated. The absence of sufficient scientific data concerning the sensitivity of the human heart for currents causing ventricular fibrillation still presents a problem.

Nevertheless, the publication of the first edition of this standard in 1977 provided engineers with data enabling them to design ME EQUIPMENT; and these requirements have proved over the years since then to ensure a very low level of RISK without being too onerous for designers.

The requirements for LEAKAGE CURRENT were formulated taking into account:

a) that the possibility of ventricular fibrillation is influenced by factors other than only electrical parameters;

b) that the values for allowable LEAKAGE CURRENTS in SINGLE FAULT CONDITION should be as high as is considered safe, taking into account statistical considerations, in order not to present designers with unnecessary difficulties, and

c) that values for NORMAL CONDITION are necessary to create a safe condition in all situations by providing a sufficiently high SAFETY factor with respect to SINGLE FAULT CONDITIONS.

The measurement of LEAKAGE CURRENTS has been described in a way that enables the use of simple instruments, avoiding different interpretations of a given case and indicating possibilities for periodic checking by the RESPONSIBLE ORGANIZATION.

Allowable values of LEAKAGE and PATIENT AUXILIARY CURRENTS for a.c. and d.c. composite waveforms with frequencies up to and including 1 kHz take account of the following considerations.

a) In general the RISK of ventricular fibrillation or pump failure increases with the value or duration, up to a few seconds, of the current passing through the heart. Some areas of the heart are more sensitive than others. That is, a current that causes ventricular fibrillation when applied to one part of the heart may have no effect when applied to another part of the heart.

b) The RISK is highest and approximately equal for frequencies in the 10 to 200 Hz range. It is lower, by a factor of nearly 5, at d.c. and by approximately 1,5 at 1 kHz. Beyond 1 kHz, the RISK decreases rapidly.[3)] The values in Table 2 apply to currents measured with the measuring device shown in Figure 11 a), which automatically allows for the reduced sensitivity at higher frequencies. SUPPLY MAINS frequencies of 50 and 60 Hz are in the range of highest RISK.

[3)] See reference 1 on page 225.

c) Although as a general rule requirements in a general standard are less restrictive than the requirements in particular standards, some of the allowable values in Table 2 have been set at such a value that:

– the majority of ME EQUIPMENT types can comply, and

– they can be applied to most ME EQUIPMENT types (existing or future) for which no particular standards exist.

EARTH LEAKAGE CURRENT

The EARTH LEAKAGE CURRENT flowing through the PROTECTIVE EARTH CONDUCTOR is not a HAZARD per se. The PATIENT and OPERATOR are protected by specifying appropriately low values for PATIENT LEAKAGE CURRENT and TOUCH CURRENT in NORMAL CONDITION and in relevant SINGLE FAULT CONDITIONS including interruption of the PROTECTIVE EARTH CONDUCTOR. However, an excessive EARTH LEAKAGE CURRENT could pose a possible problem for the installation's earthing system and any circuit breakers operated by current imbalance detectors.

See also IEC 60364-7-707.

TOUCH CURRENT

The limits are based on the following considerations:

a) The TOUCH CURRENT of ME EQUIPMENT is subject to the same values regardless of the type(s) of APPLIED PARTS, if any, because even ME EQUIPMENT that does not itself have a TYPE CF APPLIED PART may be used in situations where intracardiac PROCEDURES are performed.

b) Although TOUCH CURRENT flows from parts other than PATIENT CONNECTIONS, it can reach the PATIENT by chance contact through various paths, including a path via the OPERATOR.

c) The current density created at the heart by current entering the chest is 50 $\mu A/mm^2$ per ampere.[4)] The current density at the heart for 500 μA (maximum allowable value in SINGLE FAULT CONDITION) entering the chest is 0,025 $\mu A/ mm^2$, well below the level of concern.

d) The probability of the TOUCH CURRENT flowing through the heart and causing ventricular fibrillation or pump failure.

TOUCH CURRENT could conceivably reach an intracardiac site if careless PROCEDURES are used in handling intracardiac conductors or fluid filled catheters. Such devices should always be handled with great care and always with dry rubber gloves. The following RISK ANALYSIS is based on pessimistic assumptions about the degree of care exercised.

The probability of a direct contact between an intracardiac device and an ME EQUIPMENT ENCLOSURE is considered to be very low, perhaps 1 in 100 PROCEDURES. The probability of an indirect contact via the medical staff is considered to be somewhat higher, say 1 in 10 PROCEDURES. The maximum allowable LEAKAGE CURRENT in NORMAL CONDITION is 100 μA, which itself has a probability of inducing ventricular fibrillation of 0,05. If the probability of indirect contact is 0,1 then the overall probability is 0,005. Although this probability would appear undesirably high, it should be recalled that with correct handling of the intracardiac device this probability can be reduced to that for mechanical stimulation alone, 0,001.

The probability of the TOUCH CURRENT rising to the maximum allowable level of 500 μA (SINGLE FAULT CONDITION) is considered to be 0,1 in departments with poor maintenance PROCEDURES. The probability of this current causing ventricular fibrillation is taken as 1. The probability of accidental contact directly with the ENCLOSURE is, as above, considered

[4)] See reference 8 on page 225.

as 0,01, giving an overall probability of 0,001, equal to the mechanical stimulation alone probability.

The probability of ENCLOSURE LEAKAGE CURRENT at the maximum allowable level of 500μA (SINGLE FAULT CONDITION) being conducted to an intracardiac device via the medical staff is 0,01 (0,1 for the SINGLE FAULT CONDITION, 0,1 for accidental contact). Since the probability of this current causing ventricular fibrillation is 1, the overall probability is also 0,01. Again this probability is high; however it can be brought down to the mechanical stimulation alone probability of 0,001 by adequate PROCEDURES.

d) The probability of the TOUCH CURRENT being perceptible to the PATIENT.

The probability of 500 μA being perceptible is 0,01 for men and 0,014 for women when using grip electrodes with intact skin.[5),6)] There is a higher perceptibility for current passing through mucous membranes or skin punctures.[7)] Since distribution is normal,), there will be a probability that some PATIENTS will perceive very small currents. One person is reported to have sensed 4 μA passing through a mucous membrane.[8)]

PATIENT LEAKAGE CURRENT

The allowable value of PATIENT LEAKAGE CURRENT for ME EQUIPMENT with TYPE CF APPLIED PARTS in NORMAL CONDITION is 10 μA, which has a probability of 0,002 for causing ventricular fibrillation or pump failure when applied through small areas to an intracardiac site.

Even with zero current, it has been observed that mechanical irritation can produce ventricular fibrillation.[9)] A limit of 10 μA is readily achievable and does not significantly increase the RISK of ventricular fibrillation during intracardiac PROCEDURES.

The 50 μA maximum allowed in SINGLE FAULT CONDITION for ME EQUIPMENT with TYPE CF APPLIED PARTS is based on a value of current that has been found, under clinical conditions, to have a very low probability of causing ventricular fibrillation or interference with the pumping action of the heart.

For catheters 1,25-2 mm diameter likely to contact the myocardium, the probability of 50 μA causing ventricular fibrillation is near 0,01 (see Figure A12 and its explanation). Small cross-section area (0,22 mm^2 and 0,93 mm^2) catheters used in angiography have higher probabilities of causing ventricular fibrillation or pump failure if placed directly on sensitive areas of the heart.

The overall probability of ventricular fibrillation being caused by PATIENT LEAKAGE CURRENT in SINGLE FAULT CONDITION is 0,001 (0,1 for probability of SINGLE FAULT CONDITION, 0,01 probability of 50 μA causing ventricular fibrillation) equal to the probability for mechanical stimulation alone.

The 50 μA current allowed in SINGLE FAULT CONDITION is not likely to result in a current density sufficient to stimulate neuromuscular tissues nor, if d.c., cause necrosis.

For ME EQUIPMENT with TYPE B APPLIED PARTS and TYPE BF APPLIED PARTS where the maximum allowable PATIENT LEAKAGE CURRENT under SINGLE FAULT CONDITION is 500 μA, the same rationale applies as that for ENCLOSURE LEAKAGE CURRENT since this current will not flow directly to the heart.

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5) See reference 1 on page 225.

6) See reference 2 on page 225.

7) See reference 2 on page 225.

8) See reference 2 on page 225.

9) See reference 4 on page 225.

As the existence of an earth connection to a PATIENT is a NORMAL CONDITION, not only PATIENT AUXILIARY CURRENT but also PATIENT LEAKAGE CURRENT may flow for a prolonged period. A very low value of direct current is therefore necessary to avoid tissue necrosis, regardless of the classification of the APPLIED PART.

The appearance of MAINS VOLTAGE, from a low-impedance source, on the PATIENT CONNECTIONS of an F-TYPE APPLIED PART would have to be caused by a double failure of protective means in other ME EQUIPMENT, simultaneously connected to the PATIENT and complying with this standard or another IEC standard, or by a single failure of protective means in equipment not complying with a standard. As such this condition is extremely unlikely in good medical practice.

However the appearance of a lesser voltage, or of a LEAKAGE CURRENT from a source having an open-circuit voltage of the order of MAINS VOLTAGE, is possible.

Since the main SAFETY feature of ME EQUIPMENT with an F-TYPE APPLIED PART is that the PATIENT is not earthed by the connection to the ME EQUIPMENT, the electrical separation of an F-TYPE APPLIED PART from earth must have a minimum quality. This is assured by the requirement that, even if a hypothetical voltage of supply frequency and equal to the highest supply voltage to earth present in the location where the ME EQUIPMENT is used would appear on the PATIENT CONNECTIONS, the limit for the PATIENT LEAKAGE CURRENT would not be exceeded.

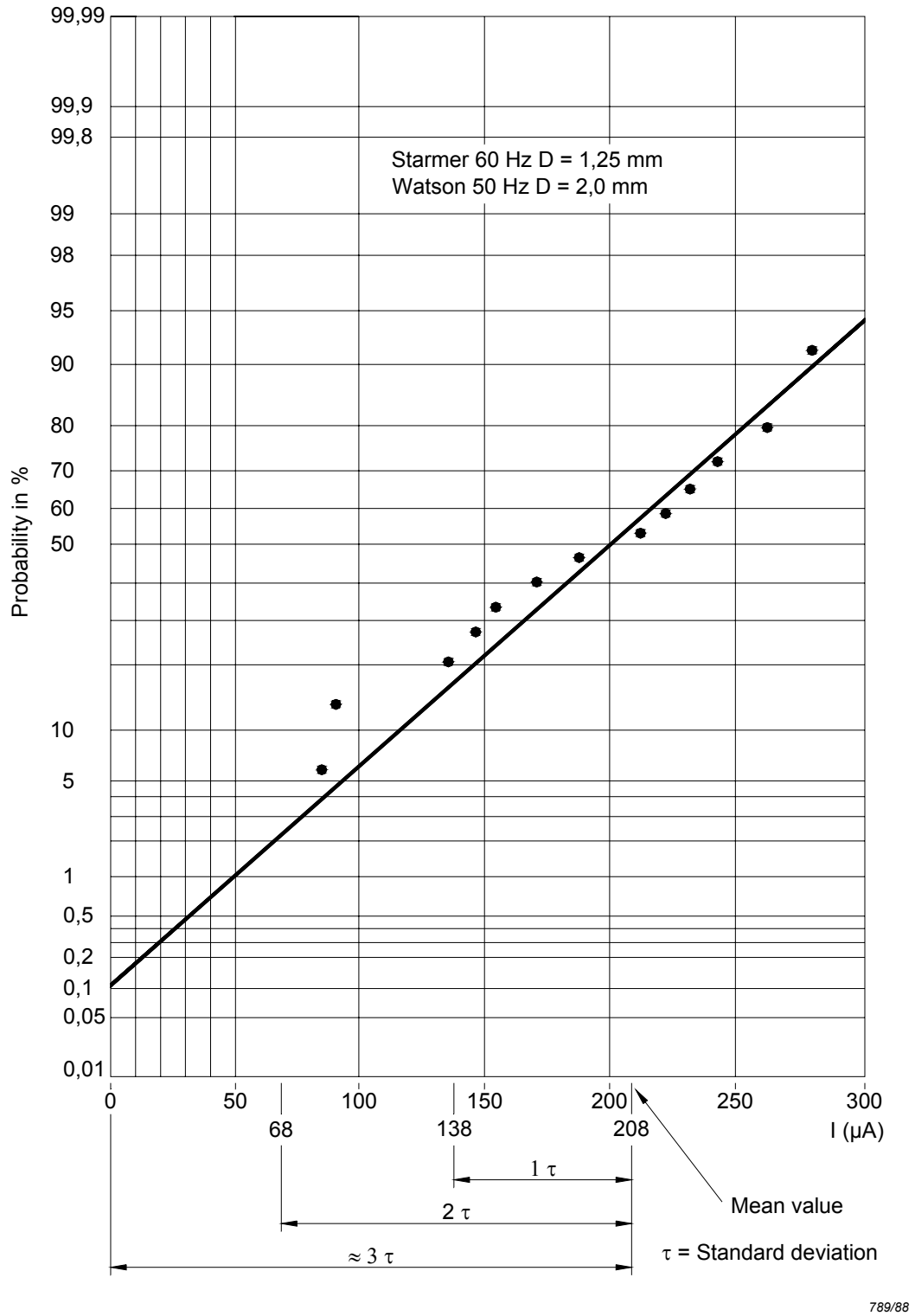
For TYPE CF APPLIED PARTS, the PATIENT LEAKAGE CURRENT will be limited to 50 μA, no worse than the previously discussed SINGLE FAULT CONDITION.

For TYPE BF APPLIED PARTS the maximum PATIENT LEAKAGE CURRENT under these conditions is 5 mA. Even this value entering the chest would produce only a current density at the heart of 0,25 $\mu A/mm^2$. This current would be very perceptible to the PATIENT, however the probability of its occurrence is very low. The RISK of harmful physiological effects is small and the MAXIMUM MAINS VOLTAGE used for this test represents a worst case, more severe than is likely to arise in practice.

PATIENT AUXILIARY CURRENT

The allowable values for PATIENT AUXILIARY CURRENT are based on similar considerations to those for PATIENT LEAKAGE CURRENT. They apply regardless of whether the PATIENT AUXILIARY CURRENT is necessary for the functioning of the ME EQUIPMENT (e.g. impedance plethysmographs) or incidental to its functioning. Lower values are given for d.c. to prevent tissue necrosis with long-term application.

7111 NOTE Refer to original papers by Starmer and Watson for interpretation of data.



7112

7113 **Figure A12 – Probability of ventricular fibrillation**

Explanation of Figure A12

Articles by Starmer[10)] and Watson[11)] provide data on ventricular fibrillation caused by 50 Hz and 60 Hz currents applied directly to the hearts of human populations with cardiac disease. Fibrillation probability was obtained as a function of the electrode diameter and the magnitude of the current. For electrodes of 1,25 mm and 2 mm diameter and currents up to 0,3 mA, the distribution appears normal. Accordingly, it has been extrapolated to encompass the values commonly used in assessing PATIENT RISK (values noted on Figure A12). From this extrapolation, it is seen that:

a) any value of current, however small, has some probability of causing ventricular fibrillation, and

b) the commonly used values have low probabilities, ranging from approximately 0,002 to 0,01.

Since ventricular fibrillation is governed by many factors (PATIENT condition, probability of current entering a more sensitive area of the myocardium, probability of fibrillation as a function of current or current density, physiology, electric field, etc.), it is reasonable to use statistics in determining the possibility of RISK for the multiple conditions.

References

1) Charles F. Dalziel; Re-evaluation of lethal electric currents, IEEE Transactions on Industry and General Applications, Vol. 1 GA–4, No. 5, September/October 1968.

2) Kohn C. Keesey, Frank S. Letcher; Human thresholds of electric shock at power transmission frequencies; Arch. Environ. Health, Vol. 21, October 1970.

3) O. Z. Roy; 60 Hz Ventricular fibrillation and rhythm thresholds and the non-pacing intracardiac catheter; Medical and Biological Engineering, March 1975.

4) E. B. Rafferty, H. L. Green, M. H. Yacoub; Disturbances of heart rhythm produced by 50 Hz leakage currents in human subjects; Cardiovascular Research; Vol. 9, No. 2, pp. 263-265, March 1975.

5) H. L. Green; Electrical Safety Symposium Report; Department of Health and Social Security; United Kingdom, October 1975.

6) C. Frank Starmer, Robert E. Whalen; Current density and electrically induced ventricular fibrillation; Medical Instrumentation; Vol. 7, No. 1, January-February 1973.

7) A. B. Watson, J. S. Wright; Electrical thresholds for ventricular fibrillation in man, Medical Journal of Australia; June 16, 1973.

8) A. M. Dolan, B. M. Horacek, P. M. Rautaharaju; Medical Instrumentation (abstract), January 12, 1953, 1978.

Subclause 8.7.3 – Allowable values

***Subclause 8.7.3* e)**

A current of 10 mA will produce no sensation of heating with a typical PATIENT CONNECTION with a contact area of the order of 1 cm^2, but a current a few times higher than this would produce a burn. The RISK of a burn depends on the magnitude of the current but not on its frequency, so the current has to be measured with a non-frequency-weighted device, such as a device similar to that shown in Figure 11 a) but without C_1 and R_1.

[10)] See reference 6 on page 225.

[11)] See reference 7 on page 225.

Subclause 8.7.4.2 – *Measuring supply circuits

For correct results of LEAKAGE CURRENT measurements, it is essential to have a common reference point within the measuring circuit. The point also has to be electrically FIXED referenced to all parts of the circuit. Also the measured LEAKAGE CURRENT may be different according to the particular supply configuration. For example, if ME EQUIPMENT that is specified for connection to a supply having one side at earth potential is connected instead to a supply having two symmetrical phases (such as a 230 V supply in the USA) the measured LEAKAGE CURRENT will be much lower than the worst case. If the installed SUPPLY MAINS of the room where the measurements are made does not represent the worst case, a specific supply circuit has to be established. This can be done by using an isolating transformer with the appropriate point in the SECONDARY CIRCUIT connected to the reference point. Accurate and reproducible results when making LEAKAGE CURRENT measurements can also be obtained without an isolating transformer. However this would depend on the quality of the SUPPLY MAINS used for the measurements. Factors that need to be considered would include transients, interference signals and voltage differences between neutral and earth in the measuring circuit.

The earth symbols in the Figures represent this common reference point, which is not connected to the protective earth of the SUPPLY MAINS. Such a separate reference point may provide additional protection for the person carrying out the measurements.

A variable-voltage transformer is necessary to provide 110 % of the RATED supply voltage to the ME EQUIPMENT. Although it would be possible to test with the supply MAINS VOLTAGE normally present in the test room and to multiply the measured LEAKAGE CURRENT values by the appropriate factor, this would not always produce the same result as testing with 110 % of the RATED supply voltage, particularly with ME EQUIPMENT that includes a switched-mode power supply.

The switches S_1 or $S_1 + S_2$ or $S_1 + S_2 + S_3$ in Figure F1 to Figure F4 (inclusive) may be omitted and the interruptions of the relevant leads may be obtained by other means.

Instead of the single or polyphase isolating transformers with adjustable output voltage(s), as shown in Figure F1 to Figure F5 (inclusive), a combination of an isolating transformer with set output voltage and an auto-transformer with adjustable output voltage may be used.

Subclause 8.7.4.3 – Connection to the measuring supply circuit

Although it is not unlikely that ME EQUIPMENT is used while placed on or in an earthed metal environment, such a position would be rather difficult to describe in a way that test results would become reproducible. The advice in the note in 8.7.4.3 d) 1) is therefore to be considered as a convention.

The likelihood that PATIENT cables have a significant capacitance to earth is usually important and of considerable influence on test results. A position providing reproducible results is therefore prescribed.

Subclause 8.7.4.5 – *Measurement of the EARTH LEAKAGE CURRENT

The measuring device represents a measuring method that takes into account the physiological effect of a current through the human body, including the heart, as well as the possibility of a low impedance contact between a PATIENT CONNECTION and the PATIENT. Although IEC 60990 specifies some measuring devices for general use, none of these would be appropriate for measuring PATIENT LEAKAGE CURRENT. As the measuring device of the 2nd edition is being retained for that purpose, it is most convenient to use the same device for all LEAKAGE CURRENT measurements, apart from the measurement of currents or current components with frequencies exceeding 1 kHz in relation to the 10 mA limit specified in 8.7.3 d).

Subclause 8.7.4.6 – *Measurement of the TOUCH CURRENT

Where metal foil is to be applied to an ENCLOSURE made of insulating material, intimate contact may be achieved by pressing the foil against the insulating material with a pressure of approximately 5 kPa (0,5 N/cm^2).

Subclause 8.7.4.7 – Measurement of the PATIENT LEAKAGE CURRENT

Subclause 8.7.4.7 b)

This test confirms that the separation between the PATIENT CONNECTIONS and other parts is adequate to limit the PATIENT LEAKAGE CURRENT to the allowed value when an external voltage is present.

If the APPLIED PART can be disconnected from the ME EQUIPMENT, it is possible that the contacts of its connector could touch an earthed object, but that situation is covered by the tests of 8.5.2.3, not by 8.7.4.7 b), which applies to the ME EQUIPMENT and the APPLIED PART together.

Subclause 8.7.4.7 c)

Some of the tests specified in the second edition of this standard related to the possible presence of MAINS VOLTAGE on a SIGNAL INPUT PART or a SIGNAL OUTPUT PART (as defined in that edition, now covered by the combined term SIGNAL INPUT/OUTPUT PART). There were various exclusions, but if none of the exclusions applied this condition was regarded as a SINGLE FAULT CONDITION. The assumption made in this third edition is that, if the ACCOMPANYING DOCUMENTS place no restrictions on what other equipment is allowed to be connected to the SIGNAL INPUT/OUTPUT PART, the presence of the MAXIMUM MAINS VOLTAGE should be regarded as a NORMAL CONDITION.

Subclause 8.7.4.7 d)

The test with an external voltage applied to unearthed metal ACCESSIBLE PARTS reflects the requirement in 8.5.2.2 for isolation between such parts and unearthed PATIENT CONNECTIONS of TYPE B APPLIED PARTS.

For TYPE BF APPLIED PARTS this test applies as well as the test of *8.7.4.7 b),* even though both test the isolation between the PATIENT CONNECTIONS and other parts, because the PATIENT LEAKAGE CURRENT may not be the same in these two situations and different limit values apply.

As explained in the rationale to 8.7.3, the presence of the MAXIMUM MAINS VOLTAGE on a PATIENT represents a worst case, more severe than is likely to arise in practice, and the allowable PATIENT LEAKAGE CURRENT for a TYPE BF APPLIED PART in this situation is 5 mA. The Italian National Committee pointed out that the application of MAINS VOLTAGE to an unearthed ACCESSIBLE PART could therefore cause a PATIENT LEAKAGE CURRENT of up to 5 mA to flow from the PATIENT CONNECTIONS of a TYPE BF APPLIED PART; whereas in the same situation a TYPE B APPLIED PART (which in general offers a lower level of SAFETY) was allowed only 500 µA. In order to resolve this anomaly, the test of 8.7.4.7 d), with 110 % of the MAXIMUM MAINS VOLTAGE on unearthed ACCESSIBLE PARTS, also applies to TYPE BF APPLIED PARTS, and in this condition the allowable PATIENT LEAKAGE CURRENT is the general 500 µA value for SINGLE FAULT CONDITION.

There is no need to perform both tests with TYPE CF APPLIED PARTS because for these the same allowable value of 50 µA applies to the PATIENT LEAKAGE CURRENT in SINGLE FAULT CONDITION and in the test condition with 110 % of the MAXIMUM MAINS VOLTAGE on ACCESSIBLE PARTS.

Subclause 8.7.4.8 – *Measurement of the PATIENT AUXILIARY CURRENT

Care should be taken that the capacitance of the measuring device and its connecting leads to earth and to the body of the ME EQUIPMENT is kept as low as possible.

Instead of an isolating transformer T_2 with an adjustable output voltage, a combination of an isolating transformer with a set output voltage and an auto-transformer with an adjustable output voltage may be used.

Subclause 8.7.4.9 – *ME EQUIPMENT with multiple PATIENT CONNECTIONS

This requirement was introduced in the second amendment to the second edition of this standard. It addresses a RISK that can arise, for example, with equipment for measuring physiological signals where an amplifier drives one electrode to reduce common-mode interference. If one of the sensing electrodes is disconnected from the PATIENT and picks up a large voltage at mains frequency, the amplifier may drive a large current into the PATIENT in a vain attempt to cancel the interference.

The requirement represents a compromise between requiring extensive testing, which with most ME EQUIPMENT would yield no useful information, and having no specific requirement to address this RISK.

Subsequently IEC 60601-2-49, Particular requirements for the SAFETY of multifunction PATIENT monitoring equipment, introduced a comprehensive set of tests, to be performed on all equipment within the scope of that standard. These include measurement of what is termed "PART LEAKAGE CURRENT" in that standard: this is the current flowing between the PATIENT CONNECTIONS of one function and the PATIENT CONNECTIONS of other function(s), which is covered in this edition of the general standard by the revised definition of PATIENT AUXILIARY CURRENT.

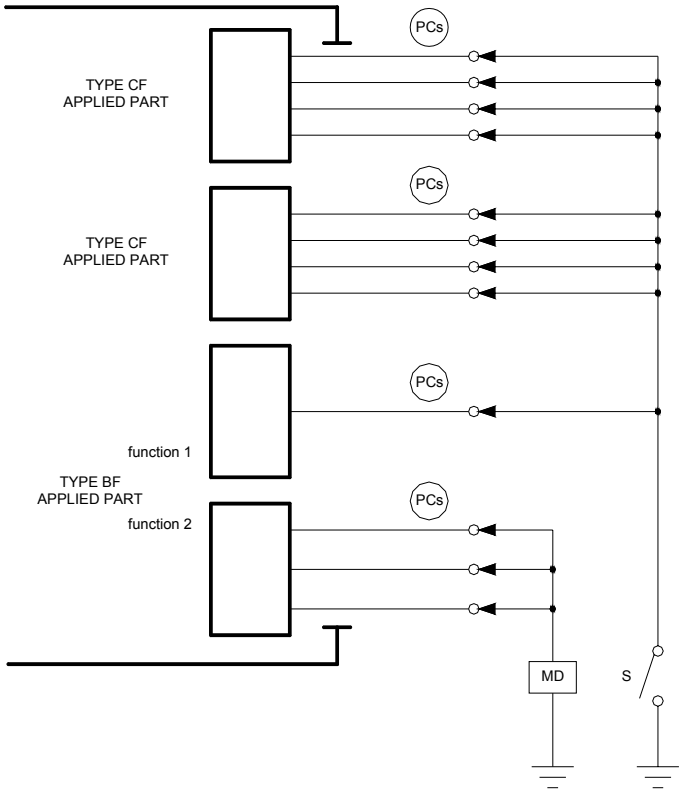
Consideration was given to incorporating these tests in this general standard, but it was decided that such specific testing should be left to particular standards. The scenarios to which they relate, such as having the PATIENT CONNECTIONS of one function in use and connected to the PATIENT while the PATIENT CONNECTIONS of another function are not in use and may make contact with earth or other objects, are likely to arise with multifunction PATIENT monitoring equipment but unlikely with most other kinds of ME EQUIPMENT.

Figure A13, based on Figure KK.101 of IEC 60601-2-49, shows an example of measuring the PATIENT LEAKAGE CURRENT from one function of a TYPE BF APPLIED PART while the PATIENT CONNECTIONS of another function of the same APPLIED PART and of two TYPE CF APPLIED PARTS are either floating or earthed.

Subclause 8.8.1 – *General

Care should be taken that the voltage applied to a REINFORCED INSULATION does not overstress either of the MEANS OF PROTECTION in the ME EQUIPMENT. If there are multiple paths between the same points, these may need to be tested separately. There may, for example, be one path from the MAINS PART to a PATIENT CONNECTION that has BASIC INSULATION plus a PROTECTIVE EARTH CONNECTION plus PATIENT CONNECTIONS isolation as required by 8.5.2.1, and a parallel path having REINFORCED INSULATION. ME EQUIPMENT parts may need to be disconnected to allow the REINFORCED INSULATION to be tested without overstressing the separate insulation of the MAINS PART or the PATIENT CONNECTIONS.

This may be avoided, for example in the case of a transformer, by the use of a voltage divider with a tapping point connected to the core or some other suitable connecting point to ensure the correct voltage division over the actual insulations, or by the use of two test transformers, correctly phased.



Legend

PCs — PATIENT CONNECTION

S — Switch to connect/disconnect PATIENT CONNECTION to/from earth

Figure A13 – ME EQUIPMENT with multiple PATIENT CONNECTIONS

Subclause 8.8.2 – *Distance through solid insulation or use of thin sheet material

The second edition of this standard placed no restrictions on the thickness of solid insulation, except as specified in 57.9.4 e) for transformers and for the need for all insulation covered by Clause 20 to be thick enough to pass the dielectric strength test. A very thin film of insulating material might pass that test but might not provide reliable insulation in all production items over their useful life.

Some National Committee comments during the development of this edition proposed introducing relevant requirements derived from IEC 60950-1 to address this omission. Both WG 14 (Testing) and WG16 (Electrical hazards) recommended accepting these proposals.

These requirements have been included in IEC 60950-1 for many years without causing problems. They should not be onerous in practice for ME EQUIPMENT, and indeed most ME EQUIPMENT designed according to the previous editions of this standard would have satisfied them.

The requirements that have been introduced are intended to be technically equivalent to those of IEC 60950-1, but the editorial structure has been changed for clarity, as follows.

– IEC 60950-1 specifies a general requirement for distance through insulation, with an exception for voltages up to 71 V. This has been changed to state explicitly that the requirement applies above 71 V.

– IEC 60950-1 specifies an exception from the requirement for distance through insulation where the requirements for thin sheet material apply, as set out in another subclause, but

that subclause does not refer explicitly to the 71 V limit. This has been made explicit by stating the requirements for thin sheet material as an alternative to the thickness requirement, under the same introductory wording.

– IEC 60950-1 specifies that “Insulation in thin sheet materials is permitted . . provided that” certain conditions are satisfied. This has been changed to an explicit requirement that insulation in thin sheet materials shall satisfy these conditions.

– IEC 60950-1 requires that insulation in thin sheet materials “is used within the equipment ENCLOSURE”. However the ENCLOSURE as defined in this standard includes all outer surfaces, including the surfaces of cables, APPLIED PARTS, etc. The requirement has therefore been rephrased.

Elsewhere in this standard the terms SUPPLEMENTARY INSULATION and REINFORCED INSULATION have mostly been replaced by references to MEANS OF PROTECTION, but they have been retained here because, as in IEC 60950-1, the requirements concerning distance through insulation and the use of thin sheet material apply to SUPPLEMENTARY INSULATION and to REINFORCED INSULATION, but not to BASIC INSULATION. Thus these requirements do not apply where BASIC INSULATION, as one MEANS OF PROTECTION, is used in conjunction with a PROTECTIVE EARTH CONNECTION as the other MEANS OF PROTECTION. Where DOUBLE INSULATION is used, these requirements apply to whichever constituent part thereof is regarded as the SUPPLEMENTARY INSULATION.

Subclause 8.8.3 – *Dielectric strength

Components designed to limit the voltage may need to be removed in order to allow the full test voltage to be applied to the insulation being tested.

The purpose of this test is to check all insulation under the worst-case condition after having achieved operating temperature. For heating elements, the worst case is achieved with heaters remaining energized during measurement.

Since the dielectric strength test is applied immediately after the humidity preconditioning treatment, with the ME EQUIPMENT still in the humidity cabinet, adequate precautions for the protection of laboratory personnel may be necessary.

***Subclause 8.8.3* a)**

The test voltage may be provided by a transformer, by a d.c. power source or by using the transformer(s) of the ME EQUIPMENT. In the last case, to prevent overheating, the test voltage may have a frequency that is higher than the RATED frequency of the ME EQUIPMENT.

The PROCEDURE and duration of the test for REFERENCE VOLTAGES (U) equal to or higher than 1 000 V a.c. or 1 500 V d.c. or peak values may be specified further by particular standards.

Subclause 8.8.4.1 – *Mechanical strength and resistance to heat and fire

Tests concerning flammability of materials will be found in IEC 60707.

Subclause 8.9 – *CREEPAGE DISTANCES and AIR CLEARANCES

For ME EQUIPMENT intended to be supplied from the SUPPLY MAINS, AIR CLEARANCE and dielectric strength requirements are based on the expected overvoltage transients that may enter the equipment from the SUPPLY MAINS. According to IEC 60664-1, the magnitude of these transients is determined by the normal supply voltage and the supply arrangements. These transients are categorized according to IEC 60664-1 into four groups as Overvoltage Categories I to IV (also known as installation categories I to IV). Elsewhere in this standard Overvoltage Category II is assumed.

The design of solid insulation and AIR CLEARANCES should be co-ordinated in such a way that, if an incident overvoltage transient exceeds the limits of Overvoltage Category II, the solid insulation can withstand a higher voltage than the AIR CLEARANCES.

The values in Table 9 to Table 11 correspond to those of IEC 60950-1 for overvoltage category II for MAINS PARTS and overvoltage category I for SECONDARY CIRCUITS. If ME EQUIPMENT is intended to be used in locations where the SUPPLY MAINS is in overvoltage category III or IV, these values will be inadequate.

A SECONDARY CIRCUIT derived from a SUPPLY MAINS will normally be Overvoltage Category I if the SUPPLY MAINS is Overvoltage Category II; the maximum transients for various SUPPLY MAINS voltages in Overvoltage Category I are shown in the column headings of Table 9.

For insulation between the ENCLOSURE and the PATIENT CONNECTION of an F-TYPE APPLIED PART special rules apply:

1) In the case of an F-TYPE APPLIED PART containing no voltage difference, the insulation between the PATIENT CONNECTIONS and the ENCLOSURE will only be stressed to the MAINS VOLTAGE in the case of a fault in other equipment connected to the PATIENT.

This condition rarely occurs; furthermore this insulation is not normally subject to the transient overvoltages found in the MAINS PART. In view of the above, the insulation necessary between the APPLIED PART and the ENCLOSURE for the case quoted, need only satisfy the requirements for BASIC INSULATION.

2) In the case of an F-TYPE APPLIED PART containing parts with voltage difference, the connection of a PATIENT CONNECTION to earth via an earthed PATIENT (NORMAL CONDITION) may subject the insulation between other parts and the ENCLOSURE to the whole of the voltage within the APPLIED PART.

Since this voltage appears in NORMAL CONDITION, even though infrequently, the relevant insulation must satisfy the requirements for DOUBLE INSULATION or REINFORCED INSULATION. In view of the low probability of this condition occurring, the CREEPAGE DISTANCES and AIR CLEARANCES given in Table 7 are considered adequate.

3) The value to be applied is the highest of the values found according to Items *d) 1)* and *d) 2)* above.

Subclause 8.9.1.6 – *Interpolation

Interpolation for CREEPAGE DISTANCES but not for AIR CLEARANCES is allowed, except where the REFERENCE VOLTAGE (U) is above 2 kV r.m.s. or 2,8 kV d.c. This approach is generally consistent with IEC 60664-1, IEC 60950-1 and IEC 61010-1.

Subclause 8.9.1.14 – *CREEPAGE DISTANCES and AIR CLEARANCES for DEFIBRILLATION-PROOF APPLIED PARTS

From IEC 60664-1, Table 11, a distance of 4 mm is adequate for pulses of 5 kV having a short duration of less than 10 ms, such voltages arising typically from the use of a defibrillator, with a reasonable SAFETY margin.

The validity of this margin, which has been retained to ensure that the ME EQUIPMENT passes the defibrillator test, and not only remains safe afterwards but also functions normally, comes from three factors:

– The values in IEC 60664-1 already have an inherent SAFETY margin;

– In practice the applied voltage even on the PATIENT'S thorax will be much less than the assumed open-circuit voltage of 5 kV, as the defibrillator will be on load, and it has an appreciable internal impedance and a series inductor that adds to this impedance;

– IEC 60664-1 allows for heavily contaminated surfaces, whereas in ME EQUIPMENT internal surfaces are clean.

Subclause 8.9.2 – *Application

***Subclause 8.9.2* a)**

Depending on the INTENDED USE/INTENDED PURPOSE of the ME EQUIPMENT, operation of the fuse or OVER-CURRENT RELEASE can be a HAZARD.

Subclause 8.9.3 – *Spaces filled by insulating compound

CREEPAGE DISTANCES are measured through the joint between two parts of an insulation barrier, except for cemented joints, i.e. those in which:

– either the two parts forming the joint are bonded by heat sealing or other similar means at the place where this is of importance;

– or the joint is completely filled with adhesive at the necessary places and the adhesive bonds to the surfaces of the insulating barrier so that humidity cannot be sucked into the joint.

In the second edition of this standard, the captions to Figures 43 to 45 referred to "uncemented joints". Item 7 of the legends to these figures referred to 57.9.4 f), second dash, "for a description of cemented joints" but did not specify any test methods other than inspection. During the preparation of this edition, the United States proposed introducing relevant requirements derived from IEC 60950-1 to address the related subject of potting.

The requirements that have been introduced are closely based on those of IEC 60950-1 and cover potting, encapsulation, cemented joints, etc. The editorial structure has been somewhat revised from that of IEC 60950-1 for clarity. These requirements have been included in 8.9 rather than 8.8 because they specify circumstances that allow exemption from the requirements for CREEPAGE DISTANCES and AIR CLEARANCES, rather than additional requirements applying to solid insulation.

Subclause 8.9.4 – *Measurement of CREEPAGE DISTANCES AND AIR CLEARANCES

Narrow gaps, running in the direction of a possible creepage path and being some tenths of 1 mm wide only, should be avoided as far as possible, for dirt and moisture may deposit there.

Subclauses 8.10.1 – *Fixing of components – and 8.10.2 – *Fixing of wiring

In many cases it will be obvious that components and wiring are adequately secured (e.g. small components soldered to a printed circuit board) without the need for specific justification in the RISK MANAGEMENT FILE; but if any relevant information is included in the RISK MANAGEMENT FILE, it should be taken into account in assessing compliance with these requirements.

Subclause 8.10.4 – *Cord-connected HAND-HELD parts and cord-connected foot-operated control devices (See also 15.4.7.)

HAND-HELD switches and footswitches are in practice exposed to severe conditions. This requirement ensures that even in the worst case, where the ENCLOSURE of such a switch is completely broken, only parts at voltages within the limits specified in 8.4.2 c), which are safe to touch, can become exposed.

Subclause 8.10.5 – *Mechanical protection of wiring

There is no requirement for specific justification to be given in the RISK MANAGEMENT FILE, but if any relevant information is included in the RISK MANAGEMENT FILE it should be taken into account in assessing compliance with these requirements.

Subclause 8.10.7 – *Insulation of internal wiring

Conductors may be routed in separated jacketed cords of adequate rating. Where conductors of different circuit categories have to be run through common cords, wiring channels, conduits or connecting devices, adequate separation is realized by sufficient rating of the conductor insulation and by arranging for sufficient AIR CLEARANCES and CREEPAGE DISTANCES, complying with the requirements of 8.9, between conductive parts in connecting devices.

Subclause 8.11.1 – Isolation from the SUPPLY MAINS

***Subclause 8.11.1* a)**

Skilled persons, such as SERVICE PERSONNEL, who need to gain access to internal, possibly hazardous, ME EQUIPMENT parts, need a means by which the ME EQUIPMENT can be isolated from the SUPPLY MAINS.

A mains isolating switch, where provided, may also serve as a functional off switch for routine use or for disabling hazardous output in an emergency. However it does not necessarily serve these purposes, nor does this standard specify any general requirement for an emergency off switch.

***Subclause 8.11.1* h)**

Such a protective device whether or not it caused the operation of an overcurrent protection device built into the ME EQUIPMENT, would be likely also to cause a fuse or circuit breaker in the installation to operate, thus removing the supply of power to other ME EQUIPMENT, possibly including life-support ME EQUIPMENT. Such a device might also cause undesirable thermal effects inside the ME EQUIPMENT and might anyway not be a reliable method of protecting against the relevant HAZARDS.

***Subclause 8.11.1* i)**

Parts that cannot be disconnected from the supply might include, for example, a circuit for room lighting or a circuit for remote control of the mains switch. Such parts may become accessible when a cover is opened, for example for the purpose of maintenance.

Subclause 8.11.2 – *MULTIPLE SOCKET-OUTLETS

This requirement reduces the likelihood of other equipment being connected that might lead to excessive LEAKAGE CURRENT.

Subclause 8.11.3.4 – *Cord anchorage

If a power cord were not adequately protected against strain and abrasion, there would be a high probability of damage to insulation providing MEANS OF PROTECTION and, with CLASS I EQUIPMENT, a high probability of breakage or disconnection of the PROTECTIVE EARTH CONDUCTOR.

Subclause 8.11.3.5 – *Cord guards

If a power cord were not adequately protected against excessive bending, there would be a high probability of breakage of power-carrying conductors, giving a RISK of fire, and, with CLASS I EQUIPMENT, a high probability of breakage of the PROTECTIVE EARTH CONDUCTOR.

The dimensional test described is identical to that specified in IEC 60950-1. The second edition of IEC 60601-1 included the wording "*Guards which fail the above dimensional test shall have to pass the test described in IEC 60335-1, Amendment 6. 1988, subclause 25.10."* This alternative has been retained but the reference is now to a later edition of IEC 60335-1. Also the requirement to perform one test in all cases, and then to perform the other test if the ME EQUIPMENT fails the first test, has been changed to allow either test to be performed first, because this makes no difference to whether the ME EQUIPMENT complies.

Subclause 8.11.3.7 – *APPLIANCE COUPLERS

A POWER SUPPLY CORD connected to a MAINS CONNECTOR is subject to similar stresses to a non-DETACHABLE POWER SUPPLY CORD. If it is not adequately anchored and protected from excessive bending, a HAZARD could result. However it is not possible in this standard to impose additional requirements on connectors complying with IEC 60320-1.

Subclause 8.11.4.1 – *General requirements for MAINS TERMINAL DEVICES

Mains terminals should ensure connections of sufficiently low resistance to avoid overheating and should minimise the RISK of disconnection. Reliable connection may be made by means of screws, nuts, soldering, clamping, crimping of conductors or equally effective methods.

Terminals of components other than terminal blocks may be used as terminals intended for external conductors.

This practice should be generally discouraged, but allowed in special cases where the terminal arrangement is adequate (accessible and clearly marked) and complying with this standard. This situation may occur for example in motor starters.

Subclause 8.11.4.4 – *Connections to mains terminals

The term "special preparation of the conductor" covers soldering of the strands, use of cord lugs, attachment of eyelets, etc., but not the reshaping of the conductor before its introduction into the terminal or the twisting of a stranded conductor to consolidate the end.

Subclause 8.11.5 – *Mains fuses and OVER-CURRENT RELEASES

Provision of fuses or OVER-CURRENT RELEASES in ME EQUIPMENT reduces the RISK that a fault in the ME EQUIPMENT will cause a protective device in the installation to operate, thus removing the supply of power to other ME EQUIPMENT, possibly including life-support ME EQUIPMENT.

It is obvious that fusing in a PROTECTIVE EARTH CONNECTION would be inappropriate.

Fusing of the neutral conductor of PERMANENTLY INSTALLED EQUIPMENT would serve no purpose and, with 3-phase equipment, might lead to overstressing of insulation in the event that such a fuse were to operate while the line connections remained intact. However an OVER-CURRENT RELEASE that interrupts all poles, including the neutral, simultaneously is acceptable.

The exemption for the case where DOUBLE INSULATION or REINFORCED INSULATION is present between all parts of opposite polarity within the MAINS PART was supported by the National Committees' responses to an inquiry during the preparation of this edition. It may apply where provision of a fuse or OVER-CURRENT RELEASE would be inconvenient, for example in a small plug-in power supply.

A.9 Clause 9 – *Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

Requirements in Clause 9 describe HAZARDS of a mechanical nature caused by ME EQUIPMENT (injury by moving parts, by rough surfaces, by sharp edges and corners, by instability, by expelled parts, by vibration and noise and by breakdown of PATIENT supports and of suspension means for ME EQUIPMENT parts). Requirements describing HAZARDS caused by damage or deterioration of ME EQUIPMENT (mechanical strength) have been collected into 15.3.

ME EQUIPMENT may become unsafe because of parts damaged or deteriorated by mechanical stresses such as blows, pressures, shocks, vibration, by ingress of solid particles, dust, fluids and moisture and aggressive gases, by thermal and dynamic stresses, by corrosion, by loosening of fastenings of a moving part or a suspended mass, and by radiation.

Effects of mechanical overloads, material failure or wear can be avoided by:

– means that interrupt or render non-hazardous the operation or the energy-supply (for example, fuses, pressure valves) as soon as overloading occurs;

– means that guard against or catch flying or falling parts (caused by material failures, wear or overload) that may constitute a HAZARD.

Protection against breakdown of PATIENT supports and suspensions can be provided by redundancy or the provision of SAFETY catches.

ME EQUIPMENT parts that are intended to be held in the hand or positioned on a bed must be sufficiently robust to withstand a fall. They may be subject to vibration and shocks, not only when transported but also when used in vehicles.

Subclause 9.2 – *Moving parts

OPERATORS, PATIENTS and other people need to be protected from MECHANICAL HAZARDS. This can be achieved in a number of ways, for example:

– By providing sufficient distance between people and HAZARDS;

– By restricting access to areas that present HAZARDS;

– By providing a barrier, whether physical or otherwise, between people and HAZARDS;

– By reducing the SEVERITY of any RISK associated with HAZARDS;

– By ensuring greater OPERATOR control over the movements causing a HAZARD; or

– By providing back-up systems so that the acceptable level of RISK is achieved when the initial control system fails.

Subclause 9.2.1 – *General

The acceptability of the RISK associated with any HAZARD involving moving parts, is a combination of the likelihood of occurrence, the SEVERITY of the HARM, and the benefits provided to the PATIENT by the ME EQUIPMENT. Assessment of the acceptability of moving parts HAZARDS for medical devices is different from other ME EQUIPMENT (e.g. machinery), in that the ME EQUIPMENT, of necessity, is often required to be placed on or very close to the PATIENT. The benefits of the particular treatments, diagnosis, or compensation etc. to the PATIENT must always be taken into account. ISO 14791, can be used as a reference.

When reference is made, in this clause, to the RISK of injury to persons, rather than to the PATIENT or OPERATOR, it should be noted, that there may be other people, in addition to the PATIENT or OPERATOR in the vicinity of ME EQUIPMENT. Depending upon the ME EQUIPMENT, visitors, family members and other non-qualifiers personnel could be in the vicinity.

Subclause 9.2.2.4 – *GUARDS and protective measures

The degree of protection required for ENCLOSURES or GUARDS protecting moving parts depends upon the general design and INTENDED USE/INTENDED PURPOSE of the ME EQUIPMENT. Factors to be taken into consideration in judging the acceptability of exposed moving parts may be the degree of exposure, the shape of the moving parts, the likelihood of accidental contact, the speed of movement and the likelihood of fingers, arms or clothing being drawn into moving parts (for example where gears mesh, where belts travel on to a pulley or where moving parts close in a pinching or shearing action).

These factors may be considered with respect to both NORMAL USE and also during setting of any adjustments, or the replacement of any ACCESSORY or attachment, possibly including the

installation instructions, because GUARDS may be provided at installation and may not be part of a single item of STATIONARY EQUIPMENT.

Features of GUARDS that may be considered include:

– removability with the use of TOOLS only;

– removability for servicing and replacement;

– strength and rigidity;

– completeness;

– creation of additional HAZARDS such as pinch points, and the necessity for additional handling because of the increased need for servicing such as for cleaning.

Protective measures addressed by this clause are also intended to include collision detection systems, such as those employing light barriers.

Subclause 9.2.2.6 – *Speed of motion

For some medical equipment there will be unavoidable HAZARDS due to moving parts. Due to the diversity of situations, it is not possible in this standard to dictate where the warnings should be placed. Depending on the application, and the level of RISK, it may be important to place a warning on the product. It may, however, be acceptable to place the warning only in the ACCOMPANYING DOCUMENTS.

Subclause 9.2.4 – *Emergency stopping devices

Emergency stopping devices are designed to prevent accidental damage by preventing or stopping movements of ME EQUIPMENT parts. There may be more than one emergency stopping devices on ME EQUIPMENT. ME EQUIPMENT may also include emergency off devices that are intended to disconnect all power to the installation. Emergency off devices are not subject to the requirements of this clause. Emergency stopping devices are only one part of the emergency switching function.

Subclause 9.2.5 – *Release of PATIENT

Attention is paid to the effect of a power interruption concerning unwanted movements, removal of compression forces and removal of PATIENTS from a hazardous position.

Subclause 9.3 – *Surfaces, corners and edges

The level of RISK associated with a sharp edge, depends upon the position of the sharp edge and the application of the ME EQUIPMENT. For this reason compliance with this subclause is checked by inspection. In cases of doubt, the test for sharp edges, described in UL standard, UL 1439, may be used as guidance.

This clause applies for surfaces accessible during NORMAL USE. Care should be given to protecting service personal, or other internal systems where damage could introduce an unacceptable RISK (i.e. fluid systems).

Subclause 9.4 – *Instability

In NORMAL USE, many types of ME EQUIPMENT are exposed to a variety of conditions during transport (movement from room to room during NORMAL USE). While the requirements of this standard attempt to represent those that may be encountered, the RISK MANAGEMENT PROCESS should evaluate the conditions under which the ME EQUIPMENT is intended to be used and how those conditions might impact SAFETY and ESSENTIAL PERFORMACNE.

Where failure to remain stable during the performance of these tests could cause injury to the OPERATOR, PATIENT and other persons (e.g. from crushing or falling); or result in the ME EQUIPMENT failing to meet the applicable requirements of this standard (such as: exposing hazardous voltages, reducing CREEPAGE and/or CLEARANCE DISTANCEs or creating breaches in

fire proof enclosures which are not clearly obvious or causing a loss of ESSENTIAL PERFORMANCE), instability should be considered to present an unacceptable RISK.

Subclause 9.5 – *Expelled parts

Expelled parts are ME EQUIPMENT parts or fragments of ME EQUIPMENT parts, such as parts of a damaged vacuum display, a mechanical spring, a gas pressure cylinder, a rotating flywheel or an exploded lithium battery that may be expelled by collision, expansion etc.

The degree of protection against "expelled parts" depends upon the likelihood of occurrence and the SEVERITY of HARM. Protective measures may be an ENCLOSURE, barrier, or electronic means (e.g. redundant means to prevent lithium battery charging current).

Subclause 9.6.1 – *General

Excessive noise may cause fatigue, interference with speech and acoustic signals, or even damage to hearing. Limits to prevent hearing damage are described in ISO standards.

In medically used rooms, much lower limits are needed for the comfort of PATIENT and medical personnel. The actual effect of ME EQUIPMENT noise is strongly influenced by the acoustical properties of the room, the insulation between rooms and interaction of ME EQUIPMENT parts.

Excessive vibration will cause discomfort to the PATIENT, OPERATOR, and other persons. Prolonged exposure may cause vascular, neurological, or osteo-articular disorders. Excessive vibration may also cause damage to ME EQUIPMENT or a shift in calibration.

Most ME EQUIPMENT covered by this standard exposes the PATIENT and OPERATOR or other persons to negligible levels of noise and vibration. The RISK MANAGEMENT PROCESS should be able to clearly identify those cases where measurements are required.

Subclause 9.6.2 – *Noise

These values are based on the potential for long term hearing impairment. The value usually used for regulatory purposes worldwide is currently 90 dBA with an offset of 5 dBA. However the latest research indicates a value of 85 dBA with an offset of 3 dBA.[12)]

Subclause 9.6.3 – *Hand Transmitted Vibration

Threshold values for vibration are much less clear than those for noise. The value used here is the UK action level for hand-transmitted vibration. It corresponds to about a 10% incidence of blanching (indicative of neurological damage) after 8 years of regular exposure according to ISO 5349-1. Even less clear are threshold values for whole body vibrations. The end points such as back pain and other adverse health effects are not easily quantifiable, and so no agreed-upon exposure standards have been developed. Relevant information of this subject may be found in standards such as ISO 5805, and ISO 8041.

Subclause 9.7– *Pressure vessels and parts subject to pneumatic and hydraulic PRESSURE

The requirements of this subclause do not represent the most stringent combination of national regulations or standards.

In some countries such regulations or standards apply.

Type of systems considered:

– Pneumatic pressure systems

– Hydraulic pressure systems

– Steam pressure systems

[12)] ACGIH Threshold Limit Values and Biological Exposure Indices (2000 handbook) ISBN: 1-882417-36-4.

– All of the above systems, additionally with Pressure vessels

HAZARDS

a) Mechanical rupture or breakage (HARM: lacerations, puncture wounds)

The requirements from Clause 45, 2nd Edition dealing with this HAZARD, have been moved to this subclause, and remain unchanged.

For pressure vessels exceeding both a maximum pressure limit and an energy limit (pressure*volume), the requirement is to determine the maximum system PRESSURE, P1, in SINGLE FAULT CONDITION and to conduct a hydrostatic overpressure test at between 1,3x and 3x P_1. The 1,3x to 3x SAFETY factor is specified in Figure 31.

Requirements have been clarified to indicate that all pressure system components must have a bursting pressure rating of at least the SINGLE FAULT CONDITION system pressure times the required Figure 31 SAFETY factor.

b) Mechanical loss of support (HARM: crush, puncture wounds)

Requirements have been clarified to specify that components in a pressure systems, such as those in a hydraulic lift system, whose integrity is relied on to reduce the RISK of injury from loss of support, must comply with the NORMAL CONDITION TENSILE SAFETY FACTORS specified in 9.8. The TENSILE SAFETY FACTOR is typically 4x for parts not impaired by wear, and 8x for parts impaired by wear. Thus parts subject to pressure whose failure could result in mechanical rupture and loss in support must be RATED for the higher of the pressure determined from Figure 31, SINGLE FAULT CONDITION TENSILE SAFETY FACTOR, or 9.7, NORMAL CONDITION SAFETY factor.

c) Leakage of toxic gas or liquid (HARM: chemical or biological cell damage)

The requirements from Clause 45, 2nd Edition dealing with this HAZARD, have been moved to this clause, and remain unchanged.

Requirements have been clarified to indicate that all pressure system components must have a bursting pressure rating of at least the SINGLE FAULT CONDITION system pressure times the required SAFETY factor from Figure 31.

d) Leakage of flammable gas or liquid (HARM: fire causing life or property damage)

The requirements from Clause 45, Second Edition dealing with this HAZARD, have been moved to this clause, and remain unchanged.

Requirements have been clarified to indicate that all pressure system components must have a bursting pressure rating of at least the SINGLE FAULT CONDITION system pressure times the required SAFETY factor from Figure 31.

Subclause 9.7.3 – *Pressure vessels

It is assumed that a hydraulic test is not necessary if the PRESSURE is less than or equal to 50 kPa or the PRESSURE X volume is less than or equal to 200 kPa * l,.

The SAFETY factors implied by Figure 31 are higher than those generally applied in testing pressure vessels. However, whereas hydraulic testing is normally used to verify that a pressure vessel is free from production faults or serious deterioration, the adequacy of the design being determined in other ways, the present hydraulic test is intended to verify the adequacy of a design where this cannot be established in other ways.

The deletion of national references in the amended text avoids subordinating the requirements of the standard to those of local regulations. The ME EQUIPMENT will sometimes have to

satisfy both, or the more demanding, assuming that there are no local regulations that conflict with this standard.

A hydraulic test is specified even for pneumatic vessels, as this is safer for the tester. In achieving the test pressure with a gas, the gas will compress resulting in more stored energy in the test vessel than would a hydraulic test method. Both methods result in the same test pressure, which is the objective of the test.

Subclause 9.8 – *Support systems

The term "support" is taken to include "suspension" and loads may include PATIENTS, OPERATORS and other masses.

Support systems can broadly be categorized as follows:

– A suspension system is one that contains flexing or rigid elements that are designed to suspend masses, including PATIENTS and OPERATORS during NORMAL USE.

– Flexing elements include ropes, cables, chains, belts, bands and springs. Additionally a jack screw nut is considered impaired by wear to the extent needing a higher TENSILE SAFETY FACTOR.

– An actuating system is one that contains elements such as electric, pneumatic or hydraulic actuators, motors, gearboxes, shafts, bearings, pulleys, sheaves, band wheels and guides.

– A support structure is generally a rigid device that can be static or moving and which supports ME EQUIPMENT, external loads and, where necessary, PATIENTS and OPERATORS.

TENSILE SAFETY FACTORS are applied to provide a margin of SAFETY to the design after all reasonable allowances for operating conditions, life, material and manufacturing variables etc., have been made.

Suspension and actuating systems have TENSILE SAFETY FACTORS that are necessarily high to minimise the possibility of deterioration through wear and fatigue.

Particular attention should be given to the fixing of structures to floors, ceilings, etc., which are subject to variable TENSILE SAFETY FACTORS.

A hidden defect is one that is not revealed during manufacture, service or normal operation of the ME EQUIPMENT but that could cause failure of a part that may result in a HAZARD. Examples are high internal stresses in heat-treated parts such as springs, broken strands of wire inside cables and porosity inside castings.

Figure A14 contains an example of determining the appropriate TENSILE SAFETY FACTOR using Table 17. Figure A15 contains an example of determining design and test loads. These examples are not intended to cover all possible cases. For a particular design, these TENSILE SAFETY FACTORS and design/test loads may vary according to the materials used, their wear characteristics, loading conditions, etc.

Subclause 9.8.3 – *Strength of PATIENT or OPERATOR support, or suspension systems

This subclause deals with forces applied on support or suspension parts of ME EQUIPMENT, intended to support or suspend the mass of a human body or part of the mass of a human body, and due to this human mass but also to accessories often times used on such support or suspension parts. For adult PATIENT or OPERATORS the 135 kg mass represent the 99 percentile of the population. For specific population, higher mass or lower mass can be use (heavy person or paediatric application).

The distribution mass of a body diagram is an average distribution based on anthropometrical data. Due to the variety of population skill or specific categories of age, it may vary. For sedentary people not having a physical activity the mass of the upper part of the body can represent a more important percentage.

The variety of ME EQUIPMENT does not allow more precision to be given in this general standard. It is up to the particular standard to define more adequately the distribution area or the worst-case position, rather than dynamic tests.

Two general dynamic tests are defined which represent common situations represented by a person sitting on or standing up.

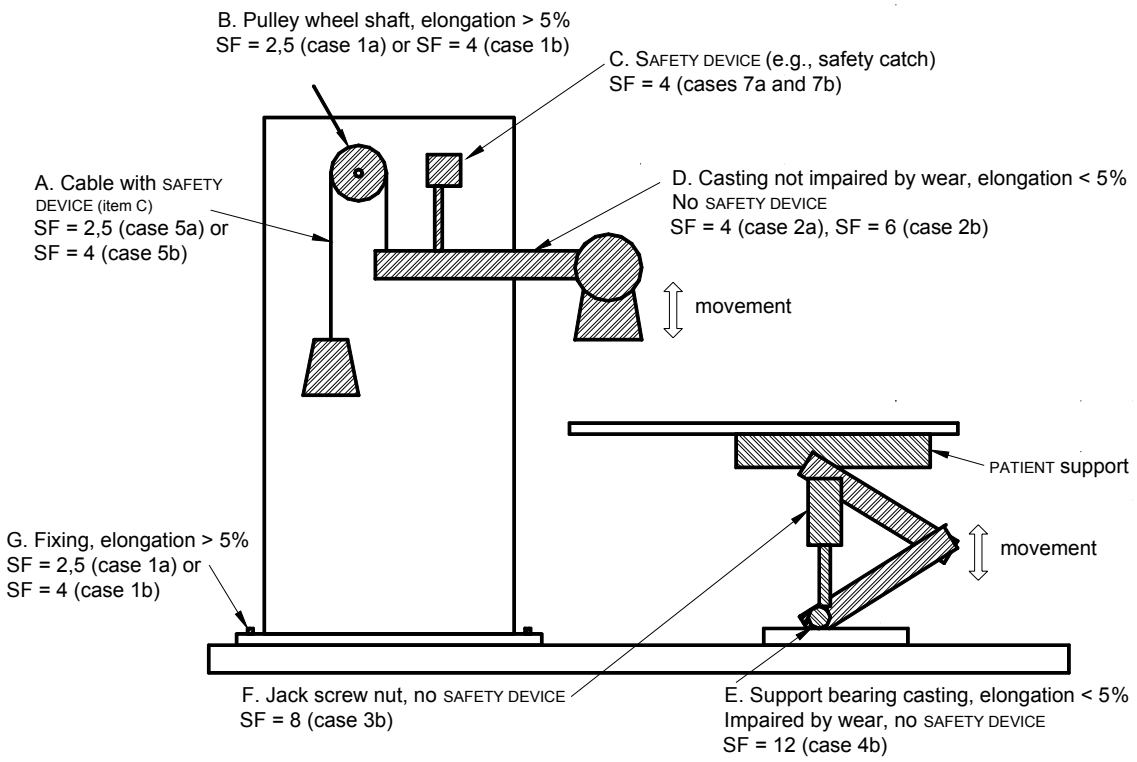
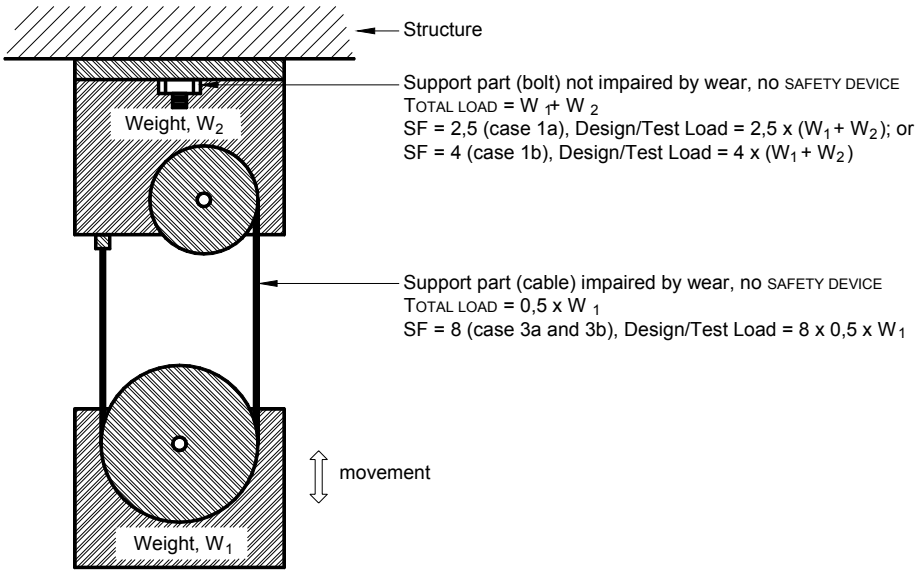


Figure A14 – Example of determining TENSILE SAFETY FACTOR using Table 17

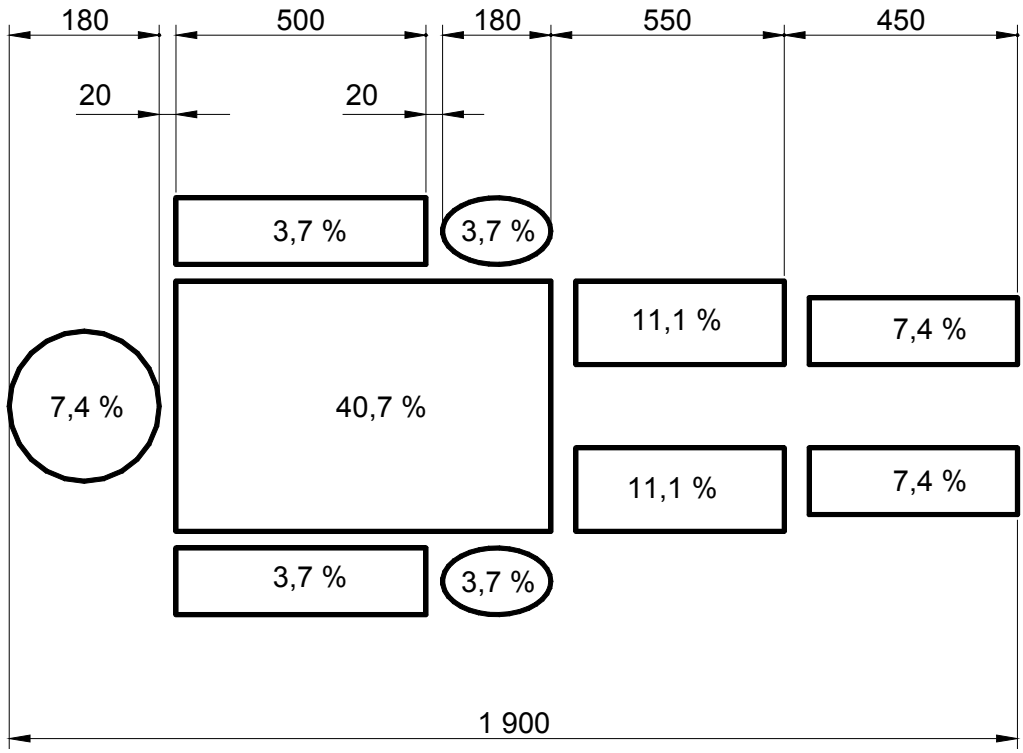


NOTE TOTAL LOAD is shown based on only static forces to obrtain actual total loads, dynamic forces also need to be included.

Figure A15 – Example of determining of design and test loads

Subclause 9.8.3.2 – *Static forces due to loading from persons

Figure A16 contains an example of human body mass distribution for PATIENT support surfaces.



Dimensions in millimetres

Figure A16 – Example of human body mass distribution

Subclause 9.8.4 – *Systems with SAFETY DEVICES

The intent of a SAFETY DEVICE is to act in the event of the failure of the primary support means subject to wear to prevent injury. The failure of the primary support means subject to wear is considered a SINGLE FAULT CONDITION if it has a TENSILE SAFETY FACTOR in accordance with Table 17, rows 5 and 6. To protect against injury in this SINGLE FAULT CONDITION, the SAFETY DEVICE acts as a backup, and must have the TENSILE SAFETY FACTOR indicated in Table 17, Row 7.

To test a SAFETY DEVICE, the primary support means subject to wear must be defeated. For example if the primary support system is a cable, the cable would be cut.

A.10 Clause 10 – *Protection against unwanted and excessive radiation HAZARDS

Radiation from ME EQUIPMENT may occur in all forms known in physics. SAFETY requirements are concerned with unwanted radiation. Protective measures are necessary for ME EQUIPMENT and for the environment and methods for determining levels of radiation must be standardized.

This clause is intended to deal with stray radiation (such as scattered radiation from radiological equipment) and incidental radiation (such as X-ray emitted by CRTs). A requirement for unintended or excessive output of radiation that ME EQUIPMENT is intended to deliver to the PATIENT is covered in 12.3.7.

For ionizing radiation IEC requirements generally comply with the International Commission for Radiation Protection (ICRP) Recommendations. Their purpose is to provide data that are immediately usable by designer and RESPONSIBLE ORGANIZATION.

Their evaluation is possible only by adequate study of operating methods and duration of operation of ME EQUIPMENT and positioning of OPERATOR and assistants, because application of worst case conditions would give rise to situations that might hamper proper diagnosis or treatment.

Recent ICRP publications also instruct the OPERATOR in methods for the restriction of intentional irradiation.

Subclause 10.8 – *Acoustic pressure (including ultrasonics)

MANUFACTURERS should be aware of the following during the design of ME EQUIPMENT:

– Unwanted noise is an environmental pollution and should be kept as low as is practical consistent with the INTENDED USE of the ME EQUIPMENT. In PATIENT care units, special attention should be paid to minimizing noise from ME EQUIPMENT that may disturb the PATIENT'S deep sleep.

– In factories and workshops, excessive noise may cause fatigue or even damage to hearing. Limits to prevent hearing damage are described in ISO standards.

– In medically used rooms, much lower limits are needed for the comfort of PATIENT and medical personnel. The actual effect of ME EQUIPMENT noise is strongly influenced by the acoustical properties of the room, the insulation between rooms and interaction of ME EQUIPMENT parts.

A.11 Clause 11 – *Protection against excessive temperatures and other HAZARDS

a) Temperatures (see 11.1)

Temperature limits are required to prevent HAZARDS for almost all types of electrical ME EQUIPMENT with the purpose of preventing rapid ageing of insulation and discomfort where ME EQUIPMENT is touched or manipulated, or injuries where PATIENTS may contact ME EQUIPMENT parts.

ME EQUIPMENT parts may be inserted into body cavities, usually temporarily but sometimes permanently.

For PATIENT contact, special temperature limits have been set.

b) Preventing fire HAZARD (see 11.2).

Within most environments where ME EQUIPMENT is used, other sources of "fuel" for combustion are typically far more significant than that provided by the ME EQUIPMENT itself. The requirements addressing fire HAZARDS in this standard focus on preventing the ME EQUIPMENT from being the source of combustion. For this reason, these requirements focus on ME EQUIPMENT that contains or is used in the presence of OXYGEN RICH ENVIRONMENTS. These requirements attempt to ensure that any potential source of ignition remains isolated from the OXYGEN RICH ENVIRONMENTS under NORMAL USE and SINGLE FAULT CONDITIONS.

Where ME EQUIPMENT is not used in such environments, assuring that the limits for operating temperatures and requirements for overload protection are met should be considered adequate.

For ME EQUIPMENT that could provide a significant source of fuel (in comparison to the normal operating environments, additional requirements should be provided by particular standards. Where no particular standard exists, such issues should be specifically

addressed in applying the RISK MANAGEMENT PROCESS as required in Clause 4 of this standard.

c) Pressure vessels (see 9.7)

Attention is drawn to the requirements dealing with pressure vessels and parts subject to pressure, where no local regulations are available.

d) Interruption of the power supply (see 11.8)

Interruption of the power supply may cause a HAZARD.

Subclauses 11.1.1 – *Maximum temperature during NORMAL USE – and 11.1.2 – *Temperature of APPLIED PARTS

Table 18 addresses limits for parts that could affect compliance of the ME EQUIPMENT with this standard in general (e.g. electrical SAFETY).

Table 19 and Table 20 addresses HAZARDS that could arise from human contact with higher temperatures. Human contact temperatures were based on clinical expertise, clinical literature ("Principles of Surgery, 7th Edition"; Schwartz. et. al.) and experimentation. In addition, the values agree with those of the European Norm EN 563.

Although the maximum surface temperature for an APPLIED PART was raised from 41°C to 43°C in response to the clinical input mentioned above, input from some clinicians pointed out that infants as well as some other (thermally) high RISK groups may be more prone to injury from heated surfaces at 43°C.

Ideally, particular standards for ME EQUIPMENT used for these PATIENT groups would have requirements for (where necessary) lower contact temperatures. In order to address those cases where such particular standards do not exist, the group felt that notification of the RESPONSIBLE ORGANIZATION when temperatures exceed the second edition limit of 41°C was adequate. However, the new 43°C limit is to be considered an absolute maximum.

The proper use of thermocouples is recognized in other standards as a valid test technique. The temperature limits are lowered (by the note) to compensate for errors that may occur in the construction and placing of the thermocouple.

Table A1 is provided as guidance for ME EQUIPMENT that creates low temperatures (cools) for therapeutic purposes or as part of its operation. Normative requirements have not been included in this standard because such ME EQUIPMENT is uncommon.

Table A1
Guidance on surface temperatures for ME EQUIPMENT that that creates low temperatures (cools) for therapeutic purposes or as part of its operation

ME EQUIPMENT and its parts		Minimum Temperature, °C [a]	
		Aluminium	Steel
External surface of ME EQUIPMENT and its parts that are likely to be touched for a time "t". [b]	t < 1 s	-20	-20
	1 s ≤ t < 10 s	-10	-15
	10 s ≤ t < 60 s	-2	-7

[a] The allowable minimum temperature limit values for external surfaces that are likely to be touched by the PATIENT, OPERATOR and other persons are based on freezing threshold values of a finger touching different materials (Frostbite threshold).

[b] The likelihood (probability) of contact and the duration of contact should be determined and documented in the RISK MANAGEMENT FILE.

Subclause 11.2.1 – *Strength and rigidity required to prevent fire HAZARDS in ME EQUIPMENT

At least all electrical parts that could cause a HAZARD, with the exception of POWER SUPPLY CORDS and other necessary interconnecting cords, should be enclosed in material that will not support combustion.

This does not preclude the use of an outer cover of other material covering an inner cover complying with the above recommendation.

For guidance on assessing fire HAZARDS, see IEC 60695-1-1.

Subclause 11.2.2 – *ME EQUIPMENT and ME SYSTEMS used in conjunction with OXYGEN RICH ENVIRONMENTS

While not a flammable mixture, the presence of an OXYGEN RICH ENVIRONMENT increases the flammability of many substances. Reports of fires in OXYGEN RICH ENVIRONMENTS in ME EQUIPMENT are unusual. However, when such fires do occur in the hospital environment they can have tragic consequences.

ME EQUIPMENT intended to operate in conjunction with an OXYGEN RICH ENVIRONMENT should be designed to minimize the likelihood of ignition of flammable materials.

Where appropriate, particular standards should specify the corresponding requirements.

***Subclause 11.2.2* a)**

Cotton is regarded to be the material with the lowest ignition temperature and energy in comparison with electronic circuits and it is assumed that it can be found in the interior of a device as dust.

The maximum surface temperature limit is based on the minimum hotplate ignition temperature for fire retardant cotton in 100 % oxygen that is given in NFPA 53 as 310 °C. The assumption was therefore made that 300 °C was an acceptable temperature limit in ME EQUIPMENT with OXYGEN RICH ENVIRONMENTS.

The worst case conditions described in the note makes it possible to provide simple numbers as limitations.

The values for sparking are taken from Kohl, H.-J. *et al*., ASTM STP 1395.

This subclause allows the use of small electronic circuits in OXYGEN RICH ENVIRONMENTS only when their power supply is limited. The resistive limitation of the power input is necessary for the SINGLE FAULT CONDITION of an open solder joint that might spark. The same reason applies to the limitation of energy in capacitances and inductances. In most cases the limitation in paragraph 4) to 300 °C is more restrictive than these. For most small components like decoupling capacitors, or where the failure of a component causes the maximum possible power to be drawn from the source, it is necessary to limit the power to 1 W. The PROCEDURE to find the necessary value to limit the power so that the 300 °C limit is not exceeded can be as follows:

– look for the smallest component that can match to the power source in a SINGLE FAULT CONDITION.
– estimate its thermal resistance
– calculate the power limitation = 200 °C / thermal resistance.

***Subclause 11.2.2* b) 2)**

The only way to find the maximum leak rate that must be considered is to find the minimum leak rate that can safely be detected by the USER.

***Subclause 11.2.2* b) 3)**

The HAZARD is: a leak occurs and is not detected, some time later an electrical failure occurs that starts an ignition. The time interval t_c for checking the seals can be calculated as follows:

– estimate the probability per time p_e of an electrical failure that exceeds the values given in 11.2.2 a)

– estimate the probability per time of the oxygen leak p_o

– determine the accepted level of RISK r = accepted probability of dangerous failures per time

– calculate: $t_c = r / (0,5 * p_e * p_o)$

***Subclause 11.2.2* b) 5)**

Serious oxygen fires have been reported where the ignition source has been a faulty electrical connector close to an oxygen outlet. The 20 cm dimension is based on estimates of the dispersion of pure oxygen to a concentration below 25 %.

Subclause 11.3 – *Constructional requirements for fire-proof ENCLOSURES OF ME EQUIPMENT

The requirements for fire ENCLOSURES from IEC 61010-1 have been included primarily as an alternate to the tests related to SINGLE FAULT CONDITIONS (associated with combustion and its consequences listed in Clause 13). By requiring flame resistance for the ENCLOSURE and materials contained within it, the probability that fire would escape such ENCLOSURES is considered minimal. Where the fire ENCLOSURE constitutes only a part of the ME EQUIPMENT, careful analysis should be performed to assure that a positive barrier to the propagation of fire exists.

Subclause 11.4 – *ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics.

While the use of flammable anaesthetics is uncommon, it was determined during the writing of the third edition that some MANUFACTURERS may still want to rate their ME EQUIPMENT as CATEGORY AP or CATEGORY APG. In order to make the third edition more usable (by removing the rarely used section on this topic) while maintaining the availability of the CATEGORY AP and CATEGORY APG RATINGS, the material has been moved to an annex and only this clause's brief reference to it remains in the body of the standard.

The final determination of whether ME EQUIPMENT should be RATED CATEGORY AP or CATEGORY APG should be determined by the MANUFACTURER based on the INTENDED USE/INTENDED PURPOSE. Requirements related to CATEGORY AP and CATEGORY APG are found in Annex G (see also the rationale for Annex G).

Subclause 11.5 – *ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents

While it was necessary to address cases where ME EQUIPMENT is used with flammable agents (such as some disinfectants) or in areas where they are commonly used and where the MANUFACTURER of the ME EQUIPMENT has given no special handling instructions or precautions, the variety of such agents, their volatility as well as many other determinant factors precludes giving specific instructions. The only reasonable solution in such cases is to assure that the MANUFACTURER evaluates and addresses the associated RISK.

Subclause 11.6.3 – *Spillage on ME EQUIPMENT and ME SYSTEM

In addition to ME EQUIPMENT that requires the use of fluids, many types are exposed to fluid spills as part of their NORMAL USE. In such cases (as well as for ME EQUIPMENT requiring fluids) the amount and location where spills may occur vary greatly. Only a proper evaluation of the ME EQUIPMENT being tested can determine an appropriate application of the requirement. Doing such an evaluation MUST be the responsibility of the MANUFACTURER and the results are to be provided to those performing the test (typically in the RISK MANAGEMENT FILE). This requirement would be an appropriate area for evaluation by writers of particular standards.

Examination of the NORMAL USE of ME EQUIPMENT should provide an adequate estimate of the amount of fluid that is likely to be spilled on it.

Subclause 11.6.4 – *Leakage

Leakage is considered to be a SINGLE FAULT CONDITION.

Subclause 11.6.5 – *Ingress of liquids and particulate matter into ME EQUIPMENT and ME SYSTEMS

Although it is unlikely that ME EQUIPMENT would be RATED for protection against particulate matter, IEC 60529 does address the possibility and it should be considered a valid option.

Subclause 11.6.8 – *Compatibility with substances used with the ME EQUIPMENT

ME EQUIPMENT, ACCESSORIES and parts thereof should be designed to be used safely with the substances with which they are intended to come into contact in NORMAL USE.

Where appropriate, particular standards should specify the corresponding requirements.

Subclause 11.8 – *Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT

For ME EQUIPMENT, in which the SAFETY of the PATIENT depends on the continuity of the power , particular standards should include requirements regarding power failure alarms or other precautions.

A.12 Clause 12 – *ESSENTIAL PERFORMANCE, accuracy of controls and instruments and protection against hazardous outputs

IEC 60601-1 is the guideline for all particular standards and must therefore contain some requirements of a more general character in order to serve this purpose. So it is necessary to have some generally formulated requirements in Clause 12.

Standardization bodies, including those outside IEC, have taken over the system of this IEC Publication in order to have a unique system of standards. In such cases it is most important to give a guideline in this section as help towards “functional” PATIENT SAFETY.

This section introduces the concept of “use error.” The term was chosen over the more commonly used terms of “user error” or “human error” because not all “use errors” are the result of oversight or carelessness on the part of the OPERATOR of the ME EQUIPMENT. All too frequently, use errors are the direct result of poor human interface design that seduces the OPERATOR into an incorrect decision.

Subclause 12.1 – *ESSENTIAL PERFORMANCE

The concept of “SAFETY” has been broadened from the simple, basic SAFETY considerations in the first and second editions of this standard to include ESSENTIAL PERFORMANCE matters, (e.g. the accuracy of physiological monitoring equipment). Application of this principle leads to the change of the title from “Safety of medical electrical equipment, Part 1: General requirements for safety” in the second edition, to “Medical electrical equipment, Part 1: General requirements for safety and essential performance”

For an explanation of ESSENTIAL PERFORMANCE, see the rationale for 3.28

Subclause 12.3.3 – *Intentional exceeding of SAFETY limits

If the control range of ME EQUIPMENT is such that the delivered output in a part of the range considerably differs from the output that is regarded as non-hazardous, means should be provided that prevent such a setting or that indicate to the OPERATOR (for example by means of an apparent additional resistance when the control is set or the bypassing of an interlock) that the selected setting is in excess of a SAFETY limit.

Where appropriate, particular standards should specify safe output levels.

Subclause 12.3.4 – *Indication of parameters relevant to SAFETY

Any ME EQUIPMENT delivering energy or substances to a PATIENT should indicate the possible hazardous output, preferably as a pre-indication, e.g. energy, rate or volume.

Where appropriate, particular standards should specify the corresponding requirements.

Subclause 12.3.6 – *Incorrect output

ME EQUIPMENT delivering energy or substances to the PATIENT should be provided with an alarm to alert the OPERATOR to any significant departure from the commanded level of delivery.

Where appropriate, particular standards should specify the corresponding requirements.

A.13 Clause 13 – *Abnormal operation and fault conditions

ME EQUIPMENT or its parts may cause HAZARDS due to abnormal operation or fault conditions, which, therefore, must be investigated.

The single fault philosophy allows a MANUFACTURER to neglect the second and further faults that occur by chance at the same time together with the SINGLE FAULT CONDITION. This requires, that the SINGLE FAULT CONDITION is detected within some time. The necessity can be illustrated by two examples, where it cannot be accepted, that they will happen:

1) A measure of protection against some SINGLE FAULT CONDITION fails. This does not deteriorate the function of the device, because the measure of protection does not contribute to it. During the rest of the useful life of the device, the SINGLE FAULT CONDITION for which the measure of protection was determined occurs, which results in a HAZARD.

2) A small oxygen leak within a device that uses oxygen increases the oxygen concentration in the vicinity of electronic components to a dangerous level. No deterioration of the function of the device will be seen. An electric component fails during the rest of the useful life of the device in such a way that an ignition occurs and the device burns, fed by oxygen.

It is obvious, that “rest of the useful life of the device” is a much too long time to be accepted. A reasonable time of detection may be estimated by RISK MANAGEMENT as described below.

The acceptable level of RISK will be determined by the MANUFACTURER of the ME EQUIPMENT.

Examples of SINGLE FAULT CONDITIONS that are likely to be detected:

– Two redundant components, e.g. two pressure sensors, allow it to detect the failure of one component and to raise an alarm.

– A potentiometer, which is used to set a displayed SAFETY-relevant variable, fails. This is obvious to the OPERATOR who tries to change the value of the variable.

Examples of fault conditions that are considered as unlikely to occur:

– a total breakdown of a DOUBLE or REINFORCED INSULATION

– interruption of a PROTECTIVE EARTH CONDUCTOR of ME EQUIPMENT with a FIXED MAINS PART.

Subclause 13.1.2 – *Emissions, deformation of ENCLOSURE or exceeding maximum temperature

– The delivery of unintended hazardous quantities of energy or substances to a PATIENT or into the NATURAL ENVIRONMENT may be described by particular standards.

  Hazardous quantities of poisonous or ignitable gas depend on the type of gas, concentration, place of emission etc.

At a power dissipation of less than 15 W, no fire HAZARD exists. Where circuits could dissipate 15 W or greater, it must be demonstrated that components within such circuits will not cause fire, molten metal, etc. to propagate in such a way as to cause a HAZARD (by setting the surroundings on fire for example). However, as in IEC 61010-1, it is considered that when such components are enclosed in a fire ENCLOSURE as defined in 11.3, adequate protection from such propagation is provided.

– The occurrence of malfunctions and/or failure to operate (breakdown), causing a direct HAZARD for a PATIENT (for example non-recognizable failures in life-supporting ME EQUIPMENT, non-recognizable measuring errors and unintended changes of PATIENT data) may be described in particular standards.

It is felt that limiting the maximum temperatures for APPLIED PARTS to the NORMAL CONDITION values is appropriate because exceeding them is known to cause injury and the PATIENT is frequently unable to pull away.

Subclause 13.2.10 – *Interruption and short-circuiting of motor capacitors

The effect of functioning centrifugal switches may be taken into account. A locked rotor condition is specified because some capacitor motors may or may not start, causing variable results. Capacitor voltage is checked to assure that its dielectric will not be stressed causing the accumulation of hazardous gases including hydrogen.

Subclause 13.2.14 – *Overload – and Table 22, last line

Temperature limits of motor windings in ME EQUIPMENT are determined after the first hour as an arithmetic average because experience of test houses has shown that ME EQUIPMENT for non-CONTINUOUS OPERATION reaches variable values that may temporarily differ from the maximum values. Therefore, lower temperature limits are required.

Subclause 13.2.14.4 – *ME EQUIPMENT RATED for non-continuous OPERATION

Where ME EQUIPMENT or parts thereof are RATED for non-CONTINUOUS OPERATION but controls allow OPERATORS to leave it in operation (should a medical or other emergency occur), the CONTINUOUS OPERATION of the ME EQUIPMENT must be considered REASONABLY FORESEEABLE MISUSE. Where SAFETY is dependent on switching the ME EQUIPMENT or parts thereof off after a prescribed period, steps should be taken to assure that intentional action is not required to do so.

A.14 Clause 14 – *PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS are not amenable to pass/fail testing on the finished product. Therefore, this standard requires that a PROCESS with certain elements be established for these subsystems. The approach is to state what is required in the PROCESS and leave it to the user of Clause 14 to determine how this is to be achieved.

Computers are increasingly used in ME EQUIPMENT, often in SAFETY-critical roles. The use of computing technologies in ME EQUIPMENT introduces a level of complexity exceeded only by the biological systems of the PATIENTS that the ME EQUIPMENT is intended to diagnose or treat. This complexity means that systematic failures can escape the practical limits of testing. Accordingly, this clause goes beyond traditional test and measurement of the finished ME EQUIPMENT and includes requirements for the PROCESSES by which it is developed. Testing of the finished product is not, by itself, adequate to address the SAFETY of PROGRAMMABLE ME EQUIPMENT.

For these reasons, this clause requires that a PROCESS with specific elements be established and followed. The intention is to establish these specific PROCESS elements, leaving the user of this clause to determine in detail how to accomplish them. This is similar to the approach taken in the ISO 9000 series. Because users of this clause are expected to be qualified to perform the identified tasks, detail has been kept to a minimum.

While iteration of some elements of the PROCESS is expected, no specific requirements to do so have been included. These requirements were omitted because the need to repeat PROCESSES or portions of them is unique to each particular device. In addition, the need for such iteration will arise from the more detailed understanding that emerges during the design PROCESS.

Because users of this standard are required to establish, maintain and apply a RISK MANAGEMENT PROCESS as part of compliance, this clause establishes those characteristics unique to programmable systems that must be considered as part of that PROCESS.

The effective application of Clause 14 will require, subject to the task in hand, competence in the following:

– application of the specific ME EQUIPMENT with emphasis on SAFETY considerations;

– ME EQUIPMENT development PROCESS;

– methods by which SAFETY is assured;

– techniques of RISK ANALYSIS and RISK CONTROL.

This is done to minimize the requirements to those that are essential to assuring SAFETY. It has also been done in recognition of the extensive and growing literature in the fields of software assurance and HAZARD assessment techniques as well as the rapid evolution of this discipline. Those applying this clause of the standard will need to employ the tools detailed in such literature as specific circumstances arise during the development of PEMS. For example, in early phases “top down” tools such as fault tree analysis will be more appropriate. As the design becomes more detailed, “bottom up” tools such as failure modes and effects analysis will come into wider use.

It is recognized that the MANUFACTURER might not be able to follow all the PROCESSES identified in Clause 14 for each constituent component of the PEMS, such as OTS software, subsystems of non-medical origin, and legacy devices. In this case, the MANUFACTURER should take special account of the need for additional RISK CONTROL measures.

Subclause 14.1 – *General

This standard requires the application of a RISK MANAGEMENT PROCESS in accordance with ISO 14971. This is particularly relevant to PEMS, because absolute assurance of the correctness of software or complex hardware is impossible, and therefore the design of a PEMS has to be carried out within a RISK MANAGEMENT PROCESS, in which RISK CONTROL measures are related to the RISKS being controlled. In fact, Clause 14 adds extra RISK MANAGEMENT and life-cycle PROCESSES. These are only required if the ME EQUIPMENT or SYSTEM is a PEMS.

Compliance VERIFICATION requires the MANUFACTURER'S internal assessment to cover not only the requirements of this clause but also those of ISO 14971.

Compliance with the requirements of Clause 14 is judged by examining the documentation produced by the PROCESSES required in the various subclauses. Clause 14 should be applied as a whole and not selectively All of this documentation is required to be in the RISK MANAGEMENT FILE.

The concept of assessment has been introduced in the compliance statement to account for methods other than inspection where necessary, such as audit. Thus, although there is no general requirement for the MANUFACTURER to operate a quality management system in accordance with ISO 9001, certain features of such a system are necessary. One feature that is commonly regarded as essential for a quality management system to be effective is a PROCESS of audit and review carried out within the organisation to confirm that it is actually following its own PROCEDURES: this is separate from any external assessment that may be carried out to demonstrate compliance with standards or regulatory requirements. This standard therefore requires that the MANUFACTURER shall not only document certain aspects of

the design PROCESS but shall also carry out an assessment to confirm that the requirements of this clause have been followed.

Subclause 14.2 – *Documentation

The expected way in which compliance with PROCESS requirements can be determined is by assuring that the documentation required for each PROCESS step has been generated. While most of the requirements of ISO 14971 are crucial components of an adequate software life-cycle, Clause 14 contains many additional PROCESS steps not required by that standard. Therefore, the documentation that these additional steps (in Clause 14) require is critical when a certification body is determining that they (the PROCESS steps) have been performed. Because Clause 14 addresses those RISKS associated with PEMS, it is required that it be included in the RISK MANAGEMENT FILE.

Since compliance with Clause 14 is determined solely by auditing to assure that the required documentation has been generated, the quality and accuracy of these documents is critical. Therefore it is required that the documents be generated, revised and maintained under a formal document control system. MANUFACTURERS would be well advised to assure that this documentation is clear and comprehensive to assist in the audit PROCESS.

Subclause 14.3 – *RISK MANAGEMENT Plan

ISO 14971 requires that a RISK MANAGEMENT plan be prepared and maintained in the RISK MANAGEMENT FILE. The plan should include the following:

a) scope of the plan, identifying and describing the ME EQUIPMENT and the life-cycle phases for which the plan is applicable;

b) a VERIFICATION plan;

c) allocation of responsibilities;

d) requirements for review of RISK MANAGEMENT activities; and

e) criteria for RISK acceptability.

In addition the to these elements, a PEMS VALIDATION plan is required because validation is seen as a necessary activity when developing a PEMS.

The RISK MANAGEMENT plan is a controlled document in the RISK MANAGEMENT FILE and a RECORD of the changes needs to be maintained if the plan changes during the course of development.

Subclause 14.4 – *DEVELOPMENT LIFE-CYCLE

A life-cycle helps ensure that SAFETY issues are considered throughout a product's development. This is important for all products and it is vital for PEMS. SAFETY can not be added to a PEMS after it has been developed. Two reasons are:

a) The actual PROCESSES used in the development of a PEMS, and the quality and rigour of those PROCESSES, are decided as a result of SAFETY factors. If it is discovered late on that inappropriate PROCESSES were used or that inadequate quality and rigour were applied, then the development will have to be repeated with correct PROCESSES;

b) Changes made at a late stage in the DEVELOPMENT LIFE-CYCLE are likely to be expensive (both in time and money), this is particularly true if a system requirement is incorrect or missing. System architecture can also be vulnerable to changes made late on. Often, the architecture is part of the SAFETY case, late changes may require significant rework in order to maintain the integrity of an architectural solution.

Mapping regulatory requirements

It should be possible to map all the regulatory activities (e.g. the requirements of Clause 14) onto the life-cycle model. This permits early VERIFICATION that all regulatory requirements for PROCESSES will be met.

Framework

A life-cycle for the development of a product provides a framework that allows the necessary SAFETY activities to take place in a timely and systematic manner. It should not impose unnecessary restrictions and it should ensure that all the required SAFETY activities take place. Obviously, the life-cycle needs to be decided early. Different life-cycle models are acceptable. One example (the V model) is shown in Annex H. Examples of different life-cycle model may be more iterative, or may permit more overlap between phases.

Phases and Tasks

The requirement for phases and tasks with well defined input, output and activity for each, ensures that:

– due consideration is given to the activities, how the activity will be done, what needs to be done before the activity can start and what the activity needs to provide;

– VERIFICATION of the PROCESS can be carried out.

Subclause 14.5 – *Problem resolution

Where appropriate, a documented system for problem resolution is required by this standard.

Problems may arise:

– with the product;

– within a PROCESS;

– between PROCESSES.

Examples of problems are:

– inconsistent requirements;

– ambiguous requirements;

– missing specifications;

– coding errors;

– incorrect operation of the PEMS.

A system for problem resolution is needed to ensure that when a problem arises, its impact on HAZARDS and their consequent RISK is managed, ad hoc methods for resolving problems can undermine the benefits obtained by using a systematic Life-cycle approach. An appropriate place to document the system for problem resolution is as part of the DEVELOPMENT LIFE-CYCLE.

Subclause 14.6.1 – *Identification of known and foreseeable HAZARDS

PEMS have extra initiating causes for HAZARDS.

Subclause 14.6.2 – *RISK CONTROL

As the choice of the PROCEDURES and tools used by a MANUFACTURER for the development of a PEMS will be influenced by many factors, this subclause requires that one of the factors for the choice is the RISK reduction required for the RISK CONTROL measure. A RISK CONTROL measure that is developed using PROCEDURES and tools that are known to be good is more likely to carry out its intended functions than one developed using PROCEDURES and tools that are known to be poor.

8221 **Subclause 14.7 – *Requirement Specification**

8222 RISK CONTROL measures are used to control the RISK of identified HAZARDS. The requirements
8223 for these measures are documented in requirement specification. The requirement should
8224 both specify what the measure does and how well it does it. ISO 14971 does not demand a
8225 requirements specification.

8226 ***Verifiable requirements***

8227 Requirements should be verifiable. This applies to both the function of the RISK CONTROL
8228 measure and how likely it is to perform correctly. Quantitative VERIFICATION of failure rates
8229 is, generally, impractical for software. VERIFICATION of a qualitative approach would be by
8230 verifying that the appropriate PROCESSES were used.

8231 ***Decomposition***

8232 Examples of a PEMS structure is shown in Annex H. Requirements to implement the RISK
8233 CONTROL measures should be specified for the PEMS and for any PESS that implements or
8234 partially implements one or more RISK CONTROL measure. This may be in a single document
8235 or in several documents.

8236 **Subclause 14.8 – *Architecture**

8237 An architecture specification is not required by ISO 14971. It is an additional requirement for
8238 PEMS because:

8239 – Often the architecture chosen will be part of a RISK CONTROL measure. RISK CONTROL
8240 measures need to be explicit for complex systems such as a PEMS.

8241 – Architecture specifications are recognized as a necessary part of a good software
8242 development PROCESS such as is required for a PEMS.

8243 There is a list of architecture features for inclusion in the specification where appropriate.
8244 This list has been selected because in particular circumstances one or more of the features
8245 could be used to control the RISK of a HAZARD. For example, the use of a HIGH-INTEGRITY
8246 COMPONENT will effectively remove any RISK that would result from the failure of that
8247 component.

8248 ***Paragraph e) Software Partitioning***

8249 This approach can be useful when there is a significant need for rigorous SAFETY validation of
8250 PEMS.

8251 The software (firmware and application layers) is distinctly divided into critical, non-critical and
8252 supervisory sections. Partitioning is used to verify that the instructions and data of the
8253 critical, non-critical and supervisory section do not interfere with each other and that there is
8254 separation of duties within the sections of the software. If there is no separation of duties
8255 within the sections of the software, all software should be defined as critical, to make sure
8256 that the analysis has taken into consideration the critical section of the software.

8257 Requirements for separating critical code from non-critical code include RISK ANALYSIS of the
8258 entire system, HAZARD mitigation strategies employed, analysis of physical resources and an
8259 analysis of logical properties (i.e., control and data coupling). In general, partitioning should
8260 separate and isolate the SAFETY-related functionality from the non-SAFETY related functionality
8261 in the design and implementation. This PROCESS can minimize, or at least reduce, the
8262 VERIFICATION necessary to assure that data shared by or passed to the critical section does
8263 not affect the specified operation of the SAFETY critical code.

8264 Elements of a PEMS architecture which might refer to partitioning criteria, could be: data flow
8265 diagrams, control flow diagrams, hierarchical decomposition graph, call tree, VERIFICATION
8266 plans, validation plans, test results, requirements specification, etc.

Partitioning includes the following steps:

a) Identification of Critical, Non-Critical and Supervisory sections. The means of identification depends upon the modularity of the code, the programming language, the code design and other specification attributes.

b) Description of the interfaces between the Critical and Non-Critical sections.

1) Identification of data or variables global to the Critical and Non-Critical sections, modules, etc., identified in Step *a)*.

2) Identification of any parameters that are passed between Critical and Non-Critical sections, modules, etc., identified in Step *a)*.

3) Description of the flow of the data, variables or parameters identified in Steps *b) 1)* and *b) 2)*.

4) Description of the mechanism which is used to prevent data corruption, overwriting or other errors of the above identified data, variables and/or parameters which would affect SAFETY critical performance.

c) Validation of the integrity of the partition. This may be accomplished by functional testing and off-NOMINAL or stress testing techniques.

There is a list of items to be taken into consideration in the architecture specification. This list has been selected because each of these items could influence the choice of architecture.

Subclause 14.9 – *Design and implementation

The technical solutions chosen need to be defined. It is often appropriate to decompose a PEMS into subsystems. Figure H1 shows examples of PEMS/ PESS structures. Reasons may include:

Keeping the complexity of subsystems manageable

The less complex the system the easier it is to understand and consequently easier to design and then maintain. The resulting design is more likely to be correct and easier to test. Coding standards should specify limits for complexity.

Architecture

The system architecture may make it logical to separate systems e.g. if diverse systems are needed they should be implemented as distinct subsystems.

Modularity

Modularity can facilitate the provision of different system options, reuse of an existing proven subsystem and the extension of system functionality.

Physical components

A sensible division of physical subsystems will help the diagnosis and repair of hardware faults.

Different technologies

Often different engineers will implement the hardware and the software design. In this case specifying each as a separate subsystem will enable each to be implemented independently.

The overall system will only function correctly if each of its constituent subsystems has been adequately specified. This leads to the requirement for a design specification for each subsystem. A design specification for a subsystem would typically include a detailed interface specification, and may include implementation details, e.g. algorithms.

Each subsystem should be tested to show that the design specification has been correctly implemented. This leads to the requirement for a test specification for each subsystem.

The design and test specifications may be documented in whatever form is practicable, e.g. they can be separate documents or they can be combined in a larger document. The design specification and the test specification for each subsystem should be identifiable.

Examples of the elements of the design environment are given in H.3. Such elements will have an influence on the quality and correctness of the design. Some elements will have been identified as the necessary development PROCESSES and methods (see 14.6.2). The descriptive data regarding the design environment facilitates VERIFICATION that the necessary PROCESSES and methods have been used.

Subclause 14.10 – *VERIFICATION

VERIFICATION must be performed between and across each of the DEVELOPMENT LIFE-CYCLE phases, as appropriate. This is necessary in order to demonstrate the integrity of the PEMS development PROCESS.

Subclause 14.11 – *PEMS VALIDATION

The final phase of any PEMS DEVELOPMENT LIFE-CYCLE model is PEMS VALIDATION. PEMS VALIDATION is intended to assure that the right product is built. Validation is important for PEMS because unexpected interactions between functions might occur that can only be discovered by validation.

PEMS VALIDATION can include tests for a high volume of data, heavy loads or stresses, human factors, security, performance, configuration compatibility, fault testing, documentation and SAFETY.

Independence is needed to avoid conflicts of interest and because the assumptions of the designer should not influence or limit the extent of the PEMS VALIDATION. . Examples of level of independence include:

– separate person
– separate management
– separate organization

Subclause 14.12 – *Modification

Typically the design of a PEMS is not completely new but is partly or even largely derived from earlier design(s). It may nevertheless be possible to treat the design as if it were completely new and to establish the RISK MANAGEMENT report and demonstrate compliance with the requirements of this standard without reference to previous documentation. If however the RISK MANAGEMENT report does need to include some information from the documentation of the previous design(s), it is then necessary to confirm that all such information remains valid despite the changes introduced in the new design.

Because demonstration of the SAFETY of a PEMS depends critically on documentation, an effective system is needed to ensure the integrity of the documentation and, if different versions of a document exist, to identify the applicability of each version.

Subclause 14.13 – *Connection of PEMS by NETWORK/DATA COUPLING to other equipment

Many hospitals are operating ME EQUIPMENT in a networked environment today. Originally, these networks were installed to optimize the business economic and technical area. For this, a fast electronic data interchange is required. Today, these networks are used for medical applications within the hospital, between hospitals, and from home.

Initially, the use was only the exchange of laboratory data. Now there are large amounts of data transported over the networks, such as medical image data. There are further requests from the user to get "real time" solutions (e.g. control of operation robots via network).

Additional guidance on NETWORKS/DATA COUPLING is found in Annex H.

A.15 Clause 15 – Constructional requirements for ME EQUIPMENT

Subclause 15.1– *Arrangements of functions of ME EQUIPMENT

Controls, instruments, indicating lamps, etc., which are associated with a specific function of the ME EQUIPMENT, should be grouped together (see Clause 13).

Subclause 15.3.1.1 – *Push test

ENCLOSURES must have adequate rigidity if they are to maintain a level of protection from internal LIVE PARTS. This requirement is harmonized with the force test of IEC 60950-1. Internal components are not subjected to the force test of IEC 60950-1 because their robustness is verified per the tests of 15.3.1.3 and 15.3.1.4.

Subclause 15.3.1.3 – *Drop test

The tests for HAND-HELD equipment or ME EQUIPMENT parts that are hand held are different from the test for PORTABLE and MOBILE equipment because of the difference in practical application.

An ENCLOSURE's resistance to impact is required to prevent unacceptable RISK during foreseeable abuse. The energy of the test impact approximates ME EQUIPMENT being inadvertently struck by an object in the hand of a passer-by or by a broomstick or mop handle during cleaning of the floor. The test equipment has been simplified and harmonized with other standards containing ENCLOSURE impact requirements, including IEC 60950-1.

Where a MANUFACTURER feels the requirements of this subclause are not necessary to mitigate an unacceptable RISK, justification shall be documented in the RISK MANAGEMENT FILE per 4.3, along with an identification of alternate requirements met. For example, FIXED ME EQUIPMENT may have one side of the ENCLOSURE protected by the floor, wall or ceiling. The MANUFACTURER must document the evaluation of the probability that the equipment may be moved or installed incorrectly. The MANUFACTURER must also evaluate and identify, through the RISK MANAGEMENT PROCESS, what resistance to impact the protected side of the ENCLOSURE must have to ensure no unacceptable RISKS are generated by failure to comply with the original requirements of this subclause.

A drop surface of wood of density > 600 kg/m^3 allows selection of most common hardwoods. Oak, beech, birch, ash and maple are acceptable. These varieties have similar hardness while hardwoods of density < 600 kg/m^3 (e.g. mahogany, elm, sweet gum, cherry) and softwoods have greatly decreased hardness in comparison.

Subclause 15.3.1.3.2 – *PORTABLE ME EQUIPMENT

This test represents NORMAL USE, as explained in rationale for 15.3.1.4. This test is not intended to represent REASONABLY FORESEEABLE MISUSE. There is not currently a test that directly addresses free fall type foreseeable abuse, however its felt the ball impact test in 15.3.1.2 represents foreseeable misuse, albeit indirectly. As stated in 4.2, if the RISK MANAGEMENT PROCESS concludes that a more severe test is appropriate, this should be done.

Subclause 15.3.1.4 – *Rough handling test

Contrary to what is often assumed, ME EQUIPMENT may be used in a hostile environment. In case of emergency, ME EQUIPMENT is carried or wheeled on trolleys over doorsteps and into elevators and subjected to bumps and vibration. Such conditions may in fact typify NORMAL USE for some ME EQUIPMENT.

The threshold test is intended to require that MOBILE ME EQUIPMENT be able to pass over common obstacles encountered in a health care setting, such as a door threshold, and determine that rough handling and instability do not cause an unacceptable RISK. Having a performance-based requirement that heavy MOBILE ME EQUIPMENT be able to pass over the 20 mm threshold provides an indirect requirement for MOBILE ME EQUIPMENT to have a minimum wheel diameter. If was felt the exception for MOBILE ME EQUIPMENT with maximum SAFE WORKING LOAD of less than 45 kg was appropriate as the operator can raise lighter MOBILE ME EQUIPMENT over the threshold. Also the RISK from instability is not as great as with heavier equipment. The 45 kg value is consistent with the exception to the 70 mm wheel diameter requirement in subclause 24.102 of IEC 60601-2-32: 1994 for X-ray accessories.

Subclause 15.3.2 – *Environmental influences

a) ME EQUIPMENT is often used or stored in environmental conditions, which are within the INTENDED USE/INTENDED PURPOSE as declared by the MANUFACTER. In such cases no HAZARD is expected. However the environmental conditions may differ from those declared and still the ME EQUIPMENT is expected to remain safe. To ensure this, the USER has to perform the periodic inspection and maintenance prescribed by the MANUFACTURER. These activities are expected to prevent any deterioration of the SAFETY level and also detect signs of commencing of any such deterioration. To ensure this, the instructions for preventive maintenance have to be easy to understand and to follow, without introducing any RISK for mix-ups or for overlooking of SAFETY-relevant symptoms.

b) The exchange of such parts is expected to be easy to perform, preferably without special tools. In addition, the disassembly of the worn out part or of the part exchanged preventively and the assembly of the spare one must not create a SAFETY HAZARD. To ensure this, the instructions for performing such activities have to be easy to understand and to follow, without introducing any RISK of mix-up.

Subclause 15.4.3 – *Batteries

If a HAZARD might develop as a result of exhaustion of the battery, means should be provided to forewarn of this condition.

Where appropriate, particular standards should specify the corresponding requirement.

Subclause 15.4.3.5 – *Excessive current and voltage protection

In order to address the HAZARDS created by less common internal energy sources, a requirement that internal sources be evaluated as part of the RISK ASSESSMENT was added.

Subclause 15.4.4– *Indicators

It is important for an OPERATOR or for SERVICE PERSONAL to be able to determine the functional status of ME EQUIPMENT. In NORMAL USE, the OPERATOR needs to be able to distinguish between ME EQUIPMENT in stand-by and ME EQUIPMENT in a fully functional state. Some ME EQUIPMENT has an extended warm-up period. Other ME EQUIPMENT has standby or battery charging modes.

It can be hazardous for ME EQUIPMENT to be left unattended in the wrong state. SERVICE PERSONAL need to be able to determine when ME EQUIPMENT is energized to avoid possible HAZARDS.

Subclause 15.4.7.3 – *Entry of liquids

The former IPX8 rating requirement for foot switches amounts to no more than “greater protection than IPX7”. By making this requirement IPX6 minimum, the requirement sets a defined level of protection while allowing higher levels where appropriate.

Subclause 15.5 – *MAINS SUPPLY TRANSFORMERS of ME EQUIPMENT and transformers PROVIDING separation in accordance with 8.5

The addition of “and transformers providing separation in accordance with 8.5” to the original title that only identified “Mains transformers” is intentional. The tests for transformers should be utilized any time that the transformer is used to establish separation between USERS, PATIENTS, etc. and a HAZARD.

Revisions to 15.5 do not change significantly current methods (including those of the second edition of this standard) of testing. The methods and requirements were simplified and now include all different types of protectors like: PTCs, feedback control (switch mode power supplies), primary or secondary overcurrent devices, etc. For those transformers that have not been tested in accordance with the 5X frequency and 5X voltage tests of 15.5.2 to establish the adequacy of insulation between the turns of a winding are shorted at the terminals (rather than external to the transformer) to assure that failure of that insulation will not cause maximum allowable temperatures to be exceeded.

Because of the difficulties that would be encountered when trying to test transformers that are RATED for high frequencies (such as those used in switch mode power supplies), the 2X frequency and voltage tests are specified in those cases as well. The 2nd edition only applied this test where the voltage exceeded 500 V.

Subclause 15.5.1.1 – *Transformers

Output windings are required to be “tested in turn” because under overload conditions, testing all windings simultaneously can cause overtemperature devices to operate which would not operate if only one winding was being overloaded. A single output winding being overloaded is actually quite likely. Therefore this combination of conditions is considered the likely worst case scenario.

Subclause 15.5.2 – *Dielectric strength

By performing the test at 5x frequency, breakdown of insulation between windings causes a change in impedance (at the higher frequency) allowing that breakdown to be detected.

Subclause 15.5.3 – *Construction of transformers used to provide separation as described in 8.5

The requirements specified in IEC 61558-1: 1998, subclause 5.12 are generally similar to those in the second edition of this standard but transformers complying with them are likely to be more readily available.

Additionally, Annex U of IEC 60950-1: 2001 includes requirements relating to the use of triple-insulated winding wire in transformers instead of a separate layer of insulation between windings (as would be traditionally be provided by bobbins for example). Transformers which use this method of separation between windings and which comply with all other requirements of this standard should generally be considered to provide an adequate level of SAFETY.

A.16 Clause 16 – *Requirements for ME SYSTEMS

Increasingly, ME EQUIPMENT is being combined with other pieces of equipment that may not have originally been intended for medical application to create systems where one or more of the elements of the system come into contact with the PATIENT. Clause 16 provides requirements to ensure the SAFETY of the PATIENT who may come into contact with ME SYSTEMS. It is intended both for the original equipment MANUFACTURER who provide such systems and for personnel from medical institutions who assemble such systems.

Clause 16 on ME SYSTEMS is intended to be used by MANUFACTURERS of combinations of electrical equipment, which includes one or more items of ME EQUIPMENT. The equipment may be separate items or may be in a single ENCLOSURE or a combination of these cases.

Clause 16 is also intended to be used by personnel from institutions for medical practice who assemble such ME SYSTEMS, as they become the MANUFACTURER by that action. In this case, engineering expertise in the application of the electrical equipment design standards is required to ensure that the ME SYSTEM complies with all requirements of Clause 16.

The application and rapid development of modern electronic and biomedical technologies in medical practice have already led to a situation that instead of a single item of ME EQUIPMENT, rather complex and extensive ME SYSTEMS of electrical equipment are applied for the diagnosis, therapy and monitoring of PATIENTS.

More and more, such ME SYSTEMS comprise equipment originally manufactured for use in different specific application fields, not necessarily medical, that are connected with each other in a direct or indirect way. ME EQUIPMENT complying with this standard may be connected with other, non-MEDICAL, ELECTRICAL EQUIPMENT. The latter equipment may, each individually, fully meet the requirements as mentioned in safety standards applicable in their specific application field. They do not always comply with the SAFETY requirements for ME EQUIPMENT and, thereby, influence the SAFETY of the whole ME SYSTEM. It is for this reason that the MANUFACTURER is required to apply RISK MANAGEMENT to the whole ME SYSTEM. One example of an additional HAZARD is the ignition of fire when an ME SYSTEM containing non-ME EQUIPMENT is used in an OXYGEN RICH ENVIRONMENT, possibly inadvertently.

The electrical equipment may be situated either in a medically used room that is intended for diagnosis, treatment or monitoring of PATIENTS, or in a non-medically used room where no medical practice is carried out. Within a medically used room, electrical equipment may be placed inside or outside a volume that is defined as PATIENT ENVIRONMENT.

There are two situations possible in medical practice.

a) Where Clause 16 does not apply

Simultaneously operated ME EQUIPMENT, i.e. different ME EQUIPMENT connected at the same time to a PATIENT but not connected to each other. Such ME EQUIPMENT can influence each other for example, high-frequency surgical equipment in the operating theatre may influence PATIENT monitoring.

NOTE Assistance can be available from the instructions for use for each ME EQUIPMENT.

b) Where Clause 16 applies

ME SYSTEMS, consisting of ME EQUIPMENT and possibly also non-ME EQUIPMENT, interconnected permanently or temporarily for a certain purpose such as diagnosis or treatment of a PATIENT. Examples: ME SYSTEMS for diagnostic X-ray examination, endoscopes with video camera, PATIENT monitoring, ultrasound equipment with a personal computer, computed tomography or magnetic resonance imaging.

The various parts of such an ME SYSTEM may be situated within the PATIENT ENVIRONMENT or outside it but still within a medically used room or may be located in a non-medically used room containing, for example, electrical power distribution or data processing equipment.

Subclause 16.1 – *General requirements for the ME SYSTEMS

Appropriate documentation concerning the standards compliance may be a declaration of conformity by the MANUFACTURER or a certificate from a test house.

ME SYSTEMS, by their nature, may be frequently modified; Clause 16 does not apply to the modification of individual items in an ME SYSTEM

Subclause 16.2 – *ACCOMPANYING DOCUMENTS of an ME SYSTEM

The documents that accompany an ME SYSTEM intended for DIRECT CARDIAC APPLICATION should provide data on such items as:

– use of rubber gloves;

– use of stop-cocks made of insulating material;

– minimum distances between PATIENT and equipment being part of the ME SYSTEM (PATIENT ENVIRONMENT);

– instructions about how to use the ME EQUIPMENT in the typical medical application, for example, use of a catheter.

For SAFETY reasons, particular attention should be paid to the different levels of HAZARDS when, within the PATIENT ENVIRONMENT, electrodes or other body sensors are used on the PATIENT, externally and internally, including direct connections to the heart.

Possible connections to the heart of a PATIENT should be kept isolated from the equipment.

The warning not to place MULTIPLE SOCKET-OUTLETS on the floor is to prevent the ingress of liquids and to prevent mechanical damage.

Furthermore, measures should be taken to ensure that, when assembling or modifying an ME SYSTEM incorporating MULTIPLE SOCKET-OUTLETS, these are mounted in such a way as to prevent ingress of liquids and to avoid mechanical damage during NORMAL USE and transportation.

Relevant safety standards for non-ME EQUIPMENT may specify or require disclosure of permissible environmental conditions. Accordingly, the environmental conditions permitted for various items in an ME SYSTEM may be different. The permissible environmental conditions for the ME SYSTEM must be specified so that no HAZARD will arise when operating it within these specified limits.

Subclause 16.3 – *Power supply

This requirement is to ensure the SAFETY level according to IEC 60601-1 at the ME SYSTEM level.

SAFETY after assembly is maintained, for example, by one or more of the following measures:

– measures that are built-in within the ME EQUIPMENT, for example, separation of relevant circuits;

– SEPARATION DEVICES provided as ACCESSORIES to the ME EQUIPMENT (see 16.5);

– SEPARATION DEVICES provided as ACCESSORIES to the ME SYSTEM;

– separating transformer;

– additional PROTECTIVE EARTH CONDUCTORS.

Non-ME EQUIPMENT may provide the specified power supply for ME EQUIPMENT in accordance with 5.5 *g,* 7.10.2.14*,* 8.2.1 and Figure 12. The specified power supply must fulfil the requirements of this standard or demonstrate that an equivalent degree of SAFETY is obtained as accepted by 4.3. See IEC/TR3 60513 for guidance.

Subclause 16.5 – *SEPARATION DEVICES

The SAFETY of some ME EQUIPMENT depends on the precondition that any SIGNAL INPUT/OUTPUT PARTS are connected only to equipment that is specified for this purpose, otherwise LEAKAGE CURRENTS may be increased by unwanted currents flowing through signal cables.

Hazardous situations may occur if the SIGNAL INPUT/OUTPUT PART of ME EQUIPMENT is connected to equipment outside the medically used room, possibly in another building and therefore connected to another mains supply branch circuit.

A SEPARATION DEVICE prevents a HAZARD to the PATIENT or OPERATOR. It should be placed as near as practicable to the ME EQUIPMENT. Additionally, the inclusion of the SEPARATION DEVICE helps to avoid HAZARDS through malfunction of equipment caused by unwanted currents flowing through cables.

The need for a SEPARATION DEVICE depends on the configuration of the ME SYSTEM.

Subclause 16.6 – *LEAKAGE CURRENTS

Relevant standards for some non-MEDICAL ELECTRICAL EQUIPMENT may have limits for TOUCH CURRENTS higher than required by Clause 16; these higher limits are acceptable only outside the PATIENT ENVIRONMENT. It is essential to reduce TOUCH CURRENTS when non-ME EQUIPMENT is to be used within the PATIENT ENVIRONMENT. LEAKAGE CURRENT reduction measures may include:

– additional PROTECTIVELY EARTHED parts;

– a separating transformer;

– an additional non-conductive ENCLOSURE.

Interconnecting cables and their connector housings are parts of the ENCLOSURE and therefore the LEAKAGE CURRENT limits within the PATIENT ENVIRONMENT, as required in 16.6.2, are applicable.

If a MULTIPLE SOCKET-OUTLET without a separating transformer is used, the interruption of its protective earthing may result in TOUCH CURRENTS equal to the sum of the individual EARTH LEAKAGE CURRENTS.

Subclause 16.6.4 – *PATIENT LEAKAGE CURRENT

For an ME EQUIPMENT, the maximum allowed values for PATIENT LEAKAGE CURRENT and total PATIENT LEAKAGE CURRENT (applicable with several APPLIED PARTS connected to the ME EQUIPMENT) are given in Table 2; see also 8.7.3. An ME SYSTEM is to provide the equivalent level of SAFETY as provided by ME EQUIPMENT within the PATIENT ENVIRONMENT (see 16.1). Therefore, the same maximum values for PATIENT LEAKAGE CURRENT and total PATIENT LEAKAGE CURRENT apply, regardless whether the APPLIED PARTS are connected to the same element of the ME SYSTEM or not. This holds for the operation of the ME SYSTEM in NORMAL CONDITION, as the single fault concept is not applicable to an ME SYSTEM.

The MANUFACTURER of an ME SYSTEM that is (re)configurable by the USER or OPERATOR may use RISK MANAGEMENT methods to determine which combinations of APPLIED PARTS, to be used in practice, will lead to high values of total PATIENT LEAKAGE CURRENT. Measurements may then be performed on a limited set of combinations, rather than on all possible permutations.

It must be noted that combinations of equipment or of APPLIED PARTS, made by the USER or OPERATOR, that are outside the range of combinations indicated by the MANUFACTURER, may lead to hazardous situations.

Subclause 16.7 – *Protection against MECHANICAL HAZARDS

Attention should be paid to the effects of interruptions causing unplanned movements, removal of compression forces, and the safe removal of PATIENTS from the PATIENT ENVIRONMENT when a hazardous situation occurs.

Subclause 16.9.2.1 – *MULTIPLE SOCKET-OUTLET

The second edition of this standard used the defined term "AUXILIARY MAINS SOCKET-OUTLET (AMSO)" to describe a socket-outlet intended for provision of mains supply to other ME

EQUIPMENT or to other separate parts of the ME EQUIPMENT. The systems collateral standard, IEC 60601-1-1, defined a term "MULTIPLE PORTABLE SOCKET-OUTLET (MPSO)". The two terms have been combined into a new term, "MULTIPLE SOCKET OUTLET (MSO)." Subclause 57.2 *e)* of the second edition required that a MPSO be designed so that it could not accept a MAINS PLUG. An exception for EMERGENCY TROLLEYS was allowed. With the combination of the two definitions and the change to 8.11.2 to require any MSO on ME EQUIPMENT to comply with 16.9.2.1, reconciles the need for rapid exchange in an emergency with the need to restrict leakage current.

MAINS CONNECTORS (see Figure 1) are not required to be FIXED since the intent is to prevent unintentional connection of other equipment that may adversely effect the SAFETY of the ME SYSTEM. Reassignment of ME SYSTEM wiring is a dangerous practice and beyond the scope of this clause. See 16.2 for disclosure requirements.[208]

Excessive TOUCH CURRENTS can occur unless casual access for additional equipment connections is impeded or prevented.

The DOUBLE or REINFORCED INSULATION as required for isolating transformers (for example, IEC 60742) is not required because the ENCLOSURE LEAKAGE CURRENT of the ME SYSTEM is less than 500 µA in SINGLE FAULT CONDITION, therefore a separating transformer is sufficient.

The CLASS I requirement for the transformer assembly, is necessary to provide connected equipment with a PROTECTIVE EARTH CONNECTION.

Isolation monitoring of the separating transformer is not necessary. SINGLE FAULT CONDITION can be detected during routine maintenance and double fault condition is of no concern. The transformer construction with PROTECTIVELY EARTHED centre tapped secondary winding is allowed, but not required.

Subclause 16.9.2.1* c), *3th dash

ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD has an impedance between the protective earth pin in the MAINS PLUG and any part that is PROTECTIVELY EARTHED that does not exceed 0,2 Ω. Similarly, the MULTIPLE SOCKET-OUTLET has an impedance that does not exceed 0,2 Ω between its MAINS PLUG and its socket-outlets. This results in an impedance that does not exceed 0,4 Ω between the MULTIPLE SOCKET-OUTLET MAINS PLUG and any part of ME EQUIPMENT that is PROTECTIVELY EARTHED.

The impedance of PROTECTIVE EARTH CONNECTIONS is allowed to exceed 0,2 Ω when the relevant circuits have limited current capability (see 8.6.3 *b)*). In such cases in ME EQUIPMENT, this results in an impedance between the protective earth pin in the MAINS PLUG and any part that is PROTECTIVELY EARTHED that exceeds 0,4 Ω.

Subclause 16.9.2.2 – *PROTECTIVE EARTH CONNECTIONS in ME SYSTEMS

All PROTECTIVE EARTH CONDUCTORS and POWER SUPPLY CORDS should be routed together.[209]

Within the PATIENT ENVIRONMENT it is important to limit potential differences between different parts of an ME SYSTEM, and an adequate connection with a protective earthing system plays an important role in limiting that potential difference. It is therefore important to prevent interruption of that protective means to any part of the ME SYSTEM.

– The additional protective earthing could be used when the TOUCH CURRENT in SINGLE FAULT CONDITION exceeds the allowable limits.

– The additional protective earthing is not necessary for ME EQUIPMENT complying with this standard. However, in the case of non-ME EQUIPMENT this will prevent TOUCH CURRENTS exceeding allowable limits.

– The use of a TOOL is not required to disconnect the mains plug because the mains plug will disconnect both the mains and the protective earth.

A.17 Clause 17 – *Requirements for electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

IEC 60601-1-2 specifies electromagnetic immunity test levels to minimize the effect of the electromagnetic environment on the ME EQUIPMENT and ME SYSTEMS covered by this standard. It specifies electromagnetic emissions limits to minimize the effect, on other equipment, of electromagnetic disturbances that may be emitted, intentionally or unintentionally, by ME EQUIPMENT and ME SYSTEMS. It also specifies requirements for Identification, marking and documents so that the MANUFACTURER of the ME EQUIPMENT or ME SYSTEM provides information to the customer or USER that is essential in determining the suitability of the ME EQUIPMENT or EM SYSTEM for the electromagnetic environment of use, and in managing the electromagnetic environment of use to permit the ME EQUIPMENT or ME SYSTEM to perform safely and provide its ESSENTIAL PERFORMANCE without disturbing other equipment.

Electromagnetic emission requirements are necessary for the protection of:

– SAFETY services;

– other ME EQUIPMENT and ME SYSTEMS;

– non-ME EQUIPMENT (e.g. computers);

– telecommunications (e.g. radio/TV, telephone, radio-navigation).

More importantly, electromagnetic immunity requirements are necessary to assure that ME EQUIPMENT and ME SYSTEMS remain safe and continue to provide their ESSENTIAL PERFORMANCE in the presence of the electromagnetic disturbances to which they can be expected to be exposed during NORMAL USE.

A.18 Clause 18 – *Requirements for protection of the NATURAL ENVIRONMENT

The ENVIRONMENTAL IMPACT of ME EQUIPMENT must be weighed against its safe medical performance. The safe medical performance could be required in some particular standards in the form of ESSENTIAL PERFORMANCE requirements. Although this standard has no specific requirements regarding safe medical performance, this must be taken into account in a Life-Cycle Assessment for the specific ME EQUIPMENT in question.

In this Clause, ENVIRONMENTAL IMPACTS are covered that are relevant in the production, but are related to the design phase of the ME EQUIPMENT. Examples for this are gluing, painting and selection of components.

Subclause 18.1 – *Introduction to design of ME EQUIPMENT for life-cycle

Environmental protection can be done by considering the whole product life-cycle that consists of the main phases: specification/design, manufacturing, useful life, and disposal, for example:

– reducing the energy necessary to produce, transport and use the ME EQUIPMENT,

– using techniques of design, production, transport and use that reduce natural resource consumption,

– using materials and substances that have less of an ENVIRONMENTAL IMPACT on soil, water or other natural resources, that do not have hazardous effects on the food chain and do not contribute to climate changes, or

– taking into account the impacts on the NATURAL ENVIRONMENT of, for example, disassembly and disposal of ME EQUIPMENT at its end of life.

The application of the requirements in Clause 18 is no problem if the MANUFACTURER of ME EQUIPMENT or an ME SYSTEM does all design. Problems could arise where components, parts or even equipment ready for connection to SUPPLY MAINS are purchased from another MANUFACTURER. However, the RISK MANAGEMENT PROCESS has to be carried out even in this case. The responsibility for all these items remains with the MANUFACTURER of the ME EQUIPMENT or the ME SYSTEM.

It is recognized that for this assessment not all the necessary information could be provided. This may be because of the lack of data from the original MANUFACTURER or because it has been kept confidential by that MANUFACTURER. In this case, the RISK MANAGEMENT PROCESS has to set priorities for the requirements in Clause 18. The essential items in this clause with a high potential of RISK are, for example, HAZARDOUS SUBSTANCES AND MATERIALS, water pollution, air contamination and disposal of hazardous substances.

In this clause, a reference to ME SYSTEMS applies only to equipment with a direct connection to SUPPLY MAINS.

Subclause 18.2.1 – *Life-Cycle Assessment (LCA) of ME EQUIPMENT

The ENVIRONMENTAL IMPACT of ME EQUIPMENT must also be weighed against its safe medical performance. The safe medical performance could be required in some particular standards in the form of ESSENTIAL PERFORMANCE requirements. Although this standard has no specific requirements regarding safe medical performance, this must be taken into account in a Life-Cycle Assessment for the specific ME EQUIPMENT in question.

The Life-Cycle Assessment is a systematic set of PROCEDURES for compiling and examining the inputs and outputs of materials and energy and associated ENVIRONMENTAL IMPACTS directly attributable to the functioning of an economic system throughout its life-cycle (IEC Guide 109). Principles of the Life-Cycle Assessment are described in ISO 14040.

The state of the art of Life-Cycle Assessment is still immature; various methods and tools are available, each with their own benefits and shortcomings. No specific approach of Life-Cycle Assessment can be required at this moment, nor any specific level of detail and thoroughness.

However, MANUFACTURERS need to apply some form of assessment and base their design decisions on the outcome of these environmental assessments. The result of that assessment should be recorded in the design documentation.

The Life-Cycle Assessment may consist of the following PROCESS steps:

a) providing the applicable requirements in sense of Clause 18**.**

b) selection of adequate materials and providing the list of those materials.

c) analysis taking into account the following aspects:

- energy, water and other resources used for producing the materials
- consumption of energy and other resources during useful life
- emissions, including gases harmful to the NATURAL ENVIRONMENT, circulation of dust
- volume and mass of material
- selection of material
- manufacturing PROCESS
- transport
- reliability
- probability of repair and frequency of preventive maintenance
- disassembly
- RECYCLING, REUSE
- disposal
- waste

d) documentation to demonstrate compliance with requirements:

- design documentation:

- specifications
- drawings etc.
- results of analysis
- list of materials used

– ACCOMPANYING DOCUMENTS:

- advice, such as for safe disposal
- warnings

In this clause, ENVIRONMENTAL IMPACTS are also covered that are relevant in the production, but are related to the design phase of the ME EQUIPMENT. Examples of this are gluing, painting and selection of components.

Application of the RISK MANAGEMENT PROCESS is required in 4.2. ISO 14971 describes the RISK MANAGEMENT PROCESS. During this PROCESS, several aspects of the impact on SAFETY of ME EQUIPMENT have to be analysed. One aspect is environmental protection.

Subclause 18.2.2 – HAZARDOUS SUBSTANCES AND MATERIALS used in conjunction with ME EQUIPMENT

The RISK MANAGEMENT PROCESS may alter the list of HAZARDOUS SUBSTANCES AND MATERIALS in Annex L.

This list should not only include those materials and substances that are required by law or regulations but also substances and materials known to be safe under NORMAL CONDITION but harmful under reasonably foreseeable conditions, including: when burning, oxidising, evaporating, milling, contacting with water or being de-composed.

The World Health Organization (WHO) provides information on substances that should be avoided because of their adverse effect on the health of human beings and the NATURAL ENVIRONMENT. Such substances should be avoided as much as possible. The selection of these substances should be based on the application of the RISK MANAGEMENT PROCESS.

Subclause 18.2.3 – *Packaging of ME EQUIPMENT

Packaging material should be included in the Life-Cycle Assessment PROCESS for ME EQUIPMENT because the MANUFACTURER of packaging material may be not the same as for the ME EQUIPMENT. Attention is drawn to already existing national standards and laws for packaging material.

Whether the application of reusable packaging has a positive ENVIRONMENTAL IMPACT depends on a number of factors, such as volume and mass of material, choice of material, energy required for transport, repair etc. The MANUFACTURER should make an assessment of the alternatives and decide on the best solution. The PROCESS and result of that assessment should be recorded.

Kind and mass of the material is useful information for RECYCLING.

There are cases where the packed ME EQUIPMENT is in a transport packaging. The receiver could be different from the person who is unpacking the ME EQUIPMENT. In these cases the receiver of the transport packaging might not be the RESPONSIBLE ORGANIZATION. Therefore the term "receiver" is used.

During the useful life, the RESPONSIBLE ORGANIZATION is mainly responsible for providing packaging materials for resterilizing ME EQUIPMENT or its parts. Therefore, this standard has no requirements for packaging materials used in sterilization PROCESSES. Nevertheless, this issue should be taken into account during the design phase by using methods that minimize packaging waste in the sterilization PROCESS.

Subclause 18.2.4 – *Consumption during useful life

Energy in the sense of this clause includes all kinds of energy, which are provided externally to the ME EQUIPMENT. The types of energy are, for instance, electrical, gas, water, and air pressure.

Subclause 18.2.4.1 – *Energy and materials to be consumed by ME EQUIPMENT

By providing the data, the RESPONSIBLE ORGANIZATION can select ME EQUIPMENT that consumes fewer resources and can use it in modes with a low consumption of resources.

Subclause 18.2.4.2 – *Energy consumption of ME EQUIPMENT

Consumption of electrical energy is in most cases directly related to the exhaust of carbon dioxide. As this is an environmental issue rather than an electrical SAFETY issue, it was decided to move this subclause into the clause dealing with the NATURAL ENVIRONMENT.

The different modes are selected because of the long-term aspect of the consumed energy. Normally all ME EQUIPMENT is marked with the rating in the active mode (all functions are switched on). But very often ME EQUIPMENT is provided with a standby mode (device is activated, but most functions are switched off). In the “off” mode, a mains switch switches off the ME EQUIPMENT. The energy consumption then depends on the location of the mains switch. If there are still energy components in connection to the mains after having switched off, the amount of energy consumed per year can be substantial.

Subclause 18.2.4.4 – *Water consumption by ME EQUIPMENT

Water is a very valuable natural resource. It should only be used if there is no other technical solution. If it is used, the use should be restricted to the necessary extent and not burden the NATURAL ENVIRONMENT.

Subclause 18.2.5.1 – *Air contamination

The list of substances including their quantities in the air as a result of cooling is aimed to help the RESPONSIBLE ORGANIZATION to meet the locally required treatment methods for the air. The list includes only substances from the cooling PROCESS, which are hazardous materials as defined by this standard or derived from the RISK MANAGEMENT PROCESS.

Furthermore, circulation of dust can cause allergic reactions and may transfer infectious diseases. This was not the main issue of this subclause as the probability of air contamination may be low, but it should be taken into account during the RISK MANAGEMENT PROCESS.

Subclause 18.2.5.2 – *Gas emission

Gases may have a direct impact on the health of human beings or on the NATURAL ENVIRONMENT.

Subclause 18.2.5.3 – *Water emission

The list of substances, including their quantities in the water after the cleaning PROCESS, is aimed at helping the RESPONSIBLE ORGANIZATION meet the locally required treatment methods for the water before it is discharged to the environment. The list includes all substances from the cleaning PROCESS regardless whether they are HAZARDOUS or non-HAZARDOUS SUBSTANCES AND MATERIALS as defined by this standard or derived from the RISK MANAGEMENT PROCESS.

Subclause 18.2.6 – *Batteries and accumulators used in conjunction with ME EQUIPMENT

Many types of batteries include the use of harmful material and their disposal is regulated in most countries.

Subclause 18.2.7 – *DISPOSABLES and MATERIALS TO BE CONSUMED by ME EQUIPMENT

DISPOSABLES are very critical to the NATURAL ENVIRONMENT because of the amount in use every day. It is not only the consumption of resources, but also the stream of waste every day. Therefore the use of DISPOSABLES should be restricted to medically justified treatments.

Subclause 18.2.8 – *Design for REUSE, RECYCLING and disposal of ME EQUIPMENT

The amount of waste generated as a result of maintenance and repair activities should be minimized through intelligent initial product and system design. Components, parts and subassemblies should be, preferably in this order, separately repairable or replaceable or disposable.

A defect in a component of the ME EQUIPMENT should not lead to a waste of time and material, therefore, components should be easily accessible.

For maintenance, repair and disposal of ME EQUIPMENT, a treatment operation should take place to remove or selectively treat units and components containing HAZARDOUS SUBSTANCES AND MATERIALS (see Table K1, category *a* and *b*).

In order to achieve an economical and safe dismantling PROCESS, it is expedient to draw up disassembly instructions at the same time as the production papers are being prepared (see Table K1, category *a* to *e*). Useful information for disassembly is in IEC Guide 109.

Homogeneous material in the sense of this requirement means that the composition, including chemical additives, reinforcement materials, and paint layers (conductive or not), is constant of the entire part. The main aim of this requirement is to have easily separable materials according to IEC Guide 109.

The mass of 50 g is used to exclude small and tiny parts that may be ignored for RECYCLING PROCESSES.

Markings have to be provided, which are necessary for disassembly during repair, reuse or end of life. Such markings are to indicate different materials, types of batteries, indications for screws to be opened etc.

Subclause 18.2.9.1 – *REUSE

For REUSE, the modularity of the ME EQUIPMENT is of major concern. The modularity also assists the ability of a piece of ME EQUIPMENT to be upgraded.

In order to increase the use of a product with regard to RECYCLING, it is necessary to force the REUSE or continued use of individual subassemblies or components if the product cannot be repaired. This can be achieved by the following measures:

– Standardization of components for entire product families.
– Good accessibility to subassemblies.
– Removal of components without damage.
– Easily separable connections, e.g. plug-in, snap, or screwed connections.
– Preventive measures against corrosion and signs of use.
– Easily cleanable parts (using environmentally compatible detergents!).
– Subsequent examination of components, e.g. adaptability.

The REUSE of components should not be detrimental to the SAFETY of the ME EQUIPMENT.

The SAFETY of components may be restricted to a certain maximum useful life (e.g. mechanical components with a dynamic load). In this case, REUSE of such a component requires a form of traceability.

Subclause 18.2.9.2 – *RECYCLING

Dangerous materials that need special treatment are either materials that contain hazardous substances or need special cleaning or disinfection treatment.

(The following rationale is taken from IEC Guide 109.) Design for Material Recyclability (DFMR) is only one aspect of a Design for Environment programme, but it is one that can be implemented without too much trouble in the short term. MANUFACTURERS should consider implementing Design for Material Recyclability in conjunction with design for disassembly recyclability. Material RECYCLING may be considered a last option, but preferable to disposal of waste. In general, the order of preference is:

– extend the life-cycle;
– reduce material content;
– re-use components/refurbish assemblies;
– re-engineer (convert and remanufacture used components and subassemblies);
– recycle materials;
– recover energy (if safe);
– dispose of waste.

Design for disassembly and recyclability: see Annex C.1 of IEC Guide 109.

Design criteria/concepts for plastic parts: see Annex C.2 of IEC Guide 109.

For guidance, the following is a non-exhaustive list of units and components containing HAZARDOUS SUBSTANCES AND MATERIALS (see Table K1, category a and b):

– capacitors containing Polychlorinated biphenyls (PCB)
– mercury relays
– batteries and accumulators
– components containing selenium
– components containing beryllium oxide
– components containing asbestos
– components containing Chlorofluorocarbons (CFC), or Halogenated Chlorofluorocarbons (HCFC)
– components containing radioactive sources
– components containing lead
– components containing copper salts
– components containing cadmium
– cathode ray tubes
– liquid crystal displays
– mercury lamps
– halogenated substances
– lithium batteries
– components containing chromium

Subclause 18.2.9.3 – *Disposal

Disposal is applicable to end of life as well as for repair and maintenance. In the requirements of this subclause, only the aspects of RISKS are addressed. But disposal has also a big impact on environmental protection and its costs for the RESPONSIBLE ORGANIZATION.

Therefore, type and extent of disposal can have aspects of competition between manufactures of the same type of ME EQUIPMENT.

A.19 Annex G – Protection against HAZARDS of ignition of flammable anaesthetic mixtures (see also the rationale for 11.4)

Section Six of the second edition of has been moved to a normative annex. This was done in recognition of the fact that flammable anaesthetics are rarely used and their use is expected to cease entirely within a short period. However, it is also recognized that the practice of medicine changes frequently and that even now some MANUFACTURERS might still want to offer ME EQUIPMENT for such applications. In order to assure that the material contained in Section SIX along with the associated CATEGORY AP and CATEGORY APG RATINGS remain available while improving the readability of the standard for most users, the material has been moved to Annex G.

Subclause G.5.3 – *Low-energy circuits

The graphs of Figure G1, Figure G2 and Figure G3 are given to assist in the design of circuits that fulfil the requirements for allowable limits stated for CATEGORY AP ME EQUIPMENT without performing the ignition test.

Extrapolation for higher voltages is not valid because the ignition condition of gases changes at higher voltages. The limit for inductances is introduced because high inductance values generally produce higher voltages.

Subclause G.5.4 – *External ventilation with internal overpressure

The amount of air or inert gas escaping, from the ME EQUIPMENT by leakage is assumed to be limited so that hygienic conditions in the medically used room are not disturbed appreciably.

For the purposes of G.5.4 and G.5.5 the term “enclosure” may represent either the ENCLOSURE as defined in 3.26 or a distinct compartment or housing.

Subclause G.5.5 – ENCLOSURES with restricted breathing

Subclause G.5.5 **a)**

This requirement is regarded as sufficient to prevent ignition in NORMAL USE during an operational period of several hours since average conditions in NORMAL USE are less stringent.

Subclause G.6.2 – *Power supply

This requirement prevents the introduction of voltages higher than those permitted by G.6.3. Such voltages can exist on earth wiring.

Subclause G.6.3 – *Temperatures and low-energy circuits

The graphs of Figure G4, Figure G5 and Figure G6 are given to assist in the design of circuits that fulfil the requirements for allowable limits stated for CATEGORY APG ME EQUIPMENT, without performing the ignition test.

Annex B
(Informative)

SEQUENCE OF TESTING

B.1 General

Tests should, if applicable, be carried out in the sequence indicated below, unless otherwise stated by particular standards. See also 5.8.

However, this does not preclude the possibility of conducting a test that preliminary inspection suggests might cause failure.

B.2 General requirements

See 4.1 and Clause 5.

B.3 Markings

See 7.1.2 to 7.10.

B.4 Energy consumption

See Subclause 18.2.4.2.

B.5 Classification

See 8.2.

B.6 Limitation of voltage or energy

See 8.4.

B.7 Determination of ACCESSIBLE PARTS

See 5.9.

B.8 Separation

See 8.5.

B.9 Protective earthing, functional earthing and potential equalization

See 8.6.

B.10 Mechanical strength

See 9.1.

B.11 Moving parts

See 9.2.

B.12 Surfaces, corners and edges

See 9.3.

9000 **B.13 Stability in NORMAL USE**

9001 See 9.4.

9002 **B.14 Expelled parts**

9003 See 9.5.

9004 **B.15 Support systems**

9005 See 9.8.

9006 **B.16 Radiation HAZARDS**

9007 See Clause 10.

9008 **B.17 Electromagnetic compatibility**

9009 See Clause 17.

9010 **B.18 Pressure vessels and parts subject to pneumatic and hydraulic PRESSURE**

9011 See 9.7.

9012 **B.19 Use error**

9013 See 12.3.1.

9014 **B.20 Temperatures – Fire prevention**

9015 See 11.1 and 11.2.

9016 **B.21 Interruption of the power supply**

9017 See 11.8.

9018 **B.22 Accuracy of controls and instruments and protection against hazardous**
9019 **outputs**

9020 See 12.2 and 12.3.

9021 **B.23 Abnormal operation, fault conditions, environmental tests**

9022 See Clause 13 and Subclause 5.7.

9023 **B.24 Humidity preconditioning treatment**

9024 See 5.7.

9025 **B.25 Dielectric strength (COLD CONDITION)**

9026 See 8.8.3.

9027 **B.26 LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS at operating**
9028 **temperature**

9029 See 8.7.4

9030 **B.27 Overflow, spillage, leakage, ingress of liquids, and compatibility with**
9031 **substances used with ME EQUIPMENT**

9032 See 11.6, except for 11.6.6 and 11.6.7.

9033 See B.31 below.

9034 **B.28 ENCLOSURES and covers**

9035 See 15.3.

9036 **B.29 Components and general assembly**

9037 See 15.4.

9038 **B.30 MAINS PARTS, components and layout**

9039 See 15.5.

9040 **B.31 Construction, layout, cleaning, disinfection and sterilization**

9041 See 15.4.8, 15.4.3.5, 15.4.9, 11.6.6 and 11.6.7.

9042 **B.32 CATEGORY AP and CATEGORY APG ME EQUIPMENT**

9043 See Annex G.

9044 **B.33 VERIFICATION of markings**

9045 See 7.1.2 and 7.1.3.

Annex C
(Informative)

GUIDE TO MARKING AND LABELLING REQUIREMENTS FOR ME EQUIPMENT AND ME SYSTEMS

C.1 Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts

The requirements for marking on the outside of ME EQUIPMENT and its parts are found in 7.2. Additional requirements for marking on the outside of ME EQUIPMENT, ME SYSTEMS and their parts are found in the subclauses listed in Table C1. Symbols and SAFETY signs used in marking on the outside of ME EQUIPMENT are found in Annex D.

Table C1– Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts[13]

Description of marking	Subclause
CATEGORY APG ME EQUIPMENT, Marking of	G.3.1
CATEGORY AP ME EQUIPMENT, Marking of	G.3.2
CATEGORY AP and APG, Marking of major parts	G.3.3
CATEGORY AP and APG ME EQUIPMENT, Marking of parts	G.3.5
Depressurizing pressure system elements, Warning about	9.7.2
Electrical power input, Marking of	18.2.4.3
Emergency stop device actuator, Marking of	9.2.4
FUNCTIONAL EARTH TERMINAL, Marking of CLASS II ME EQUIPMENT	8.6.9
HAZARDOUS SUBSTANCES AND MATERIALS, Marking of	18.2.2
Hazardous voltage, Warning of	8.11.1 *i)*
Mass of PATIENT, if designed for less than 135 kg, Marking of	9.8.3.1
Moving parts, Warning of	9.2.1
MULTIPLE SOCKET-OUTLET, Marking of	16.9.2.1 *b)*
Overbalancing during transport, Warning about	9.4.2.1
POTENTIAL EQUALIZATION CONDUCTOR terminal, Marking of	8.6.7
Prohibition against pushing, leaning, resting, Warning of	9.4.2.3
Reservoir or liquid storage chamber, Marking of overflow HAZARD	11.6.2
SAFETY DEVICE intended to function only once, Marking of	9.8.4.3
Separating transformer assembly, Marking of	16.9.2.1 *d)*
Surfaces where application of force results in a RISK of overbalancing, Marking of	9.4.2.3
Transport conditions, Warning for	9.4.2.1

C.2 Marking on the inside of ME EQUIPMENT, ME SYSTEMS or their parts

The requirements for marking on the inside of ME EQUIPMENT and its parts are found in 7.3. Additional requirements for marking on the inside of ME EQUIPMENT, ME SYSTEMS and their parts are found in the subclauses listed in Table C2. Symbols used in marking on the inside of ME EQUIPMENT are found in Annex D.

[13] See 7.2.1 for the minimum requirements for marking on ME EQUIPMENT and on interchangeable parts.

9062 **Table C2 – Marking on the inside of ME EQUIPMENT, ME SYSTEMS or their parts**

Description of marking	Subclause
FUNCTIONAL EARTH TERMINAL, Marking of CLASS II ME EQUIPMENT	8.6.9
Hazardous Energies, Marking of capacitors or the connected circuit parts	8.4.4
HAZARDOUS SUBSTANCES AND MATERIALS, Marking of	18.2.2
Hazardous voltage, Marking of parts	8.11.1 *i)*
Separating transformer assembly, Marking of	16.9.2.1 *d)*
THERMAL CUT-OUTS and OVER-CURRENT RELEASES, Marking of technical characteristics	15.4.2.2 *b)*

9063 ## C.3 Marking of controls and instruments

9064 The requirements for marking of controls and instruments are found in 7.4. Additional
9065 requirements for marking of controls and instruments are found in the subclauses listed in
9066 Table C3.

9067 **Table C3 – Marking of controls and instruments**

Description of marking	Subclause
Parts exceeding the permitted voltage for parts that can be touched, Marking of	8.11.1 *i)*
Varying the temperature setting of THERMOSTATS, Clear indication of	15.4.2.2 *a)*

9068 ## C.4 ACCOMPANYING DOCUMENTS, General

9069 The requirements for general information to be included in the ACCOMPANYING DOCUMENTS are
9070 found in 7.10.1. Additional requirements for general information to be included in the
9071 ACCOMPANYING DOCUMENTS are found in the subclauses listed in Table C4.

9072 **Table C4 – ACCOMPANYING DOCUMENTS, General**

Description of requirement	Clause
CATEGORY AP and CATEGORY APG ME EQUIPMENT and parts	G.3.4
Defibrillation voltage, any necessary recovery time	8.5.5
Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS, Additional requirements	17
Fixing of structures to floor, wall, ceiling, etc.	9.8.1
Lifting points, Indication of	9.4.4 *a)*
Mass of PATIENT, if support systems designed for less than 135 kg	9.8.3.1
MATERIALS TO BE CONSUMED, MEDICAL DISPOSABLES and DISPOSABLES, listing of	18.2.7 *c)*
ME SYSTEMS, Addition requirements	16.2
Packaging	18.2.3
Parts to be exchanged after inspection or preventive maintenance, List of	15.3.2 *b)*
SAFETY DEVICE intended to function only once, Instructions to call SERVICE PERSONNEL	9.8.4.3

9073 ## C.5 ACCOMPANYING DOCUMENTS, Instructions for use

9074 The requirements for information to be included in the instructions for use are found in 7.10.2.
9075 Additional requirements for information to be included in the instructions for use are found in
9076 the subclauses listed in Table C5.

9077 **Table C5 – ACCOMPANYING DOCUMENTS, Instructions for use**

Description of requirement	Subclause
APPLIED PARTS (hot or cold), Temperature of	11.1.2
Cleaning or disinfection PROCESSES, Specification of	11.6.6
Energy saving modes, List of	18.2.4.2
FUNCTIONAL EARTH TERMINAL, CLASS II ME EQUIPMENT	8.6.9
Mass of accessories	9.8.3.2
MOBILE ME EQUIPMENT, Requirement that more than one person is needed to move	9.4.2.6
Moving parts, Warning of	9.2.1
POTENTIAL EQUALIZATION CONDUCTOR terminal, Information on the function and use of	8.6.7
Reservoir or liquid storage chamber, Information on overflow HAZARD	11.6.2
Symbols and SAFETY signs used for marking, Explanation of	7.6.1
Transport conditions, Warning for	9.4.2.1
Water consumption, Information on	18.2.4.4

9078 ## C.6 ACCOMPANYING DOCUMENTS, Technical description

9079 The requirements for information to be included in the technical description are found in
9080 7.10.2. Additional requirements for information to be included in the technical description are
9081 found in the subclauses listed in Table C6.

9082 **Table C6 – ACCOMPANYING DOCUMENTS, Technical description**

Description of requirement	Clause
Air contamination, List of HAZARDOUS SUBSTANCES AND MATERIALS	18.2.5.1
Batteries and accumulators, materials used	18.2.6
Batteries and accumulators, type, mode of extraction, insertion and disposal of batteries	18.2.6
CLASS II ME EQUIPMENT with isolated internal screens, Explanation of	8.6.9
Disassembly instructions	18.2.8
Energy consumption for active, standby and “off” modes, Data on	18.2.4.2
Energy consumption per hour	18.2.4.3
HAZARDOUS SUBSTANCES AND MATERIALS, List of	18.2.2
Kinds of energy and MATERIALS TO BE CONSUMED, Description of	18.2.4.1
Network requirements for PEMS intended to be connected to an outside network	14.13
REUSE, RECYCLING and disposal	18.2.9
Water emissions, List of HAZARDOUS SUBSTANCES AND MATERIALS	18.2.5.3

9083

Annex D
(Informative)

SYMBOLS ON MARKING
(See Clause 7)

Introduction

Symbols are frequently used on ME EQUIPMENT in preference to words with the intention of obviating language differences and permitting easier comprehension of a marking or indication, sometimes in a restricted space.

If, for the purpose of this standard, symbols are necessary, symbols defined in IEC 60417 or ISO 7000 are to be used. IEC/TR 60878 provides a useful compendium of graphical symbols used on electrical equipment in medical practice.

For symbol requirements not met by the symbols in this document, refer in the first instance to published IEC or ISO symbols, noting that, where necessary, two or more symbols may be grouped together to convey a particular meaning and that, provided the essential communicative characteristics of the basic symbol are maintained, some latitude in graphic design is permissible.

In the following tables, the symbol graphic and description are provided for information.

Table D1 – General symbols

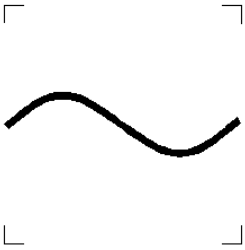
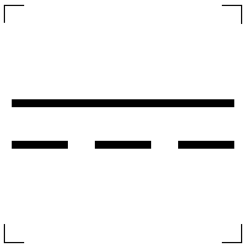
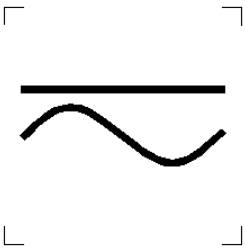
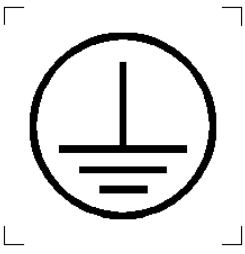
No.	Symbol	Reference	Title
1		IEC 60417-5032	Alternating current
2		IEC 60417-5032-1	Three-phase alternating current
3		IEC 60417-5032-2	Three-phase alternating current with neutral conductor
4		IEC 60417-5031	Direct current
5		IEC 60417-5033	Both direct and alternating current
6		IEC 60417-5019	Protective earth (ground)

Table D1 – General symbols

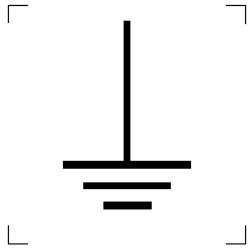
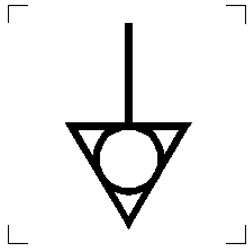
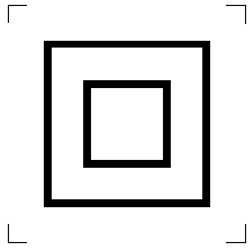
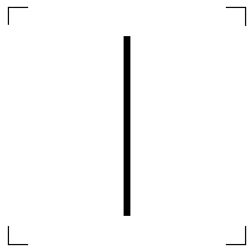
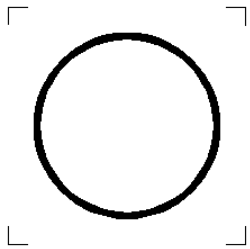
No.	Symbol	Reference	Title
7		IEC 60417-5017	Earth (ground)
8		IEC 60417-5021	Equipotentiality
9		IEC 60417-5172	CLASS II equipment
10		ISO 7000-0434	Attention, consult ACCOMPANYING DOCUMENTS In case of application as a safety sign, the rules according to ISO 3864-1 are to be adhered to. See safety sign ISO 3864-1, B.3.1, “General warning, caution, risk of danger”.
11		IEC 60417-5007	“ON” (power)
12		IEC 60417-5008	“OFF” (power)

Table D1 – General symbols

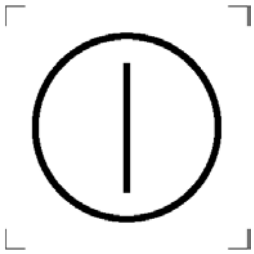
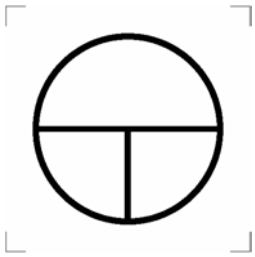
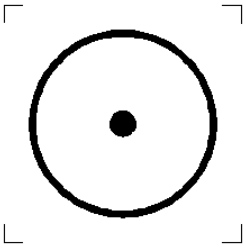
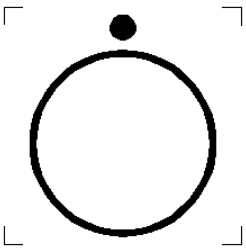
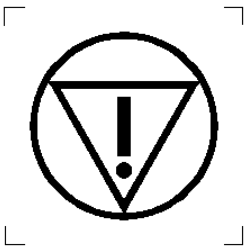
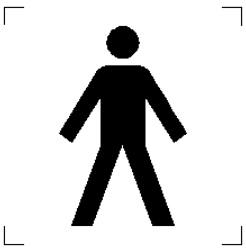
No.	Symbol	Reference	Title
13		IEC 60417-5010	"ON" / "OFF" (push-push)
14		IEC 60417-5011	"ON" / "OFF" (push button)
15		IEC 60417-5264	"ON" for part of the EQUIPMENT
16		IEC 60417-5256	"OFF" for part of the EQUIPMENT
17		IEC 60417-5638	Emergency stop
18		IEC 60417-5840	TYPE B APPLIED PART NOTE: Subclause 7.2.8 requires that for clear differentiation with Symbol 17, Symbol 16 shall not be applied in such a way as to give the impression of being inscribed within a square.

Table D1 – General symbols

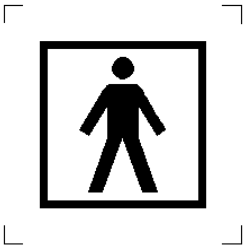
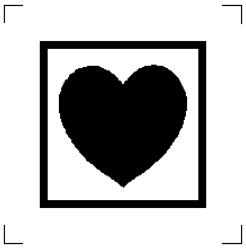
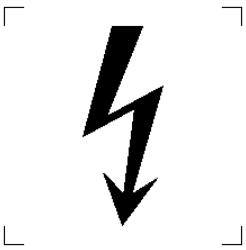
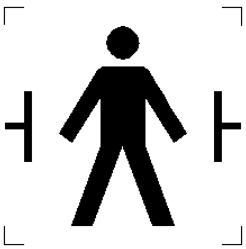
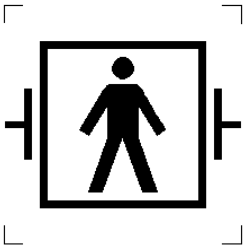
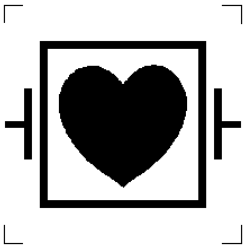
No.	Symbol	Reference	Title
19		IEC 60417-5333	TYPE BF APPLIED PART
20		IEC 60417-5335	TYPE CF APPLIED PART
21		IEC 60417-5331	CATEGORY AP
22		IEC 60417-5332	CATEGORY APG
23		IEC 60417-5036	Dangerous voltage
24		IEC 60417-5841	Defibrillation-proof TYPE B APPLIED PART

Table D1 – General symbols

No.	Symbol	Reference	Title
25		IEC 60417-5334	Defibrillation-proof TYPE BF APPLIED PART
26		IEC 60417-5336	Defibrillation-proof TYPE CF APPLIED PART
27		IEC 60417-xxx1Pr	Hazardous substances

9104

Table D2 – SAFETY signs

1		ISO 3864-1, Clause 5, Table 1	Warning sign NOTE Background colour: yellow Triangular band: Black Symbol or text: Black
2		ISO 7010-xxx2	Pushing prohibited

Table D2 – SAFETY signs

3		ISO 7010-xxx3	Sitting prohibited
4		ISO 7010-xxx4	Stepping prohibited

9105

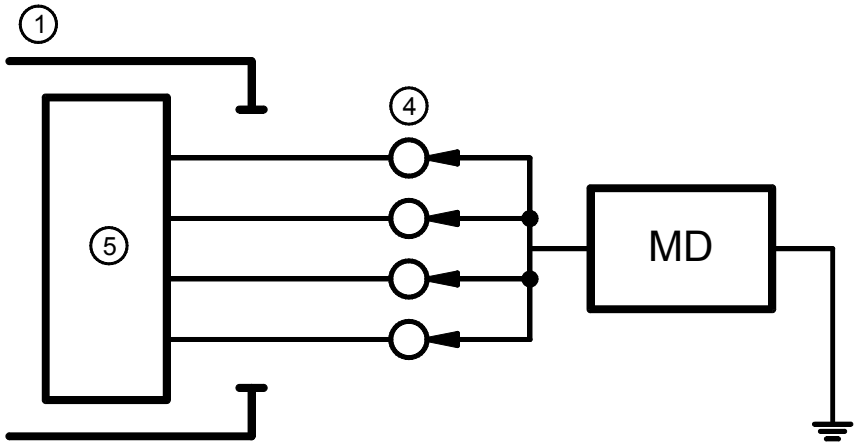
Table D3 – General codes

1	**N**	IEC 60445	Connection point for the neutral conductor on PERMANENTLY INSTALLED EQUIPMENT
2	**IPXN**	IEC 60529	N = 1 Protection against vertically falling water drops 2 Protection against vertically falling water drops when enclosure tilted up to 15° 3 Protected against spraying water 4 Protected against splashing water 5 Protected against water jets 6 Protected against powerful water jets 7 Protected against the effects of temporary immersion in water 8 Protected against the effects of continuous immersion in water

9106

Annex E
(Informative)

EXAMPLES OF THE CONNECTION OF THE MEASURING DEVCIE (MD) FOR MEASUREMENT OF THE PATIENT LEAKAGE CURRENT AND PATIENT AUXILIARY CURRENT
(See 8.7)

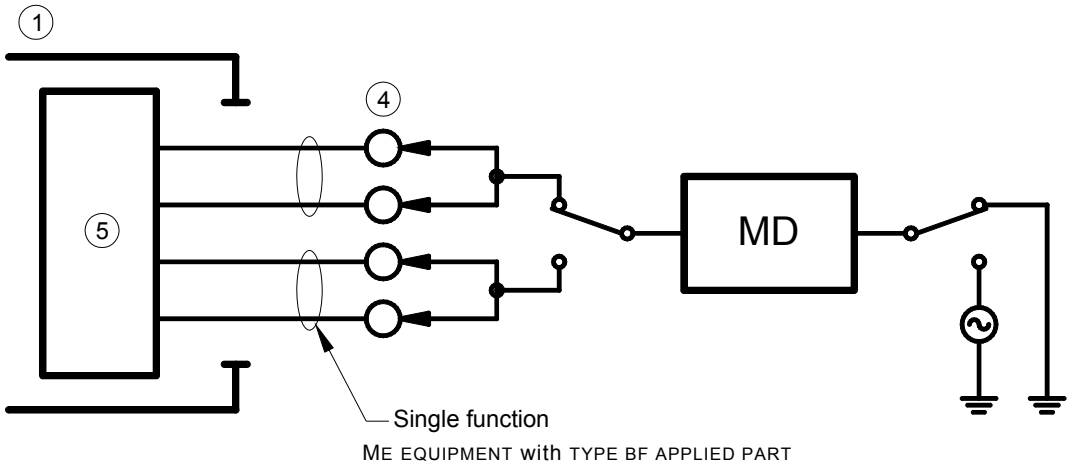


ME EQUIPMENT with TYPE B APPLIED PART

From all PATIENT CONNECTIONS connected together.

For legends, see page 87.

Figure E1 – TYPE B APPLIED PART



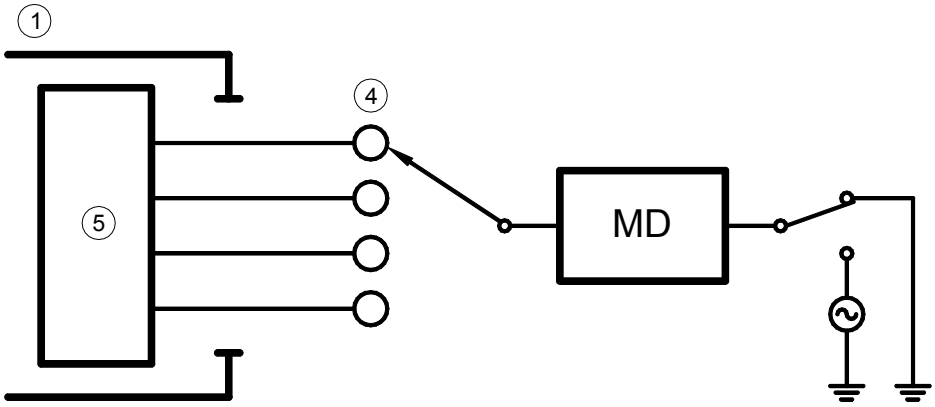
ME EQUIPMENT with TYPE BF APPLIED PART

From and to all PATIENT CONNECTIONS of a single function connected together.

For legends, see page 87.

Figure E2 – TYPE BF APPLIED PART

9118



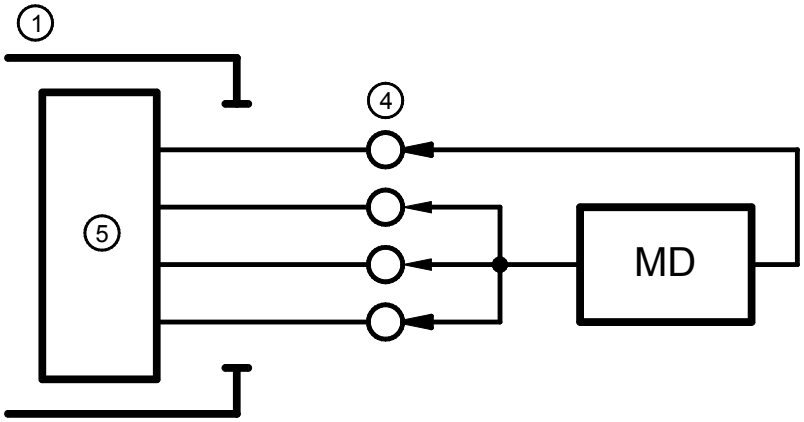
ME EQUIPMENT with TYPE CF APPLIED PART

From and to every PATIENT CONNECTION.

For legends, see page 87.

9119 **Figure E3 – TYPE CF APPLIED PART**

9120



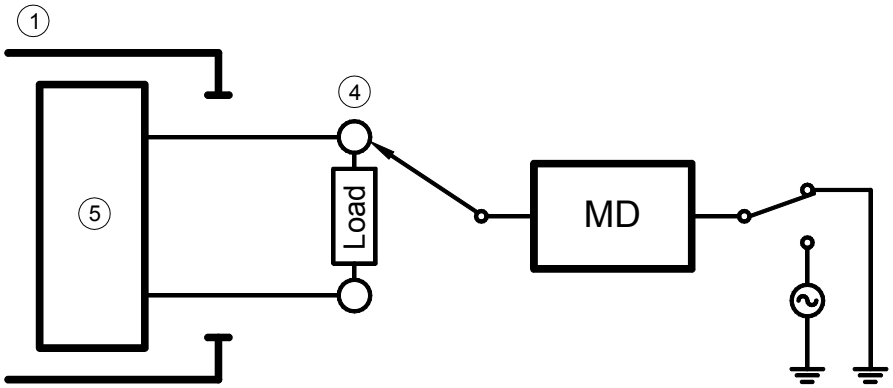
ME EQUIPMENT with TYPE B APPLIED PART, TYPE BF APPLIED PART or TYPE CF APPLIED PART

Between any single PATIENT CONNECTION and all other PATIENT CONNECTIONS connected together

For legends, see page 87

9121 **Figure E4 – PATIENT AUXILIARY CURRENT**

9122



ME EQUIPMENT with MANUFACTURER specified loading of the PATIENT CONNECTIONS of the APPLIED PART

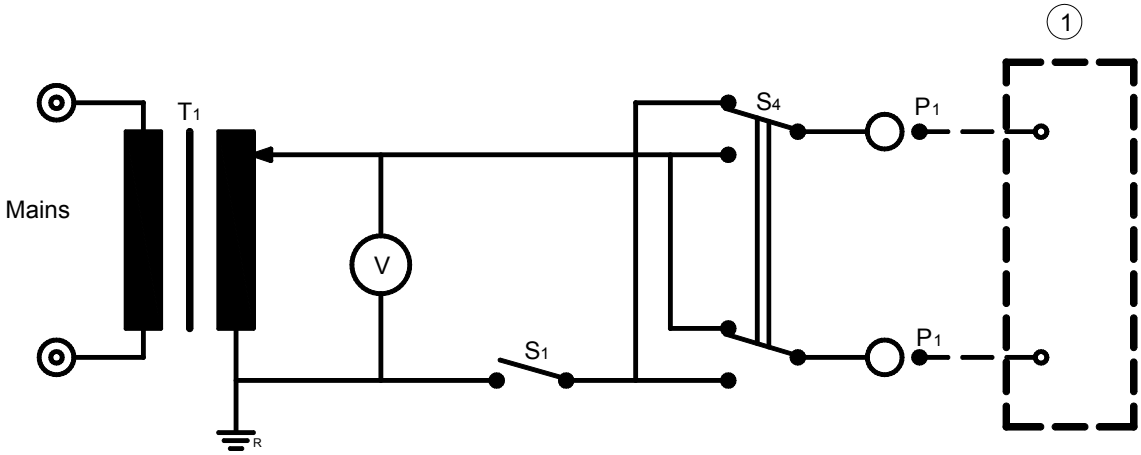
From and to every PATIENT CONNECTION.

For legends, see page 87.

9123 **Figure E5 – Loading of the PATIENT CONNECTIONS if specified by the MANUFACTURER**

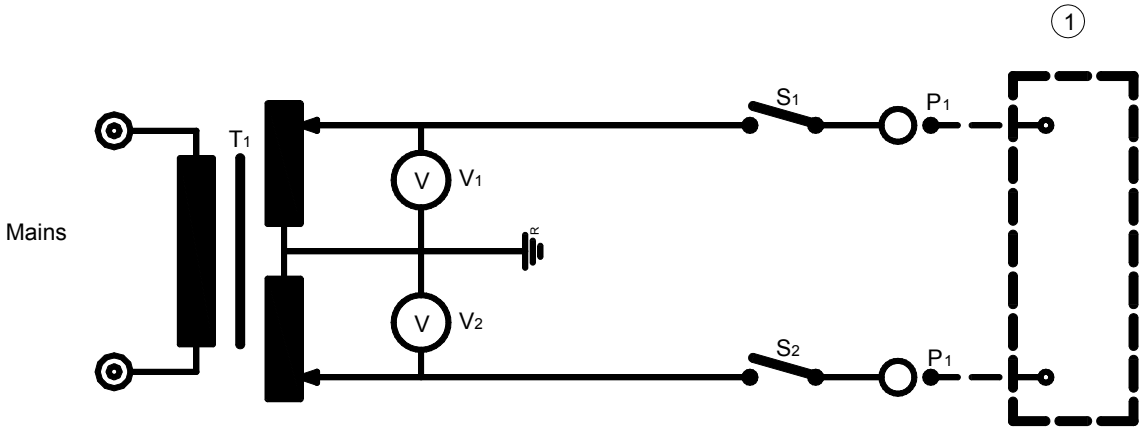
Annex F
(Informative)

SUITABLE MEASURING SUPPLY CIRCUITS



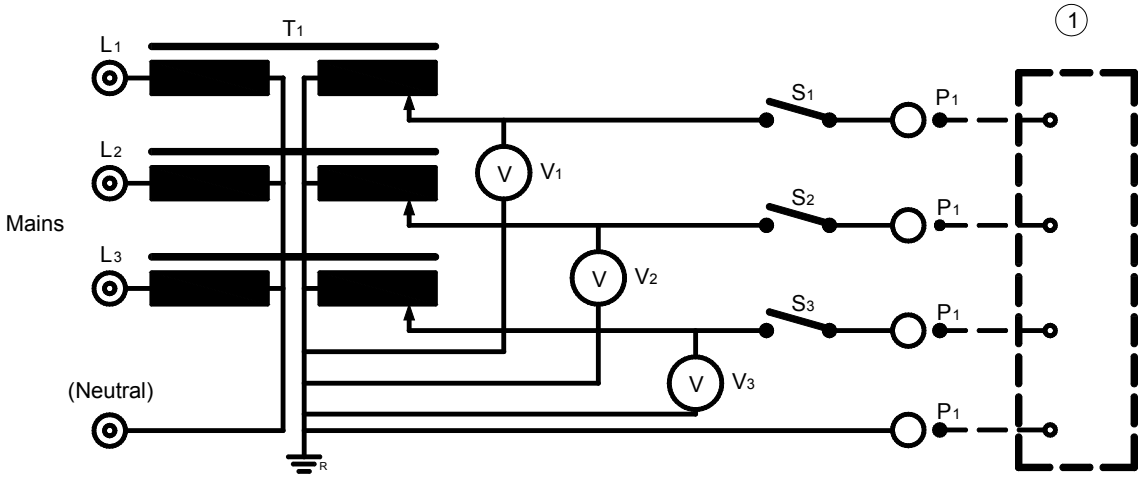
For legends, see page 87.

Figure F1 – Measuring supply circuit with one side of the SUPPLY MAINS at approximately earth potential
(see 8.7.4.2)



For legends, see page 87.

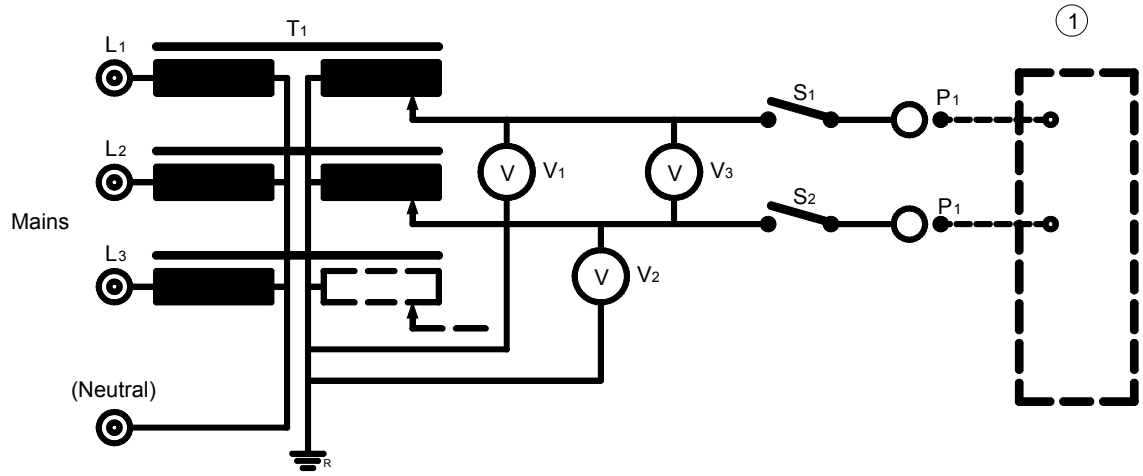
Figure F2 – Measuring supply circuit with SUPPLY MAINS approximately symmetrical to earth potential
(see 8.7.4.2)



9138

9139 For legends, see page 87.

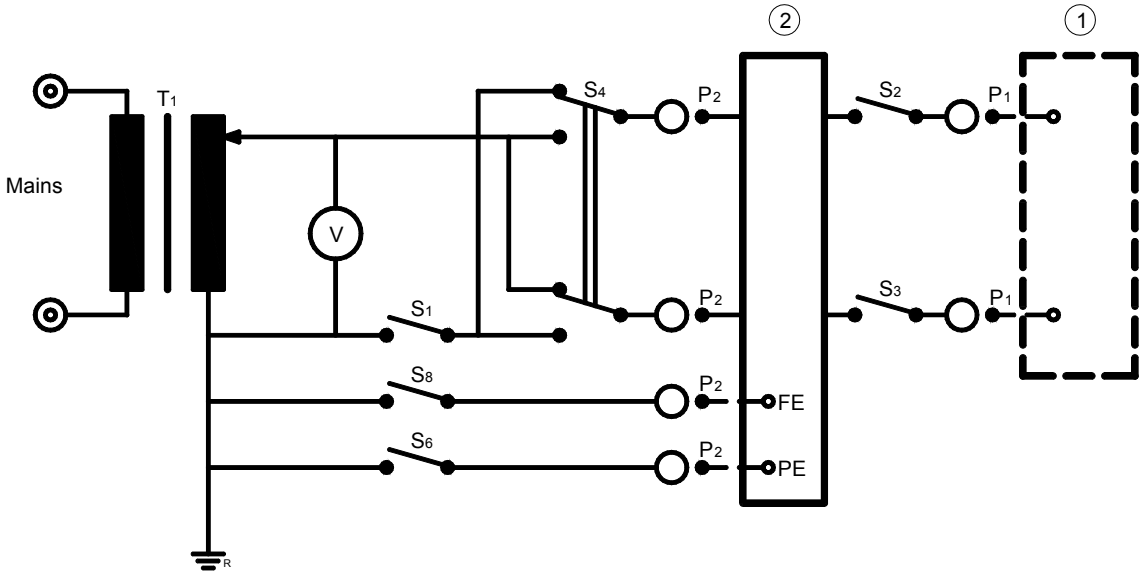
9140 **Figure F3 – Measuring supply circuit for polyphase ME EQUIPMENT specified for connection to a**
9141 **polyphase SUPPLY MAINS**
9142 **(see 8.7.4.2)**



9143

9144 For legends, see page 87.

9145 **Figure F4 – Measuring supply circuit for single-phase ME EQUIPMENT specified for connection to a**
9146 **polyphase SUPPLY MAINS**
9147 **(see 8.7.4.2)**



For legends, see page 87.

Figure F5 – Measuring supply circuit for ME EQUIPMENT having a separate power supply unit or intended to receive its power from another equipment in an ME SYSTEM (see 8.7.4.2)

Annex G
(Normative)

PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETIC MIXTURES

This annex replaces the former Section SIX: "Protection against HAZARDS of ignition of flammable anaesthetic mixtures" of the second edition.

G.1 Introduction

G.1.1 Applicability

Where ME EQUIPMENT is used in areas in which flammable anaesthetics or flammable agents for disinfection or skin cleaning are applied, an explosion RISK may exist if such anaesthetics or agents are mixed with air, or with oxygen or nitrous oxide.

Ignition of such a mixture may be caused by sparks or by contact with parts having a high surface temperature.

Sparks may be caused where electrical circuits are opened or closed by operation of switches, connectors, fuses or OVER-CURRENT RELEASES and the like.

In HIGH VOLTAGE parts, sparks may be caused by corona. Static discharges may cause sparks.

The probability of ignition of such anaesthetic mixtures depends on their concentration, the appropriate minimum ignition energy, the presence of high surface temperatures and the energy of sparking.

The HAZARD caused by an ignition depends on the location and on the relative quantity of the mixture.

G.1.2 Industrial equipment and components

The constructional requirements of IEC 60079 are generally not appropriate for ME EQUIPMENT for several reasons:

a) they lead to constructions of a size, weight or design that are not applicable for medical reasons or that may not be sterilizable;

b) some constructions allow an explosion inside an enclosure, but prevent propagation outside it. Such a construction, which may be inherently safe, would be unacceptable in an operating theatre where continuity of operation of ME EQUIPMENT is essential-,

c) industrial requirements were made for flammable agents mixed with air. They cannot be applied to mixtures with oxygen or nitrous oxide used in medical practice;

d) in medical practice flammable anaesthetic mixtures occur only in relatively small quantities.

However some of the constructions described in IEC 60079 are acceptable for CATEGORY AP ME EQUIPMENT (see G.5.1).

G.1.3 Requirements for ME EQUIPMENT

In this annex, the location of flammable anaesthetic mixtures is described:

– as much as necessary for the construction of ME EQUIPMENT, as minimum for specified conditions of exhaust and absorption;

– as much as necessary for the allocation of ME EQUIPMENT and the construction of the electrical installation in IEC 60364.

This annex additionally provides information on flammable concentrations of a number of flammable agents, their usual application concentrations, ignition temperatures, lowest

ignition energy and flash-points. Requirements for ventilation and exhaust of areas, maintenance of a minimum relative humidity and permission to use certain equipment types in certain areas may be subject to local (hospital) or national and possibly legal regulations.

The recommendations, limits and tests of this annex are based on the results of statistical considerations obtained from experiments with the most readily flammable mixtures of ether vapour with air and with oxygen, using the test apparatus described in G.7. This is justified because combinations with ether have the lowest ignition temperatures and the lowest ignition energies of commonly used agents.

Where temperatures or circuit parameters of ME EQUIPMENT used in a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR exceed allowable limits and sparking cannot be avoided the relevant parts and circuits can be enclosed in ENCLOSURES with pressurized inert gas or clean air or in ENCLOSURES with restricted breathing.

ENCLOSURES with restricted breathing delay the build-up of an ignitable concentration. They are recognized because it is assumed that a period in which ME EQUIPMENT is used in a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR is followed by a period of ventilation during which such a concentration will disappear.

For ME EQUIPMENT containing or used in a FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE, requirements, limits and tests are far more stringent.

These recommendations apply not only to NORMAL CONDITION but, additionally, in the SINGLE FAULT CONDITION, as indicated in 4.5. Only two exemptions from an actual ignition test are recognized, these being either the absence of sparks and limited temperature or limited temperature and restricted circuit parameters.

G.2 Locations and basic requirements

G.2.1 FLAMMABLE ANAESTHETIC MIXTURE WITH AIR

Where a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR occurs because of a leakage or discharge of a FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE from an ENCLOSURE, it is considered to propagate to a volume surrounding the leakage or discharge point at a distance from 5 cm to 25 cm from such a point.

G.2.2 FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE

A FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE may be contained in a completely or partly enclosed ME EQUIPMENT part and in the PATIENT'S respiratory tract. Such a mixture is considered to propagate to a distance of 5 cm from an ENCLOSURE part where leakage or discharge occurs.

G.2.3 ME EQUIPMENT or parts thereof specified for use with FLAMMABLE ANAESTHETIC MIXTURE WITH AIR (in a location defined in G.2.1) shall be CATEGORY AP or APG ME EQUIPMENT and shall comply with the requirements of G.4 and G.5.

G.2.4 ME EQUIPMENT or parts thereof specified for use with FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE (in a location defined in subclause G.2.2) shall be CATEGORY APG ME EQUIPMENT and shall comply with the requirements of G.4 and G.6.

Parts of CATEGORY APG ME EQUIPMENT in which a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR occurs shall be CATEGORY AP or APG ME EQUIPMENT and shall comply with the requirements of Clauses G.2, G.3 and G.4.

Compliance with the requirements of G.2.3 and G.2.4 is checked by inspection and by the appropriate tests of G.3, G.4 and G.5.

These tests shall be performed after applicable tests according to 11.6.6.

G.3 Marking, ACCOMPANYING DOCUMENTS

G.3.1 CATEGORY APG marking

CATEGORY APG ME EQUIPMENT shall be marked on a prominent location with a green-coloured band at least 2 cm wide imprinted with the characters "APG", PERMANENTLY AFFIXED and CLEARLY LEGIBLE (see Symbol IEC 60417-5332 [Table D1, Symbol 22] and 7.1). The length of the green-coloured band should be at least 4 cm. The size of the marking should be as large as possible for the particular case. If this marking is impossible, the relevant information shall be given in the instructions for use.

G.3.2 CATEGORY AP marking

CATEGORY AP ME EQUIPMENT shall be marked on a prominent location with a green-coloured circle of at least 2 cm diameter, imprinted with the characters "AP", PERMANENTLY AFFIXED and CLEARLY LEGIBLE (see Symbol IEC 60417-5331 [Table C1, Symbol 21]and 7.1).

The size of the marking should be as large as possible for the particular case. If this marking is impossible, the relevant information shall be given in the instructions for use.

G.3.3 Placement of markings

The marking according to G.3.2 and G.3.3 shall be present on the major part of the ME EQUIPMENT if this part is CATEGORY AP or CATEGORY APG. It need not be repeated on detachable parts that can only be used together with the marked ME EQUIPMENT.).

G.3.4 ACCOMPANYING DOCUMENTS

ACCOMPANYING DOCUMENTS shall contain an indication to enable the RESPONSIBLE ORGANIZATION to distinguish the parts of ME EQUIPMENT (see G.3.5) that are CATEGORY AP and CATEGORY APG.

Compliance is checked by inspection (see 7.10).

G.3.5 Marking when parts of ME EQUIPMENT are CATEGORY AP or CATEGORY APG

On ME EQUIPMENT in which only certain ME EQUIPMENT PARTS are CATEGORY AP or CATEGORY APG, the marking shall clearly indicate which parts are CATEGORY AP or CATEGORY APG.

Compliance is checked by inspection.

G.4 Common requirements for CATEGORY AP and CATEGORY APG ME EQUIPMENT

G.4.1 Electrical connections

a) CREEPAGE DISTANCES and AIR CLEARANCES CLEARANCE between the connection points of POWER SUPPLY CORD shall be according to Table 7, values for SUPPLEMENTARY INSULATION.

b) Connections, except those in the circuits described in G.5.3 and G.6.3, shall be protected against accidental disconnection in NORMAL USE or shall be so designed that connection or disconnection can be performed only with the use of a TOOL.

c) CATEGORY AP ME EQUIPMENT and CATEGORY APG ME EQUIPMENT shall not be provided with a DETACHABLE POWER SUPPLY CORD unless the circuit complies with the requirements of G.5.3 and G.6.3.

Compliance is checked by inspection or measurement.

G.4.2 Construction details

a) Opening of an ENCLOSURE providing protection against the penetration of gases or vapours into the ME EQUIPMENT or into parts thereof shall be possible only with the aid of a TOOL.

Compliance is checked by inspection.

b) To avoid the likelihood of arcing and sparking due to foreign objects penetrating the ENCLOSURE:

– top covers of ENCLOSURES shall have no openings; openings for controls are permitted if these openings are covered by the control knob;

– openings in side-covers shall have such dimensions that penetration by a solid cylindrical object of more than 4 mm diameter is prevented;

– openings in base plates shall have such dimensions that penetration by a solid cylindrical object of more than 12 mm diameter is prevented.

Compliance is checked by means of a cylindrical test rod of 4 mm diameter for side-covers and 12 mm diameter for base plates. The test rod is not to enter the ENCLOSURE when applied in all possible directions without appreciable force.

c) Where insulation of electrical conductors equal to one MEANS OF PATIENT PROTECTION may contact a part containing a FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE or ignitable gases alone or oxygen, a short circuit of these conductors or a short circuit of one conductor to a conductive part containing the gas or mixture shall not result in loss of integrity of such a part or result in an inadmissible temperature or in a HAZARD in such a part (see G.6.3 *a)*).

Compliance is checked by inspection. In case of doubt, a short-circuit test (without explosive gases) should be performed and the temperature in the relevant part should be measured if possible. The short-circuit test need not be performed if the product of the open-circuit voltage in volts and the short-circuit current in amperes does not exceed 10.

G.4.3 Prevention of electrostatic charges

a) Electrostatic charges shall be prevented on CATEGORY AP and CATEGORY APG ME EQUIPMENT by a combination of appropriate measures such as:

– the use of antistatic materials with a limited electrical resistance as specified in G.4.3 *b)*, and

– provision of electrically conductive paths from ME EQUIPMENT or its parts to a conductive floor or to the protective earth system or the potential equalization system or via wheels to an antistatic floor of the medically used room.

b) The electrical resistance limits of anaesthetic tubing, mattresses and pads, castor tyres and other antistatic material shall comply with ISO 2882.

Compliance with the allowable resistance limits given in ISO 2882 is checked by measurements according to ISO 471, ISO 1853 and ISO 2878.

G.4.4 Corona

Parts and components of ME EQUIPMENT operating at more than 2 000 V a.c. or more than 2 400 V d.c. that are not included in ENCLOSURES in compliance with G.5.4 or G.5.5 shall be so designed that corona cannot be produced.

Compliance is checked by inspection and measurement.

G.5 Requirements and tests for CATEGORY AP ME EQUIPMENT, parts and components thereof

G.5.1 General

ME EQUIPMENT, ME EQUIPMENT parts or components shall not ignite FLAMMABLE ANAESTHETIC MIXTURES WITH AIR in NORMAL USE and NORMAL CONDITION.

ME EQUIPMENT, ME EQUIPMENT parts or components complying with one of the G.5.2 to G.5.5 are considered to comply with the requirement of this subclause.

ME EQUIPMENT, ME EQUIPMENT parts or components complying with the requirements of IEC 60079 for pressurized enclosures (IEC 60079-2), for sand filled enclosures (IEC 60079-5) or for oil-immersed equipment (IEC 60079-6) as well as with the requirements of this standard (excluding those of G.5.2 to G.5.5), are considered to comply with the requirements for CATEGORY AP ME EQUIPMENT.

G.5.2 Temperature limits

ME EQUIPMENT, ME EQUIPMENT parts or components not producing sparks and not producing operating temperatures of surfaces, in contact with gas mixtures in NORMAL USE and NORMAL CONDITION, exceeding 150 °C in case of restricted vertical air circulation by convection, or exceeding 200 °C in case of unrestricted vertical air circulation, if measured at an ambient temperature of 25 °C, are considered to comply with the requirements of G.5.1.

The operating temperatures are measured during the tests mentioned in 11.1.

G.5.3 *Low-energy circuits

ME EQUIPMENT, ME EQUIPMENT parts or components that may produce sparks in NORMAL USE and NORMAL CONDITION of the ME EQUIPMENT (for example, switches, relays, plug connections that can be detached without the use of a TOOL, including connections inside ME EQUIPMENT that are not sufficiently locked or secured, and brush motors) shall comply with the temperature requirements of G.5.2 and additionally the voltage U_{max} and the current I_{max}, which can occur in their circuits, taking into account the capacitance C_{max} and the inductance L_{max} shall comply with the following:

$U_{max} \leq U_{zR}$ with a given current I_{zR}, see Figure G1, and

$U_{max} \leq U_c$ with a given capacitance C_{max}, see Figure G2, and

$I_{max} \leq I_{zR}$ with a given voltage U_{zR}, see Figure G1, and

$I_{max} \leq I_{zL}$ with a given inductance L_{max} and a $U_{max} \leq 24$ V, see Figure G3.

– The graphs of Figure G1, Figure G2 and Figure G3 have been obtained with the test apparatus according to G.6 with the most readily flammable mixtures of ether vapour with air (ether volume percentage 4,3 ± 0,2 %) for an ignition probability (without SAFETY factor) of 10^{-3}.

– Extrapolation of the graph of Figure G1 is allowed for combinations of currents and corresponding voltages within the limitations $I_{zR} \cdot U_{zR} \leq 50$ W.

Extrapolation for voltages of more than 42 V is not valid.

– Extrapolation of the graph of Figure G2 is allowed for combinations of capacitances and corresponding voltages within the limitations:

$$\frac{C}{2}U^2 \leq 1{,}2mJ$$

Extrapolation for voltages of more than 242 V is not valid.

If the equivalent resistance R is less than 8 000 Ω, U_{max} is additionally determined with the actual resistance R.

– Extrapolation of the graph of Figure G3 is allowed for combinations of currents and corresponding inductances within the limitations

$$\frac{L}{2}I^2 \leq 0{,}3mJ$$

Extrapolation for inductances larger than 900 mH is not valid.

– Voltage U_{max} is taken as the highest supply voltage occurring in the circuit under investigation with the sparking contact open, taking into account the MAINS VOLTAGE variations required in 4.8.

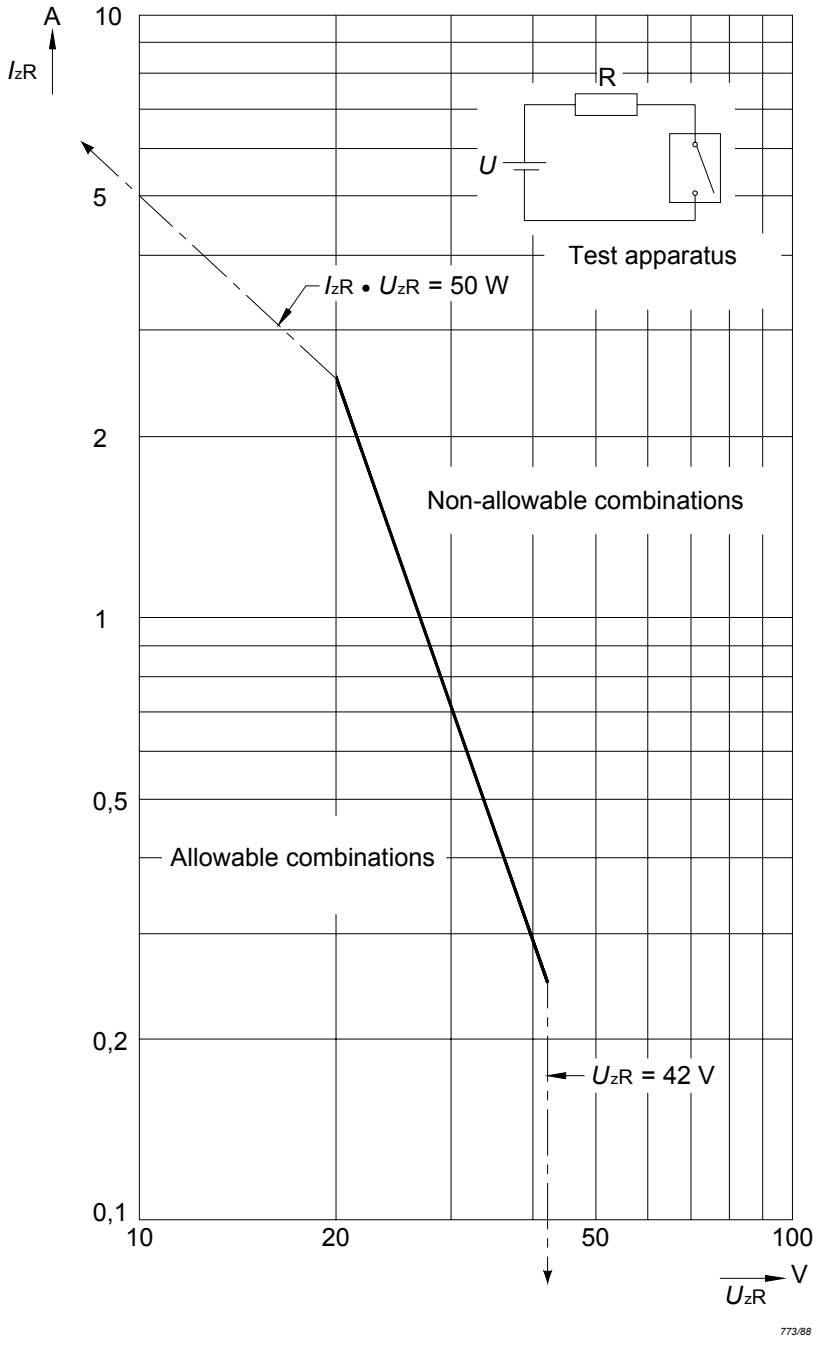
– Current I_{max} is taken as the highest current flowing in the circuit under investigation with the sparking contact closed, taking into account the MAINS VOLTAGE variations required in 4.8.

– Capacitance C_{max} and inductance L_{max}, are taken as the values that occur at the component under investigation that produces sparks in the ME EQUIPMENT.

– If the circuit is supplied with a.c., the peak value is taken into account.

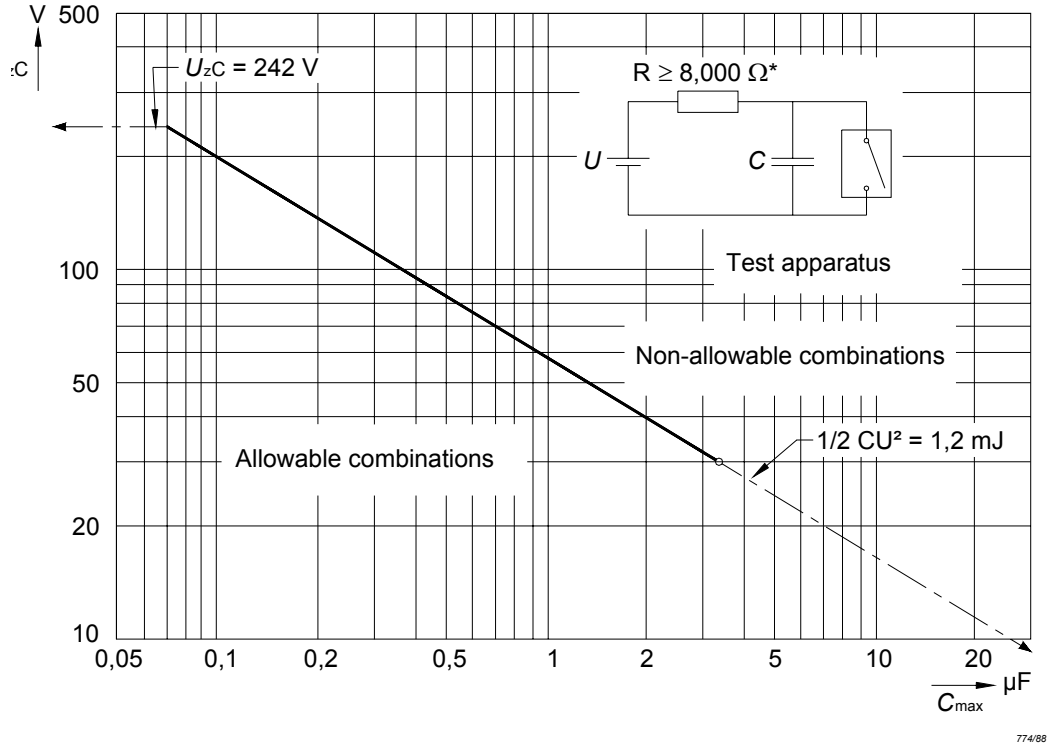
– If the circuit is complicated and consists of more than one capacitance, inductance and resistance, or a combination thereof, an equivalent circuit is calculated to determine the equivalent maximum capacitance, the equivalent maximum inductance and additionally the equivalent U_{max} and I_{max}, either as d.c. values or as a.c. peak values.

Compliance is checked either by temperature measurement and determination of U_{max}, I_{max}, R, L_{max} *and* C_{max} *and application of Figure G1, Figure G2 and Figure G3, or by examination of the design data.*



9387

9388 **Figure G1– Maximum allowable current I_{zR} as a function of the maximum allowable voltage U_{zR}**
9389 **measured in a purely resistive circuit with the most flammable mixture of ether vapour with air**



* 8 000 Ω or the actual resistance, if *R* is less than 8 000 Ω

Figure G2 – Maximum allowable voltage U_{zC} as a function of the capacitance C_{max} measured in a capacitive circuit with the most flammable mixture of ether vapour with air

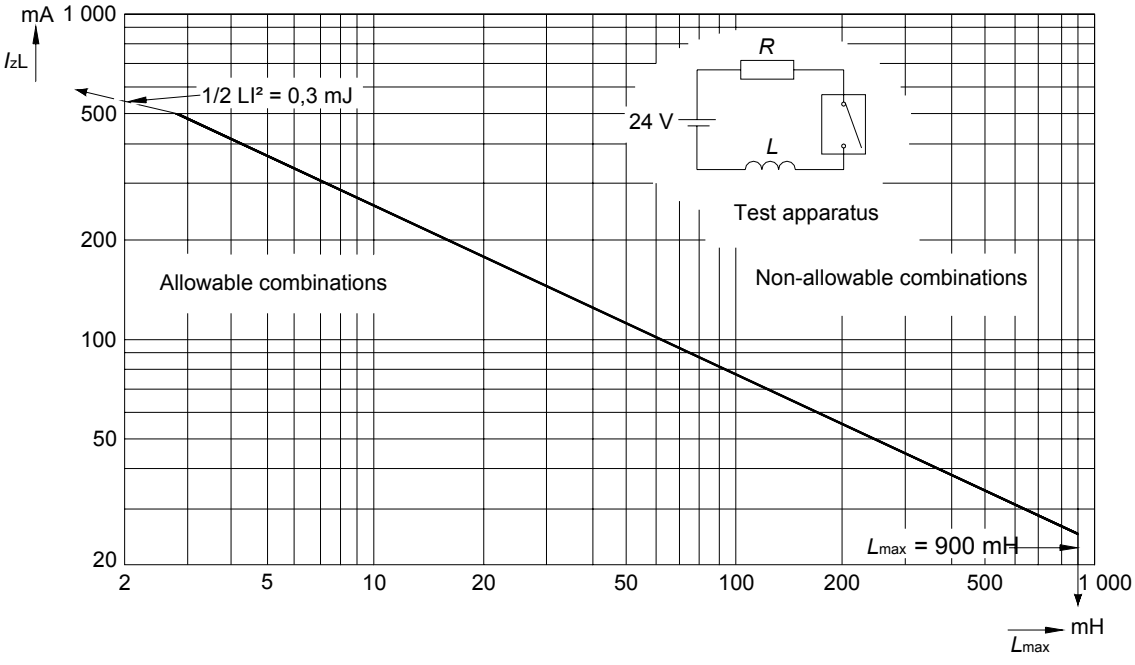


Figure G3 – Maximum allowable current I_{zL} as a function of the inductance L_{max} measured in an inductive circuit with the most flammable mixture of ether vapour with air

G.5.4 *External ventilation with internal overpressure

Where ME EQUIPMENT, ME EQUIPMENT parts or components are enclosed in an ENCLOSURE with external ventilation by means of internal overpressure the following requirements shall apply:

a) FLAMMABLE ANAESTHETIC MIXTURES WITH AIR that might have penetrated into the ENCLOSURE of ME EQUIPMENT or of an ME EQUIPMENT part shall be removed by ventilation before the ME EQUIPMENT or the ME EQUIPMENT part can be energized, and subsequently the penetration of such mixtures during operation shall be prevented by maintenance of overpressure within the ME EQUIPMENT or the ME EQUIPMENT part by means of air not containing flammable gases or vapours or by means of a physiologically acceptable inert gas (for example nitrogen).

b) The overpressure inside the ENCLOSURE shall be at least 75 Pa in NORMAL CONDITION. The overpressure shall be maintained at the site of potential ignition even if the air or inert gas can escape through openings in the enclosure that are necessary for the normal operation of ME EQUIPMENT or of ME EQUIPMENT parts.

Energizing ME EQUIPMENT shall only be possible after the required minimum overpressure has been present for a time sufficient to ventilate the relevant ENCLOSURE so that the displaced volume of air or of inert gas is at least five times the volume of the ENCLOSURE. (However, ME EQUIPMENT may be energized at any time or repeatedly if the overpressure is continuously present.)

c) If the overpressure drops below 50 Pa during operation, ignition sources shall be de-energized automatically by means that either shall be located in a place where the requirements and tests of G.4 do not apply, or comply with the requirements of G.5.

d) The external surface of the ENCLOSURE in which the internal overpressure is maintained shall not attain in NORMAL CONDITION and NORMAL USE an operating temperature exceeding 150 °C, measured in an ambient temperature of 25 °C.

Compliance with the requirements of G.5.4 a) *to G.5.4* d) *is checked by temperature, PRESSURE and flow measurements and inspection of the PRESSURE monitoring device.*

G.5.5 ENCLOSURES with restricted breathing

Where ME EQUIPMENT, ME EQUIPMENT parts or components are enclosed in an ENCLOSURE with restricted breathing the following requirements shall apply:

a) *ENCLOSURES with restricted breathing shall be so designed that the formation of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR inside the enclosure does not occur whilst the ENCLOSURE is surrounded by a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR of a high concentration for a period of at least 30 min but without any PRESSURE difference to the space inside the ENCLOSURE.

b) If the required tightness is obtained by gaskets or sealing, the material used shall therefore be resistant to ageing.

Compliance is checked by application of test B-b of IEC 60068-2-2, Clause 15, temperature 70 °C ± 2 °C, duration 96 h.

c) If the ENCLOSURE contains inlets for flexible cords, their gas-tightness shall be maintained when the cords are stressed by bending or pulling. The cords shall be fitted with adequate anchorages to limit these stresses (see 21.3 *d)*).

Compliance with the requirements of G.5.5 a), *G.5.5* b) *and G.5.5* c) *is checked by application of the following tests:*

After completion of the test of subclause G.5.4 b) *if relevant, an internal overpressure of 400 Pa is created and 30 pulls of the value shown in Table G1 are applied to each flexible cord alternately, in the axial direction of the cord inlet and in the least favourable*

perpendicular direction, each pull without jerks and of 1 s duration. At the end of the test the overpressure shall not be reduced to less than 200 Pa.

Table G1 – Gas-tightness of cord inlets

Mass (*m*) of ME EQUIPMENT (kg)	Pull (N)
$m \leq 1$	30
$1 < m \leq 4$	60
$m > 4$	l00

When the ENCLOSURE of ME EQUIPMENT parts or components is sealed or gas-light and no doubt exists that the ENCLOSURE complies with the aforementioned requirement, the ENCLOSURE is tested by inspection only.

The operating temperature of the external surface of the ENCLOSURE shall not exceed 150 °C measured at an ambient temperature of 25 °C. The steady state operating temperature of the ENCLOSURE is also measured.

G.6 Requirements and tests for CATEGORY APG ME EQUIPMENT, parts and components thereof

G.6.1 General

ME EQUIPMENT, ME EQUIPMENT parts or components shall not ignite FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE. This requirement applies both in NORMAL USE and in the event of any applicable SINGLE FAULT CONDITION, as described in 4.5.

ME EQUIPMENT, ME EQUIPMENT parts or components that do not comply with the requirements of G.6.3 are tested by a CONTINUOUS OPERATION test over a period of 10 min in an ether/ oxygen mixture (ether volume percentage 12,2 % ± 0,4 %) after the thermal steady state condition has been attained, but not longer than 3 h after switching on.

G.6.2 *Power supply

Parts or components of CATEGORY APG ME EQUIPMENT that operate in a FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE shall be supplied from a source that is isolated from earth by at least insulation equal to one MEANS OF PATIENT PROTECTION and from electrical parts by insulation equal to two MEANS OF PATIENT PROTECTION.

Compliance is checked by inspection of circuit diagrams and measurement.

G.6.3 *Temperatures and low-energy circuits

ME EQUIPMENT, and ME EQUIPMENT parts or components are considered to comply with the requirements of G.6.1 without being tested according to G.6.1 if, in NORMAL USE, NORMAL CONDITION and SINGLE FAULT CONDITIONS (see 4.5):

a) no sparks are produced and no temperatures exceeding 90 °C occur, or

b) a temperature limit of 90 °C is not exceeded, ME EQUIPMENT or ME EQUIPMENT parts contain components that may produce sparks in NORMAL USE, NORMAL CONDITION and applicable SINGLE FAULT CONDITIONS, but the voltage U_{max} and the current I_{max} that can occur in their circuits, taking into account the capacitance C_{max} and the inductance Lmax, comply with the following:

$U_{max} \leq L_{zR}$ with a given I_{zR}, see Figure G4, and

$U_{max} \leq U_{zC}$ with given C_{max}, see Figure G5, as well as

$I_{max} \leq I_{zR}$ with a given voltage U_{zR}, see Figure G4, and

$I_{max} \leq I_{zL}$ with a given inductance L_{max} and $U_{max} \leq 24$ V, see Figure G6.

– The graphs in Figure G4, Figure G5 and Figure G6 have been obtained with the test apparatus according to F.8 with the most readily flammable mixture of ether vapour with oxygen (ether volume percentage 12,2 ± 0,4 %) for an ignition probability of 10^{-3}. The maximum allowable values of I_{zR} (Figure G4), U_{zC} (Figure G5) and I_{zL} (Figure G6) include a SAFETY factor of 1,5.

– Extrapolation of the curves of Figure G4, Figure G5 and Figure G6 is limited to the areas indicated.

– Voltage U_{max} is taken as the highest no-load voltage occurring in the circuit under investigation, taking into account MAINS VOLTAGE variations as required in 4.8.

– Current I_{max} is taken as the highest current flowing in the circuit under investigation, taking into account MAINS VOLTAGE variations as required in 4.8.

– Capacitance C_{max} and inductance L_{max} are taken as values that occur in the relevant circuit.

– If the equivalent resistance R in Figure G5 is less than 8 000 Ω, U_{max} is additionally determined with the actual resistance R.

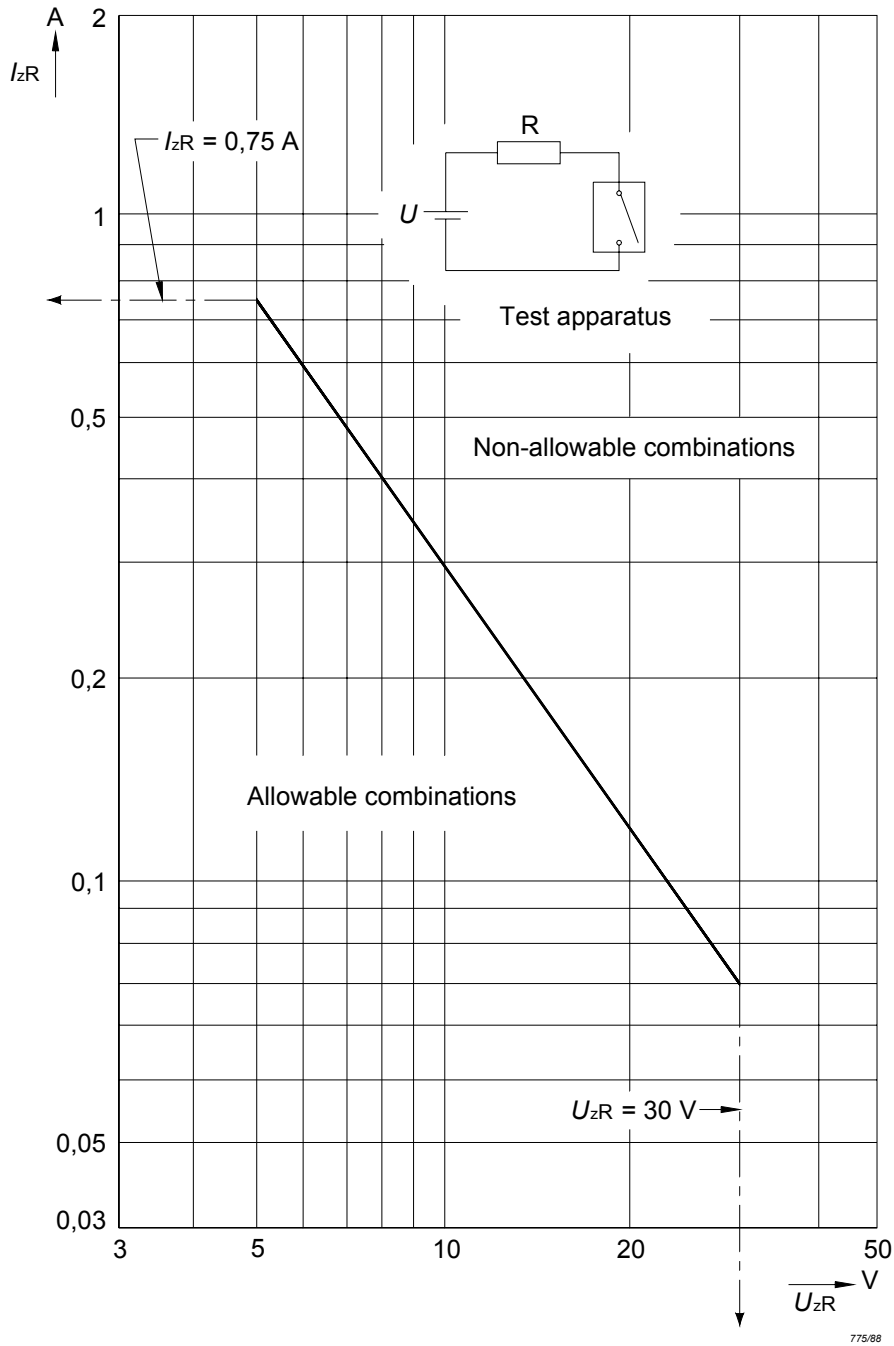
– If the circuit is supplied with a.c., the peak value is taken into account.

– If the circuit is complicated and consists of more than one capacitance, inductance and resistance or a combination thereof an equivalent circuit is calculated to determine the equivalent maximum capacitance, the equivalent maximum inductance and, additionally, the equivalent U_{max} and I_{max} either as d.c. values or a.c. peak values.

– If the energy produced in an inductance or capacitance in a circuit is limited by voltage-limiting or current-limiting devices preventing the limits of Figure G4, Figure G5 and Figure G6 being exceeded, two independent components shall be applied, so that the required limitation of voltage or current is obtained even in the case of a first fault (short circuit or open circuit) in one of these components.

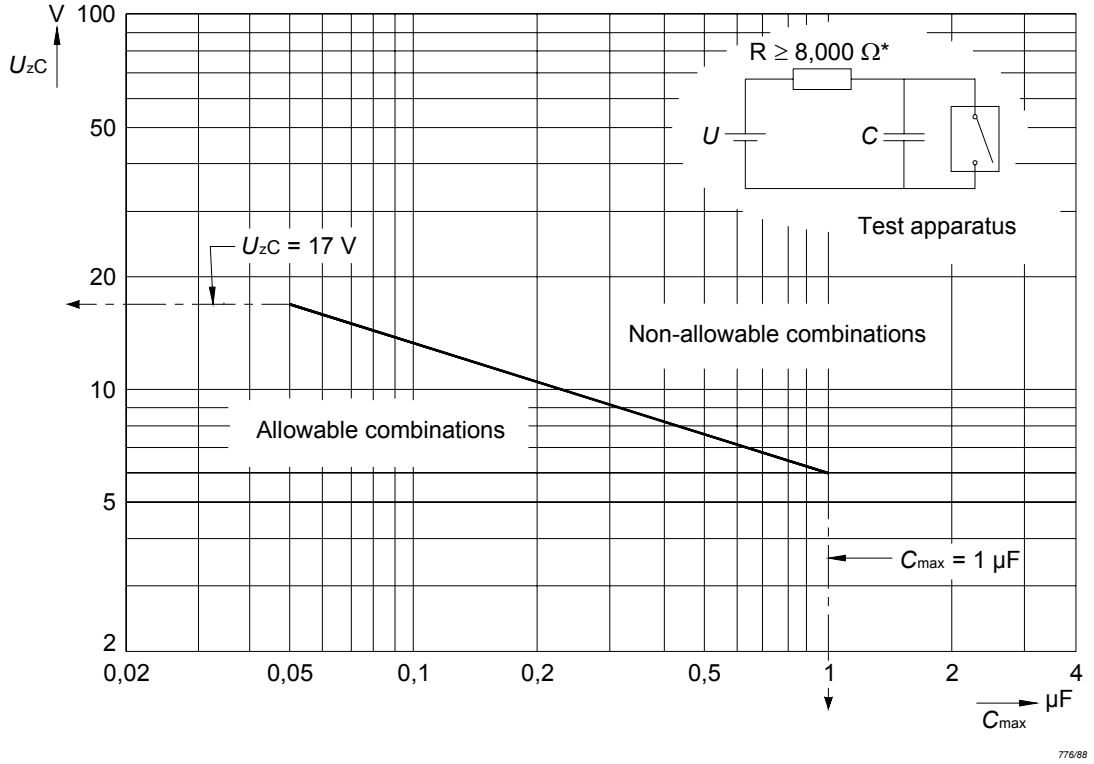
This requirement does not apply to transformers designed and made according to this standard and to wire-wound current-limiting resistors provided with a protection against unwinding of the wire in the event of rupture.

Compliance is checked by inspection, temperature measurements, comparison with design data or by measurement of U_{max}, I_{max}, R, L_{max} and C_{max} and using Figure G4, Figure G5 and Figure G6.



9514

9515 **Figure G4 – Maximum allowable current I_{zR} as a function of the maximum allowable voltage U_{zR}**
9516 **measured in a purely resistive circuit with the most flammable mixture of ether vapour with**
9517 **oxygen**



* 8 000 Ω or the actual resistance, if R is less than 8 000 Ω

Figure G5 – Maximum allowable voltage U_{zC} as a function of the capacitance C_{max} measured in a capacitive circuit with the most flammable mixture of ether vapour with oxygen

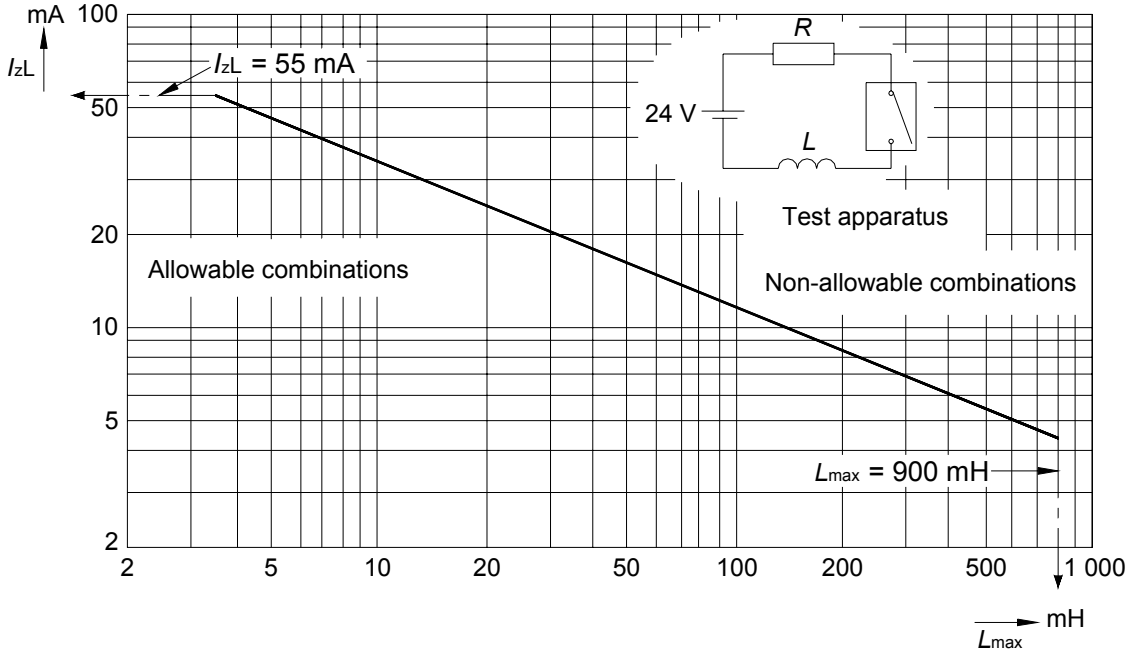


Figure G6 – Maximum allowable current I_{zL} as a function of the inductance L_{max} measured in an inductive circuit with the most flammable mixture of ether vapour with oxygen

G.6.4 Heating elements

ME EQUIPMENT, ME EQUIPMENT parts and components that heat a FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE shall be provided with a non-SELF-RESETTING THERMAL CUT-OUT, as an additional protection against overheating.

Compliance is checked by the corresponding test of 15.4.2.1.

The current-carrying part of the heating element shall not be in direct contact with the FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE.

Compliance is checked by inspection.

G.6.5 Humidifiers

See ISO 8185.

G.7 Test apparatus for flammable mixtures

Formally Appendix F of the second edition.

The test apparatus comprises an ignition space with a volume of at least 250 cm^3, which contains the prescribed atmosphere or mixture and a contact arrangement (see Figure G7) providing sparks by opening and closing.

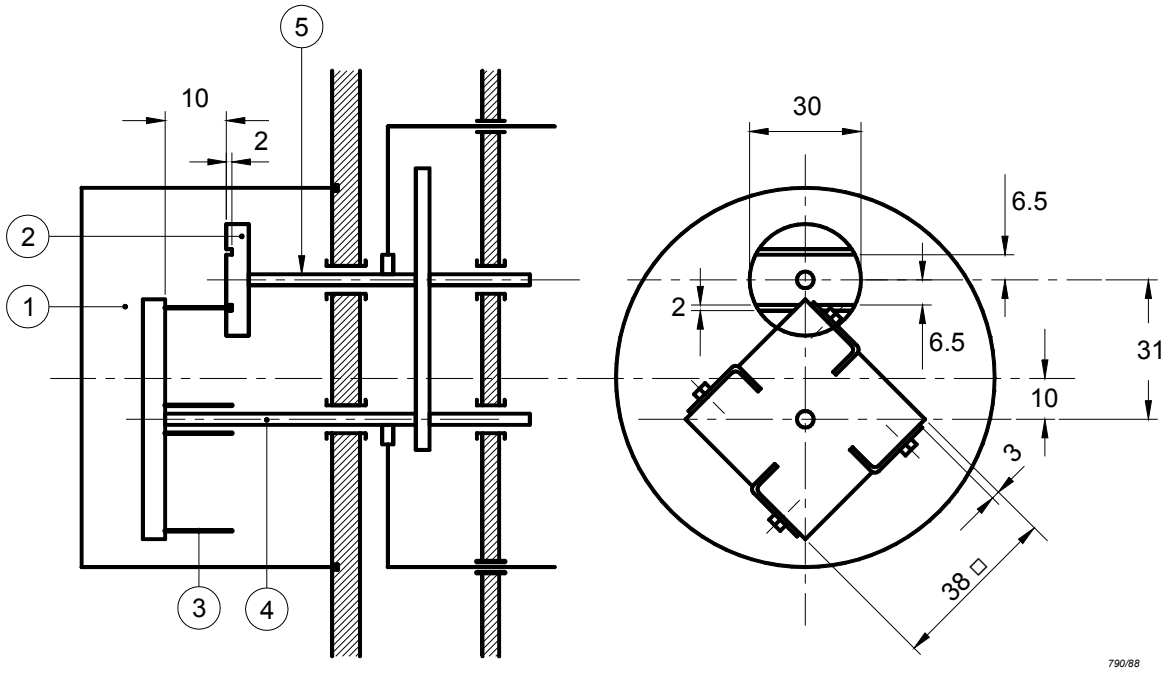
The contact arrangement consists of a cadmium disk with two groves and a second disk with four tungsten wires having a diameter of 0,2 mm that slides over the first disk. The free length of the tungsten wires is 11 mm. The shaft to which the tungsten wires are connected rotates with a speed of 80 rev/min. The shaft connected to the cadmium disk turns in opposite direction to the shaft connected to the disk with wires.

The ratio of the rotation speed of the shaft connected to the wires and the other shaft is 50:12.

Both shafts are isolated from each other and from the frame.

The ignition space must be able to support an internal overpressure of 1,5 MPa.

With the contact arrangement, the circuit to be tested is closed or opened and it is checked if the sparks will ignite the atmosphere or mixture under test.



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Dimensions in millimetres

Legend:

1 Ignition space
2 Cadmium disk
3 Tungsten wire
4 Shaft of wire disk
5 Shaft of disk with grooves

9551 **Figure G7 – Test apparatus**

Annex H
(Informative)

PEMS STRUCTURE, DEVELOPMENT LIFE-CYCLE AND DOCUMENTATION

H.1 Examples for PEMS/PESS structures

A PEMS can be a very simple piece of MEDICAL ELECTRICAL EQUIPMENT or a complex medical electrical system or anything in between.

Figure H1 shows some possible examples of a PEMS.

Figure H1 *a)* shows a complex system. The PEMS breaks down into a number of major subsystems, which in turn are made up of subsystems, which include a PESS.

Figure H1 *b)* shows a simpler implementation. In this case the intermediate major subsystem level is missing and the PESS is a subsystem of the PEMS itself.

Figure H1 *c)* illustrates the simplest implementation of a PEMS. In this case the PEMS and the PESS are the same.

The structure of the PEMS is extremely important for implementing SAFETY requirements. An architecture should be documented for the PEMS that describes the structure of the PEMS and the relationship between each PESS and the PEMS as a whole. The architecture should indicate:

– The division of the PEMS into components, especially those implemented in each PESS and including software components;

– The functions to be performed by each PESS and its components (including where appropriate SAFETY-related functions);

– The interfaces between software components;

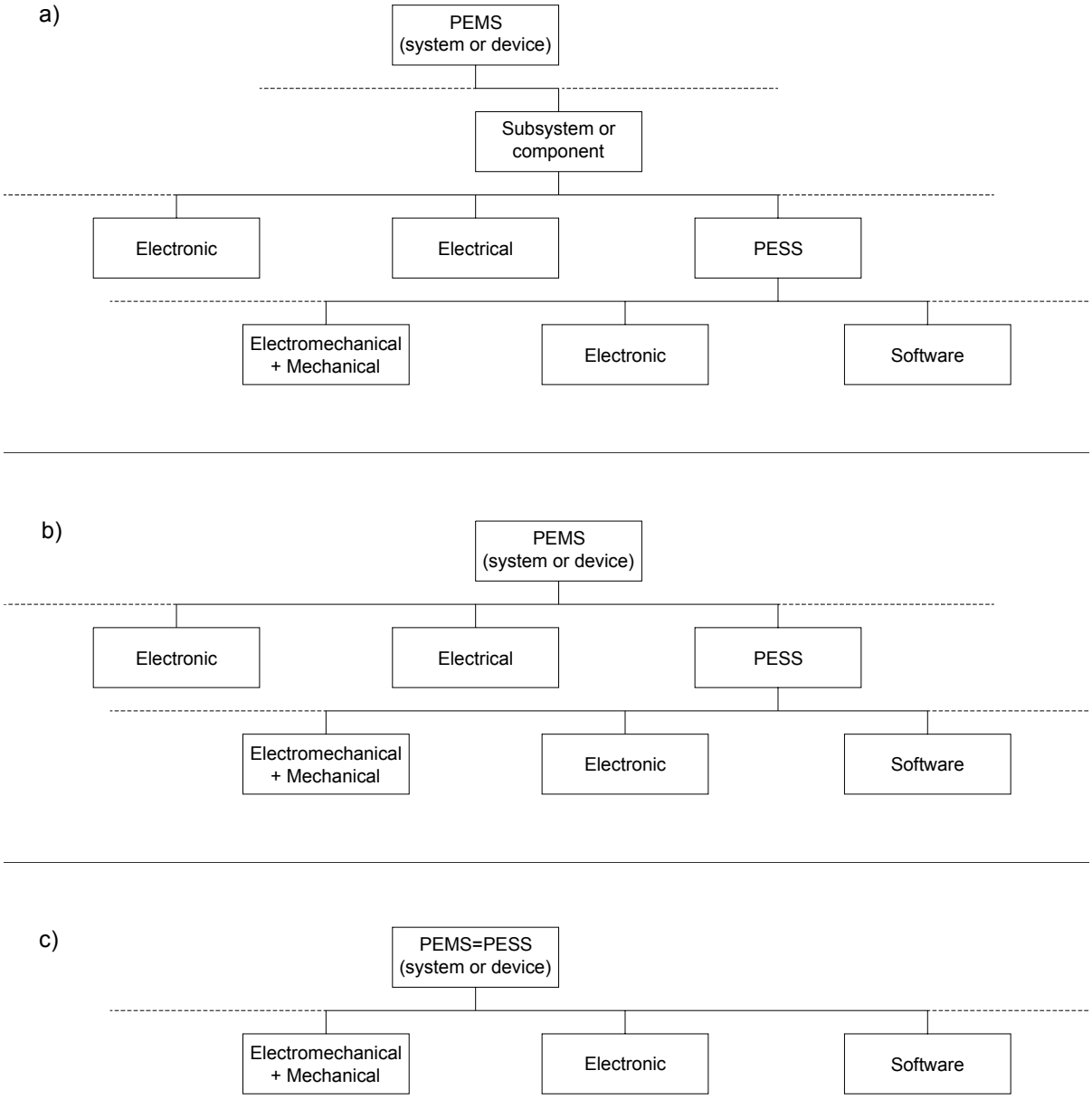
– The interfaces between software components and components external to the software.

H.2 DEVELOPMENT LIFE-CYCLE model

Compliance with the PEMS clause of this standard (Clause 14) requires that a DEVELOPMENT LIFE-CYCLE be specified and then followed; it does not require that any particular DEVELOPMENT LIFE-CYCLE is used, but it does require that the DEVELOPMENT LIFE-CYCLE has certain attributes. These requirements can be found in 14.4.

The DEVELOPMENT LIFE-CYCLE is a part of the overall product life-cycle.

Figure H2 illustrates a model of the DEVELOPMENT LIFE-CYCLE. In this model, a decomposition process is followed by an integration process. A symbolic triangle illustrates that there are interactions between the DEVELOPMENT LIFE-CYCLE and manufacturing. As the design is decomposed from the requirements the functional building blocks, architecture and technology are decided. The decomposition process concludes when the design information enables the components of the PEMS to be built (examples of such design information are circuit diagrams and software code). Following the decomposition the components are integrated together. VERIFICATION is carried out as the components are integrated to determine whether or not the implementation satisfies the requirements. At the conclusion of the integration process a PEMS VALIDATION is carried out to determine whether or not the PEMS works as intended.



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9593 **Figure H1 – Examples of PEMS/ PESS structures**

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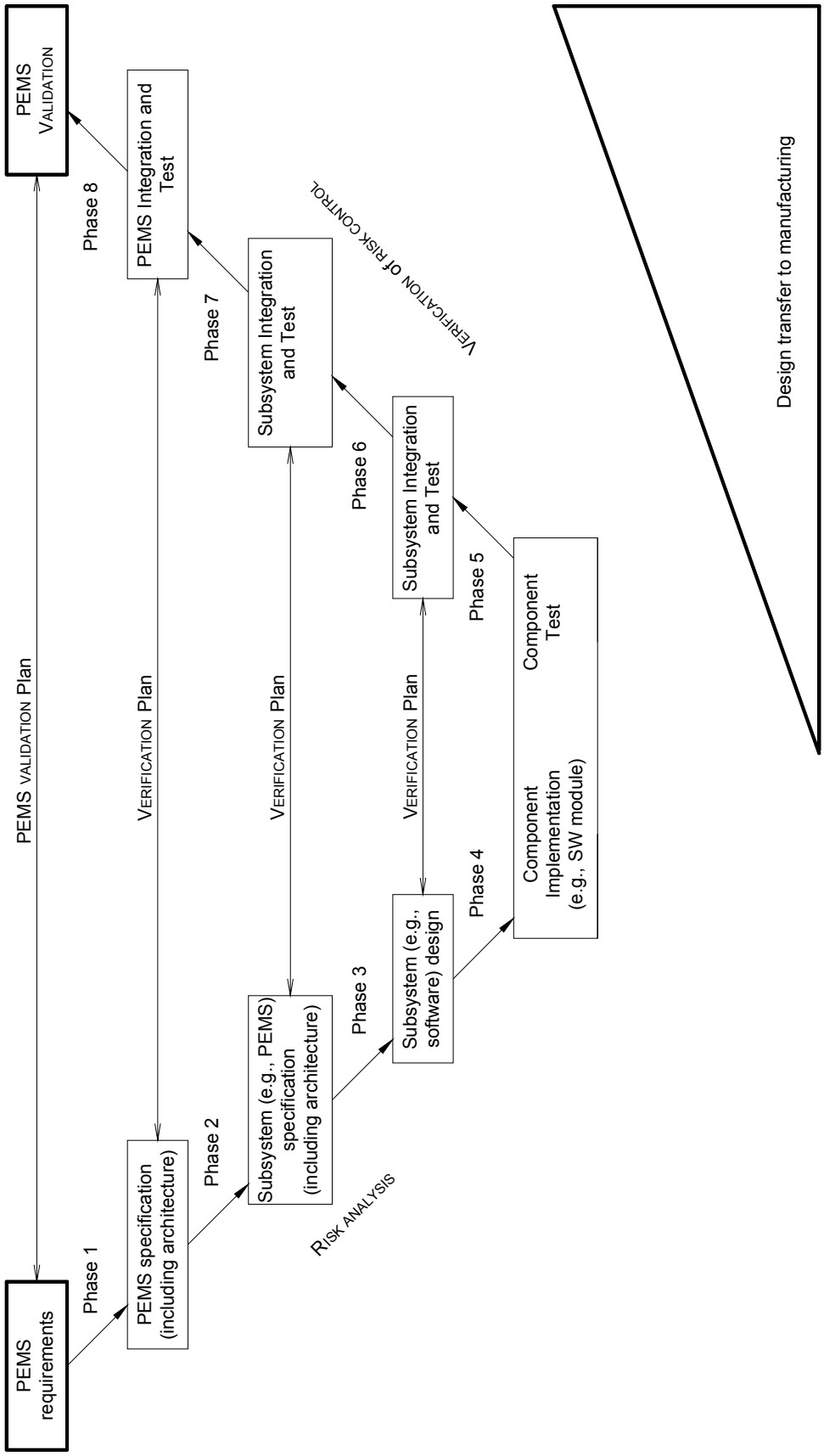


Figure H2 – A DEVELOPMENT LIFE-CYCLE model for PEMS

Clause 14 requires that the DEVELOPMENT LIFE-CYCLE used specifies the documentation requirements. It does not, however, specify the relationship of documentation to the DEVELOPMENT LIFE-CYCLE. Table H1 suggests a correlation of the documentation requirements with the DEVELOPMENT LIFE-CYCLE phases shown in Figure H2.

Table H1 – Suggested correlation of the documentation requirement to the DEVELOPMENT LIFE-CYCLE phases

	Phase							
Document	1	2	3	4	5	6	7	8
DEVELOPMENT LIFE-CYCLE 14.4	*							
PEMS requirement specification 14.7	*							
PEMS VALIDATION plan 14.11		*						
PEMS architecture specification 14.7		*						
VERIFICATION plan 14.10		*						
Subsystem (e.g. PESS) requirement specification 14.7			*					
PESS architecture specification 14.8			*					
Subsystem design specification 14.9				*				
Subsystem test specification 14.9			*	*				
VERIFICATION methods and results 14.10				*	*	*	*	
PEMS VALIDATION methods and results 14.11								*
* The document is suggested for that phase.								

H.3 Software PROCESSES

H.3.1 DEVELOPMENT LIFE-CYCLE

A DEVELOPMENT LIFE-CYCLE, such as the one illustrated in Figure H2, consists of a number of PROCESSES that are composed of activities. Each activity is performed to accomplish specific goals. The activities can be broken down further into tasks. To apply RISK MANAGEMENT, confidence in the engineering activities on which the RISK MANAGEMENT is based is needed. In particular, this is a requirement for the software life-cycle.

H.3.2 Requirements specification

To determine which functions create or control RISKS, it is necessary to fully identify the requirements of the PEMS/PESS. It is not possible to do an adequate RISK ANALYSIS without complete requirement specification. The requirements should include, as appropriate to the PEMS software:

– Functional and capability requirements, including performance, physical characteristics, and environmental conditions under which the software is to perform;

– Interfaces external to the software;

– SAFETY requirements including RISK CONTROL measures for hardware failures and potential software defects and specifications related to methods of operation and maintenance, environmental influences, and RISK CONTROL;

- Software driven alarms, warnings and OPERATOR messages;
- Security requirements, where lack of security would compromise SAFETY;
- Human-factors engineering requirements related to the use of the PEMS, including those related to support for manual operations, human-equipment interactions, constraints on personnel, and areas needing concentrated human attention that are sensitive to human errors and training;
- Data definition and database requirements;
- Installation and acceptance requirements for the PEMS software;
- Documentation to be developed;
- Operation and execution requirements;
- Maintenance requirements.

H.3.3 Third party and off-the shelf (OTS) software

To have the ability to identify known or foreseeable HAZARDS, it is also necessary to characterise any third party or OTS software used in the PEMS. The developer should establish software requirements for third party or OTS software. These requirements should include the following:

- Title and MANUFACTURER, version level, release date, patch number and upgrade designation;
- The system hardware and software necessary to support proper operation (e.g. processor type and speed, memory type and size, and system, communication and display software requirements);
- Interfaces to the software component;
- SAFETY critical and RISK CONTROL measure functions dependent on the software component.

H.3.4 Integration

The developer should establish an integration plan to integrate the components of each PESS and of the PEMS. The plan should include the approach, responsibilities and sequence, and include all software components. If the PESS software is built using incremental integration methods, sufficient regression testing should be performed to ensure that previous VERIFICATION is still sufficient. Integration tests should include test cases which expose software behaviour not only in response to the normal case, but also in response to exceptional, stress and/or worst case conditions.

H.3.5 Configuration management

Because the RISK ANALYSIS relies on the requirements of the software, configuration management and change control are necessary to ensure that additional software functionality is not added during development without being considered by the RISK MANAGEMENT PROCESS. A configuration management plan should be established that describes:

- The items to be controlled;
- The configuration management activities;
- PROCEDURES and schedule for performing these activities;
- Responsibilities for performing these activities;
- PROCEDURES to control the receipt, installation, and acceptance of each software component.

A scheme should be established for the unique identification of software configuration items and version control. This scheme should include third-party and OTS software components.

H.3.6 Modification/change control

For modification/change control, the following should be performed;

– Identification and recording of change requests;

– Analysis and evaluation of the changes;

– Approval or disapproval of the request;

– Implementation, VERIFICATION and release of the modified software.

An audit trail should be maintained, whereby each modification, the reason for the modification, and authorization of the modification can be traced. RECORDS of the history of controlled items should be retrievable.

H.4 Design and implementation

During application of the DEVELOPMENT LIFE-CYCLE model, design and implementation will include the selection of:

a) the design environment, e.g.:

  – software development methods;

  – computer aided software engineering (CASE) tools;

  – programming language;

  – hardware and software development platforms;

  – simulation tools;

  – design and coding standards;

b) electronic components;

c) redundant hardware;

d) human-PEMS interface;

e) energy sources;

f) environmental conditions;

g) third-party software;

h) networking options.

These elements of the design environment can be characterized in general and in the specific manner of their use in the design and implementation PROCESS.

H.5 Documentation

Figure H3 includes all of the documentation required by Clause 14 and ISO 14971. It is intended to show an example structure only. Particular documentary references can be consolidated or distributed among several documents. The clause numbers proceeded by a "#" are references to the clause numbers in ISO 14971. Other numbers refer to the subclauses of this standard.

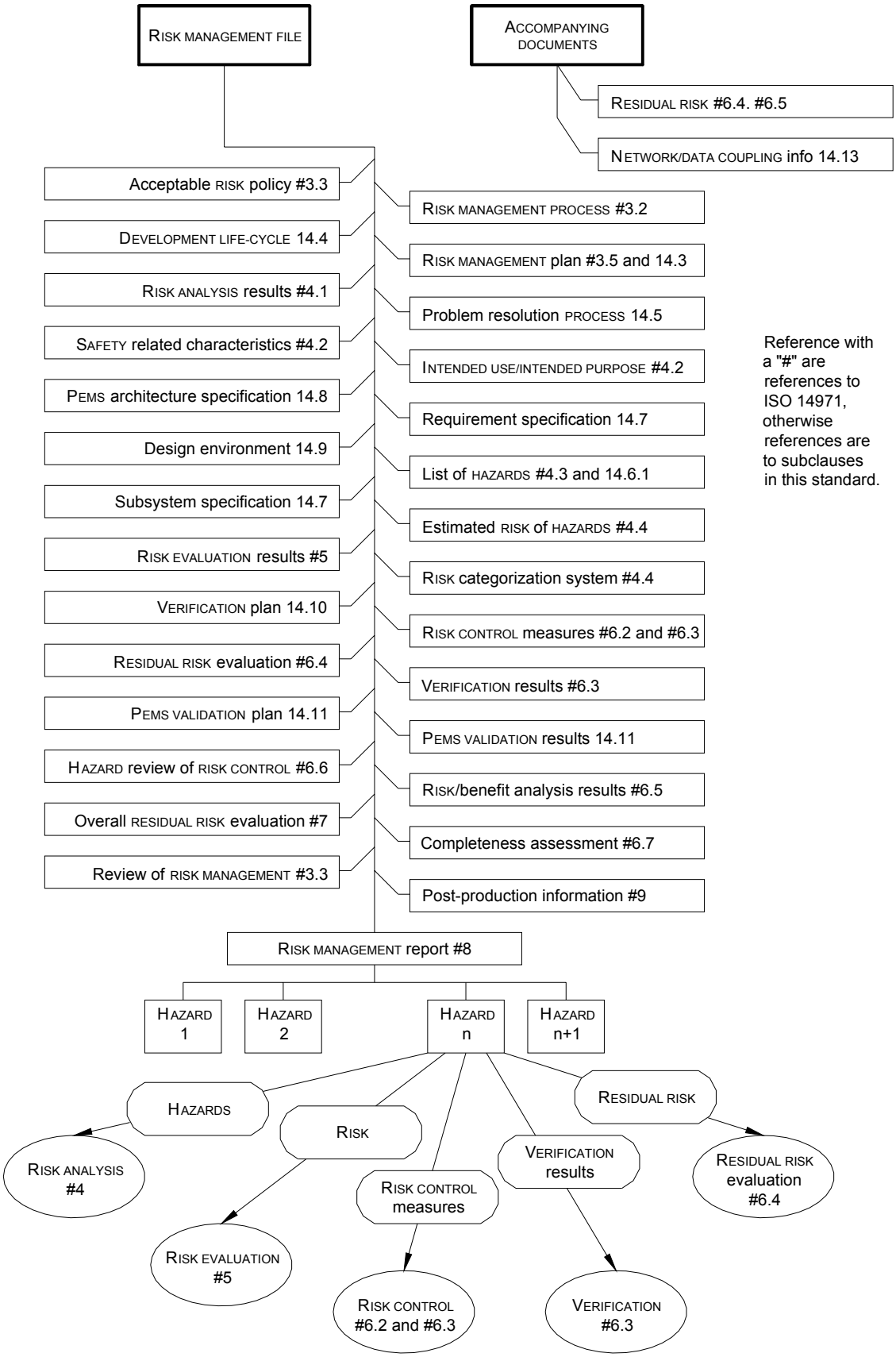


Figure H3 – PEMS documentation requirements from Clause 14 and ISO 14971

H.6 NETWORK/DATA COUPLING

H.6.1 General

In the context of this standard, the information transmitted as a part of NETWORK/DATA COUPLING is that intended by the MANUFACTURER to be transmittable (i.e. not through illegal or illicit actions of unauthorized persons).

NETWORK/DATA COUPLING as used in this standard does not include information transferred across USER interfaces. The MANUFACTURER must stipulate the possible information types and their transmission protocols in the technical description (see 14.13).

H.6.2 System integration responsibilities

ME EQUIPMENTS and ME SYSTEMS will sometimes be used together to create a large system. This is likely to become more frequent with the increasing use of computers to analyse clinical data and control treatment.

Sometimes ME EQUIPMENT will have been designed by the MANUFACTURER to work with other ME EQUIPMENT, however, it will often be the case that the separate ME EQUIPMENT will not have been designed to work with each other. Someone has to be responsible for ensuring that all the separate ME EQUIPMENT work together satisfactorily in the integrated system; in other words, someone has to be responsible for designing the integrated system. Ultimately, the responsibility for the integrated system belongs to the RESPONSIBLE ORGANISATION. The role of system integrator may be performed by the RESPONSIBLE ORGANIZATION or it may be assigned to a third-party.

It is recognized that the system integrator often has to comply with particular regulatory requirements.

In order to perform its function, the system integrator needs to know:

– how the integrated system is intended to be used;

– the required performance of the integrated system;

– the intended configuration of the system;

– the constraints on the extendibility of the system;

– the specifications of all ME EQUIPMENT and other equipment to be integrated;

– the performance of each ME EQUIPMENT and other equipments; and

– the information flow in and around the system.

This information will not be available to the individual MANUFACTURERS, and for this reason each individual MANUFACTURER can not carry out the role of system integrator. In any case the system integrator has to be a single person or organisation that has overall responsibility, this overall responsibility can not be shared between several different MANUFACTURERS. The responsibility of a MANUFACTURER is limited to providing the required information on their equipment (see 14.13).

The RESPONSIBLE ORGANISATION decides:

– what equipment to purchase;

– what equipment is integrated into a system;

– how the integrated system is used.

These activities are outside the scope of this standard.

Obviously a RESPONSIBLE ORGANISATION can employ a MANUFACTURER to integrate their system. In this case the whole system can become a MEDICAL ELECTRICAL SYSTEM and it will be the MANUFACTURER'S responsibility to provide a correctly integrated system. In this case the system could be separately regulated.

The system integrator should be competent to assess and address the HAZARDS that are likely to arise from integrating a system and to ensure that the RESIDUAL RISKS of the individual PEMS are maintained.

Typically a system integrator would:

– plan the integration of any MEDICAL ELECTRICAL EQUIPMENT OR MEDICAL ELECTRICAL SYSTEM and non-medical equipment in accordance with the instructions provided by the various MANUFACTURERS;

– perform RISK MANAGEMENT on the integrated system; and

– pass on any MANUFACTURER'S instructions to the RESPONSIBLE ORGANISATION where these are required for the safe operation of the integrated system. These instructions should include warnings about the HAZARDS of any change of configuration.

H.7 Data Coupling of PEMS in Hospitals[210]

H.7.1 Introduction

From the viewpoint of a PEMS MANUFACTURER, any type of a NETWORK/DATA COUPLING is a source of additional causes for hazards. In principle any NETWORK/DATA COUPLING that is outside the control of the PEMS MANUFACTUER should never be presumed to be 100% reliable. Observing the basic SAFETY requirements a MANUFACTURER has to look at the integration of a PEMS into a NETWORK/DATA COUPLING under the following two aspects:

a) The NETWORK/DATA COUPLING itself is unsafe — SAFETY measures shall be implemented inside the PEMS.

b) The NETWORK/DATA COUPLING itself is safe — SAFETY measures are implemented within the NETWORK/DATA COUPLED PEMS.

H.7.2 Causes of HAZARDS associated with NETWORK/DATA COUPLING

According to legal requirements (e.g. in the United States and Europe), ME SYSTEMS comprising PROGRAMMABLE ELECTRONIC SUBSYSTEMS shall be designed such that their:

– repeatability,

– reliability, and

– performance

is ensured according to their INTENDED USE/INTENDED PURPOSE for the sake of the PATIENT'S SAFETY. Adequate measures shall be applied to eliminate or to reduce any RISK as far as reasonably practicable in the case of a system fault.

RISK MANAGEMENT must take into account any HAZARDS that can occur in the system. These HAZARDS include all effects on the INTENDED USE/INTENDED PURPOSE that:

– adversely affect the intended therapy or diagnosis, or

– could result in injury or death of the PATIENT.

It is irrelevant whether these HAZARDS result in immediate or delayed, direct or indirect HARM to the PATIENT.

In NETWORK/DATA COUPLED systems, likely causes for HAZARDS are:

– loss of data

– inappropriate data interchange

– corrupted data

– inappropriate timing of data

– unexpected receipt of data

– unauthorized access to data

When identifying the causes of HAZARDS associated with NETWORK/DATA COUPLING, at least the following should be considered:

– remote servicing (external access to the network)
– operating system (compatibility of operating systems)
– modification/upgrades of software (operating systems, applications, etc.)
– interface compatibility (data collisions, data formats)
  - connections (modification of hardware, network connectors)
  - network interface boards (compatibility)
  - network protocols (DICOM, HL7, etc.)
– packet address structure/timing
– normal network loads/bandwidth
– peak network load
– data media (longevity and retrievability)
– security (viruses, worms, unauthorized software updates or upgrades)
– maximum acceptable response time
– acceptable failure rate of the network (network availability)
– availability of the network (planned and unplanned maintenance)
– inconsistency in interfaces/formats resulting in loss of fidelity during information transfer
– heterogeneous network topologies

When considering the potential causes for HAZARDS listed above, the following questions should be taken into account:

a) Disruption/misinterpretation of the INTENDED USE/INTENDED PURPOSE

Can the INTENDED USE/INTENDED PURPOSE of each constituent PEMS be disturbed by the network or be inadvertently changed by the system integrator?

b) Incorrect data flow to or from each constituent PEMS

What are the data transferred by the network used for, and to which tasks are they related? What are the consequences of a breakdown of the NETWORK/DATA COUPLING?

c) Deviation from the specified operational characteristics of any constituent PEMS

What are the operational characteristics of the PEMS and to what degree are they affected by the NETWORK/DATA COUPLING?

d) Incomplete characterization of NETWORK/DATA COUPLING parameters

Is the network topology, configuration, parameters (e.g. open or closed, bandwidth, transmission protocol) completely characterized? Are there any breakdown characteristics/concepts and what are these?

e) Excessive use/load of the NETWORK/DATA COUPLING by the network nodes

What is the planned number of network nodes and their assumed degree of use? Are the resources sufficient to meet the needs of both the NETWORK/DATA COUPLING itself and the devices connected to it?

f) Use errors

What skills are required by the OPERATOR for the effective operation of the system?

g) Inadequate configuration management

Do periodic service tasks alter the network's characteristics (e.g. after remote access, updates or upgrades)? Does the RESPONSIBLE ORGANIZATION ensure that modifications to each constituent PEMS are reviewed and approved?

H.7.3 Network classification based on the consequence to the PATIENT

H.7.3.1 Consequence to the PATIENT

In order to relate the causes in H.7.2 to the consequences for the PATIENT, it may be useful to classify NETWORK/DATA COUPLINGS both by the consequences and the reaction time, where reaction time is the time delay between a NETWORK/DATA COUPLING failure and the onset of HARM to the PATIENT. Table H2 contains an example of a NETWORK/DATA COUPLING classification based on these considerations.

Table H2 – NETWORK/DATA COUPLING classification

Consequence	Reaction time*)	Class	Example(s)
Death/serious injury	Second(s)	A	Infusion (closed loop); false control of a surgical robot
	Minute(s)	A	Suppressed alarm transmission
	Hour(s)	A/B	False therapy data to ventilator
Medium injury	Second(s)	A	Wrong alarm transmission, false control of a surgical robot
	Minute(s)	A/B	Wrong alarm transmission, false control of a surgical robot
	Hour(s)	A/B	Falsified image; loss of a therapy report
Minor injury	Second(s)	B	
	Minute(s)	B	Loss of a radiograph
	Hour(s)	B/C	
Negligible	Second(s)	C	
	Minute(s)	C	
	Hour(s)	C	

H.7.3.2 Class "A" NETWORK/DATA COUPLING (PATIENT vital data, time critical)

This is the NETWORK/DATA COUPLING for all time critical application/PROCESSES. It is not linked to any other network, because a link could cause uncontrollable HAZARDS. All resources are available only for the nodes of this network. The availability must be close to 100 %. Disruptions shall be avoided and shall last for only a few minutes per year. Responsibility is assigned to a single PEMS MANUFACTURER/system contractor only. Network nodes comply with the requirements established by this MANUFACTURER/contractor. An example of this class is a PATIENT monitoring network.

H.7.3.3 Class "B" NETWORK/DATA COUPLING (PATIENT vital data, non time critical)

This is the NETWORK/DATA COUPLING for non-time critical application/PROCESSES that handle therapeutic or diagnostic PATIENT data. This NETWORK/DATA COUPLING may be linked to another one by a defined and controllable/secured interface. The availability needs to be very high, and, because of a lack of alternatives, disruptions should last only for short periods.

– The responsibility is assigned to the RESPONSIBLE ORGANIZATION and/or system integrator. In the case of multiple PEMS, the data priority contention must be defined.

– The network nodes must follow selected criteria/minimum set of parameters. A radiology network may serve as an example.

H.7.3.4 Class "C" NETWORK/DATA COUPLING

This is the NETWORK/DATA COUPLING for any applications (including PATIENT administrative/ demographic data), which operate on validated PATIENT data only and are not assigned to class "A" or "B" networks. Also, it can be accepted that these applications are unavailable for a longer period because there are alternatives. Example is the general hospital administration network.

– The responsibility is assigned to the RESPONSIBLE ORGANIZATION.

– There are any types of network nodes.

H.7.4 NETWORK/DATA COUPLING parameters

The usage of an NETWORK/DATA COUPLING for exchange of data either between PEMS or between PEMS and other information technology equipment requires the knowledge about both the structure of the NETWORK/DATA COUPLING and the PROCESSES/functions running inside them. This is important because MANUFACTURERS of PEMS or NETWORK/DATA COUPLINGS should select the configuration of their products such that:

– they comply with internationally recognized network standards (Ethernet, Fast Ethernet, GigaBitEthernet, FDDI, etc.) and use the available bandwidth appropriately according to the INTENDED USE/INTENDED PURPOSE.

– they achieve the optimal performance for their application

A mixture of different NETWORK/DATA COUPLINGS configurations/parameter settings emerge which are not always compatible for the different NETWORK/DATA COUPLINGS nodes in spite of the fact that they comply to valid international standards.

To avoid or at least to minimize the resulting potential of disruption, a match of a minimum set of NETWORK/DATA COUPLINGS parameters derived from the relevant standards is required.

To ensure a reliable installation of NETWORK/DATA COUPLED PEMS and minimize the RISK to PATIENTS, the PEMS MANUFACTURER, the RESPONSIBLE ORGANIZATION, and the system integrator need to communicate all relevant technical parameters to each other. This level of detail is necessary to avoid inappropriate assumptions that result in unacceptable RISK.

Table H3 contains a list is given of parameters potentially required to be specified. Due to the rapid evolution of NETWORK/DATA COUPLINGS technology, this table should be seen as a starting point.

9890 **Table H3 – Example of potential parameters required to be specified for NETWORK/DATA**
9891 **COUPLING**

Objects	Description		
Application and Operating System:			
Operating System / Version:			
Network protocols:			
Detailed data for specific application / transport protocol (if used)			
HL7	HL 7 version		
	Formats of message types used		
	Free fields (which are used)		
	Ports		
	HL7 Protocol (TCP/IP Lower Layer)		
DICOM Service classes	**A) Test:**	Verification	
	B) Transfer:	Storage	
		Query/Retrieve	
	C) Documentation:	Print management	
	D) Organisation:	Modality work list management	
		Performed procedure step	
	E) Information:	Study contents notification	
		Patient management	
		Storage commitment	
		Study component management	
		Results management	
	F) External Storage:	Media storage	
DICOM Objects	e.g. COMPUTER RADIOGRAPHY IMAGE		
	Other Modality Objects		
DICOM host name			
DICOM AET called			
DICOM AET calling			
DICOM Port called			
DICOM Port calling			
Detailed Parameters with respect to the lower protocol layers			
Network data	**Physical connection**		
	Network interface card parameters		
Network-Administration			
Port number of connected Switch / HUB / Router			
IP-Address			
Subnet mask			
Host-Name			
IT-Domain			
Active-Directory / LDAP Server			
Default Gateway (Access via Router)			
Remote Control			
Remote Monitoring			
Modem Connection			
Remote Service IP-Address			
Other Parameters			

Annex J
(Informative)

ME SYSTEMS ASPECTS

J.1 Combinations of ME EQUIPMENT and non-ME EQUIPMENT

J.1.1 Introduction

A summary is given of situations that may occur when different combinations of equipment are used in various medical environments. To keep this summary short, no more than two items of equipment (A and B) are used per situation.

J.1.2 Localities in a medical environment

The following localities are foreseen (see also Table J1):

– the PATIENT ENVIRONMENT as part of a medically used room;

– a medically used room, excluding the PATIENT ENVIRONMENT;

– the non-medically used room (a room not designed for medical treatment, for example, an office or a storage room).

A protective earth can be dedicated to each of the three localities listed above.

NOTE A potential difference *(V)* can exist between the protective earths in different localities. In case of an interruption of protective earthing (fault condition) for equipment in the PATIENT ENVIRONMENT, this potential difference may appear on the ENCLOSURE of the equipment causing a SAFETY HAZARD for the OPERATOR or for the PATIENT if the OPERATOR simultaneously touches the equipment and the PATIENT, or for the PATIENT if the equipment is of TYPE B.

J.1.3 Basic principles

– PATIENTS should only be connected to APPLIED PARTS of MEDICAL ELECTRICAL EQUIPMENT complying with this standard. Other equipment should comply with relevant IEC or ISO standards.

– In fault condition the allowable TOUCH CURRENT is 500 µA.

– All equipment complying with the safety standard applicable to the originally intended, non-medical use, herein called IEC XXXXX, and placed in the PATIENT ENVIRONMENT needs measures to limit the TOUCH CURRENT, if this exceeds the values specified in 16.6.2.

J.1.4 An example

Two items of equipment are placed within the PATIENT ENVIRONMENT (see situation No. 1 in Table J1).

There are three possibilities designated 1a, 1b, and 1c:

1a: Items A and B both comply with IEC 60601: Clause 16.6 is satisfactory.

1b: Item A complies with IEC 60601 and item B complies with IEC XXXXX: only the TOUCH CURRENT of item B has to be limited when any single PROTECTIVE EARTH CONDUCTOR or the equivalent conductor of the equipment, is interrupted, if necessary, by applying an additional protective earth or a separating transformer to item B.

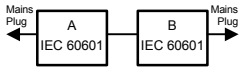
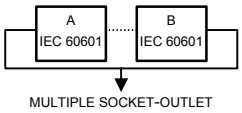
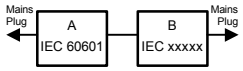
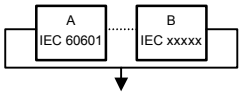
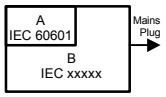
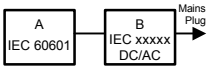
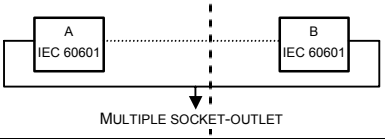
1c: Item A is powered from item B. Item B needs the measures for a power supply as described by the MANUFACTURER and must fulfil the requirement of 16.3. If necessary, apply an additional protective earth or a separating transformer to item B.

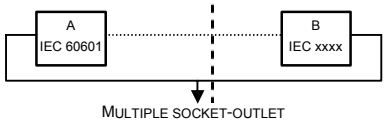
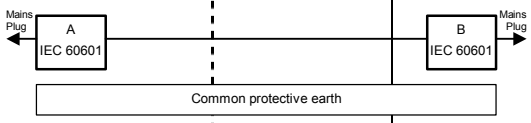
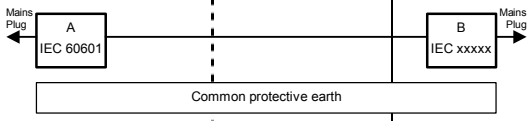
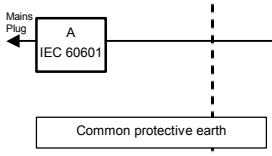
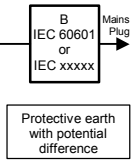
NOTE Situations 2 and 3 can be derived from Table J1.

J.2 Examples of application of MULTIPLE SOCKET-OUTLETS (MSO)

Figure J1 contains some examples of **MULTIPLE SOCKET-OUTLETS.**

9936 **Table J1 – Some examples of MEDICAL ELECTRICAL SYSTEMS for illustration**

Situation No.		Medically used room: Inside the PATIENT ENVIRONMENT	Medically used room: Outside the PATIENT ENVIRONMENT	Non-medically used room	Examples of possible causes for exceeding LEAKAGE CURRENT limits	Practical means of compliance Apply 16.5 in all situations
1	**1a** Items A and B are ME EQUIPMENT				No causes of exceeding LEAKAGE CURRENT	– No further measures are necessary
	1b Items A and B are ME EQUIPMENT powered via a MULTIPLE SOCKET-OUTLET				Earth conductor of the MULTIPLE SOCKET-OUTLET is broken	– Additional PROTECTIVE EARTH CONNECTION (for A or B) or, – Separating transformer
	1c Item A is ME EQUIPMENT and B is Non-ME EQUIPMENT				Due to high TOUCH CURRENT of B	– Additional PROTECTIVE EARTH CONNECTION (for B) or, – Separating transformer (for B)
	1d Item A is ME EQUIPMENT and B is non-ME EQUIPMENT powered via a MULTIPLE SOCKET-OUTLET				The earth conductor of the MULTIPLE SOCKET-OUTLET is broken or, Due to high TOUCH CURRENT of B	– Additional PROTECTIVE EARTH CONNECTION (for A or B) or, – Separating transformer
	1e Item A is ME EQUIPMENT powered from specified power supply in item B				Due to high TOUCH CURRENT of B	– Additional PROTECTIVE EARTH CONNECTION (for B) or, – Separating transformer (for B)
	1f Item A is ME EQUIPMENT powered from NON-ME EQUIPMENT power supply in B					
2	**2a** Items A and B are ME EQUIPMENT				No causes of exceeding LEAKAGE CURRENT	– No further measures are necessary
	2b Items A and item B are ME EQUIPMENT powered via a MULTIPLE SOCKET-OUTLET				Earth conductor of the MULTIPLE SOCKET-OUTLET is broken	– Additional PROTECTIVE EARTH CONNECTION (for A or B) or, – Separating transformer

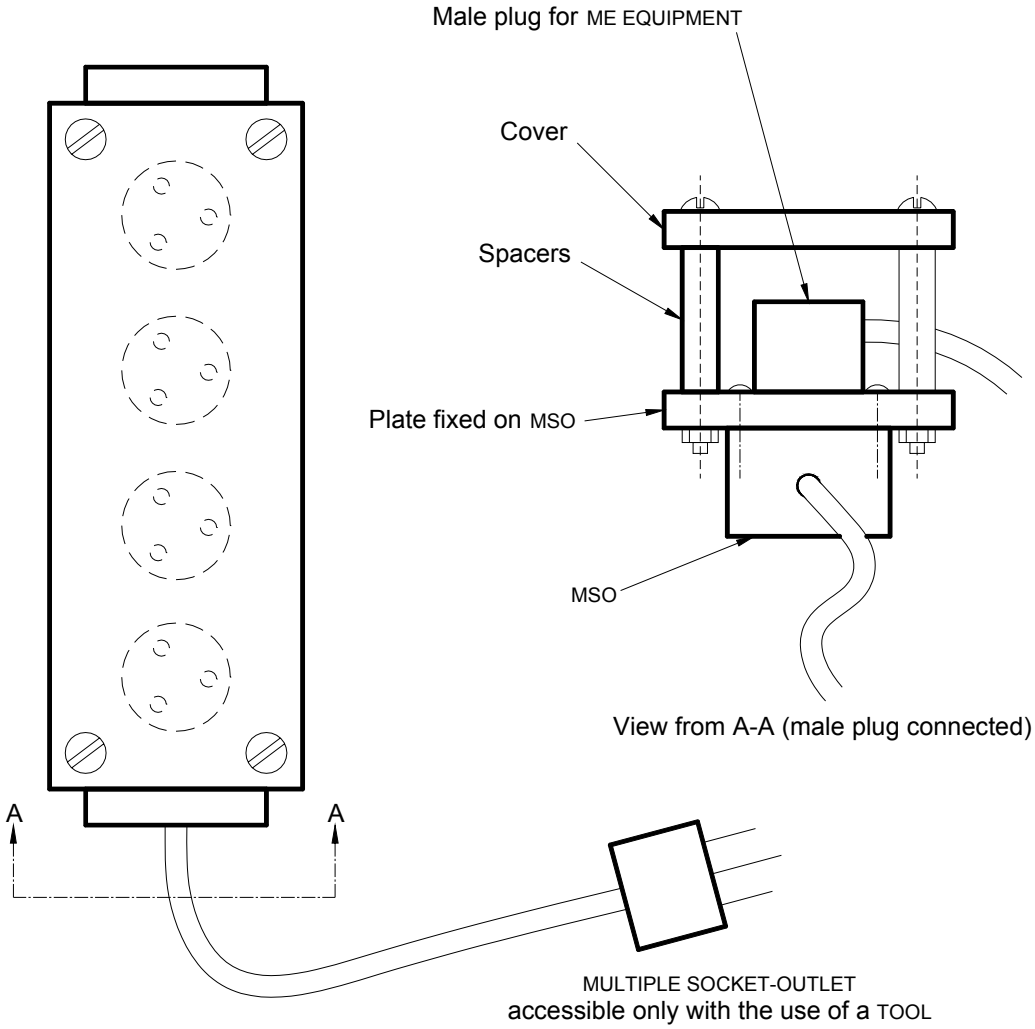
Situation No.		Medically used room: Inside the PATIENT ENVIRONMENT / Outside the PATIENT ENVIRONMENT	Non-medically used room	Examples of possible causes for exceeding LEAKAGE CURRENT limits	Practical means of compliance Apply 16.5 in all situations
2	**2c** Item A is ME EQUIPMENT and item B is non-ME EQUIPMENT			Due to high TOUCH CURRENT of B See rationale of 16.5	– Do not use metal connector housing or, – SEPARATION DEVICE
	2d Item A is ME EQUIPMENT and item B is non-ME EQUIPMENT powered via a MULTIPLE SOCKET-OUTLET			The earth conductor of the MULTIPLE SOCKET-OUTLET is broken	– Additional PROTECTIVE EARTH CONNECTION (for A or B) or, – Separating transformer
3	**3a** Items A and B are ME EQUIPMENT			No causes of exceeding LEAKAGE CURRENT	– No further measures are necessary
	3b Item A is ME EQUIPMENT and item B is non-ME EQUIPMENT			Due to high TOUCH CURRENT of B See rationale of 16.5	– Do not use metal connector housing for SIGNAL INPUT/OUTPUT PART or, – SEPARATION DEVICE
	3c Item A is ME EQUIPMENT and item B in is ME EQUIPMENT or non-ME EQUIPMENT			*a)* Potential difference between PROTECTIVE EARTH CONNECTION's of A and B *b)* Due to high TOUCH CURRENT of B. See rationale of 16.5	– Additional PROTECTIVE EARTH CONNECTION for (A), – SEPARATION DEVICE. – Do not use metal connector housing

NOTE 1 IEC 60601: MEDICAL ELECTRICAL EQUIPMENT in compliance with IEC 60601

NOTE 2 IEC xxxxx: Non-medical equipment in compliance with relevant IEC safety standards.

NOTE 3 Separating transformer: see 16.9.2.1

NOTE 4 If equipment "B" is outside the PATIENT ENVIRONMENT and if equipment "A" is a CLASS II equipment and has accessible conductive parts connected to the PROTECTIVE EARTH CONNECTION of equipment "B" than additional SAFETY measures may be necessary for example: Additional protective earth for "B" or separating transformer or SEPARATION DEVCIE.


Male plug for ME EQUIPMENT
Cover
Spacers
Plate fixed on MSO
MSO
View from A-A (male plug connected)
A
A
MULTIPLE SOCKET-OUTLET
accessible only with the use of a TOOL

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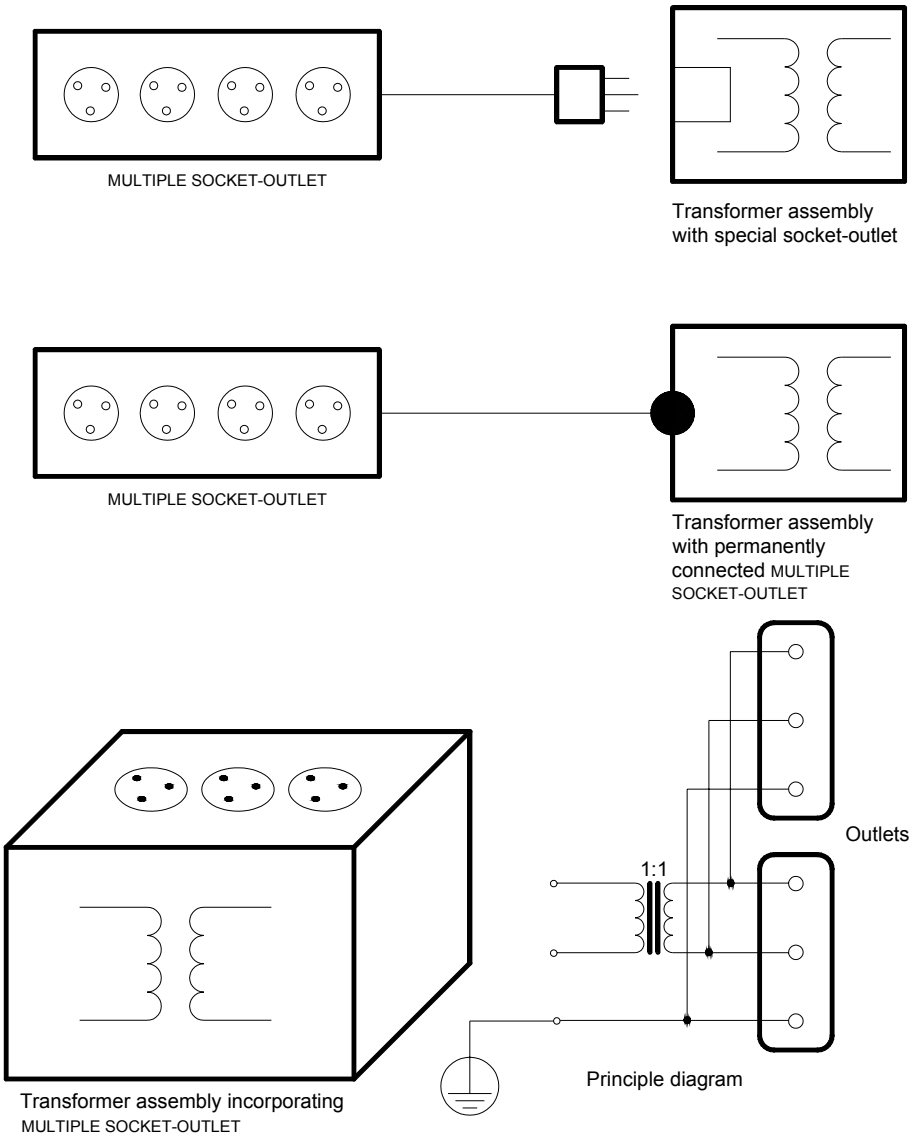

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Figure J1 – Examples of application of MULTIPLE SOCKET-OUTLETS (MSO)

Annex K
(Informative)

INSTRUCTIONS FOR AN EASY-TO-DISMANTLE CONSTRUCTION

Table K1 – Instructions for an easy-to-dismantle construction

	Construction element contains	Dismantling instructions	Possible point of separation	Note
a	ENVIRONMENTALLY HAZARDOUS SUBSTANCES(e.g. oil)	Remove prior to disassembly for RECYCLING or disposal purposes		Quick and RISK less removability is essential.
b	Units and components containing HARMFUL SUBSTANCES AND MATERIALS	Separate, recycle or dispose of separately	Easily removable connection	Still operative after end of use.
		(usually special waste treatment).	Predetermined breaking point; point of separation easily accessible with parting-off tools.	No harmful substances may be released during removal PROCESS.
c	Reusable subassemblies or components.	Subassemblies or components must not be	Easily removable connections	Still operative after end of use.
		damaged when they are removed from the devices.	Predetermined breaking point at the fixing device, accessibility for parting-off tools at the fixing device.	The severed part of the fixing device must be easily removable from the reusable part.
d	Subassemblies or components intended for special use or RECYCLING purposes	Separate subassemblies or components for which well-established disposal methods exist	Connection removable by mechanical decoupling, temperature, ultrasound, etc.	Still operative after end of use.
	or the removal of which reduces the volume of the parts to be disposed of (e.g. concrete ballast weights).	(e.g. engines, electric controls, cathode ray tubes, cables, large single-type plastic parts) or which deliver high single-type substance proceeds (e.g. stainless steel)	Predetermined breaking point, point of separation easily accessible for parting-off tools.	Recyclability must not be impaired by severed, but still clinging parts (e.g. metal on a plastic part, copper on steel)
e	Appliances, subassemblies, or components that do not fit into any of the categories a to d.	Rough shredding.		Metal fractions are separated, the remainder is disposed of (thermal treatment, landfill) or, if possible, recycled as energy.

Annex L
(Normative)

HAZARDOUS SUBSTANCES AND MATERIALS

Table L1 – HAZARDOUS SUBSTANCES AND MATERIALS

Substance	Formula	cas-number
ME EQUIPMENT and packaging		
Asbestos (all types)	n.a.	1332-21-4
Aromatic Hydrocarbons, Halogenated	n.a.	n.a.
Antimony and -compounds	Sb	7440-36-0
Arsenic and -compounds	As	7440-38-2
Beryllium and -compounds	Be	7440-41-7
Chromium(VI) -compounds	Cr (VI)	n.a.
Cobalt and -compounds	Co	7440-48-4
Lead and -compounds*(Printed Circuit Boards and cables exempted)*	Pb	7439-92-1
Benzene	C6H6	71-43-2
Cadmium and -compounds	Cd	7440-43-9
Mercury and -compounds	Hg	7439-97-6
CFCs (ChloroFluorCarbons) (all)	n.a.	n.a
Halons	n.a.	n.a
HCFCs (HydroChloroFluorCarbons) (all)	n.a.	n.a
- HCFC 142 b	C2H3F2CL	unknown
- HCFC 22	CHF2CL	unknown
- HCFC blend A	n.a.	unknown
- HCFC 141 b	C2H3F2CL	unknown
CHCs (ChlorinatedHydroCarbons) (all)	n.a.	n.a.
- Methane, Dichloro-	CH2Cl2	75-09-2
- Methane, Tetrachloro- (Carbontetrachloride)	CCl4	56-23-5
- Ethane, 1,1,1-Trichloro- (Methylchloroform)	C2H4CL3	71-55-6
- Ethylene, Tetrachloro- (Per)	C2CL4	127-18-4
- Ethylene, Trichloro- (Tri)	C2HCL3	79-01-6
Ethylene, Chloro-1- (Vinylchloride)	C2H3CL	75-01-4
Lead(Pb)carbonate (neutral)	PbCO3 (*)	598-63-0
Lead(Pb)sulfate	PbSO4 (*)	7446-14-2
Phenol, Pentachloro-	C6H5(OH)CL5	87-86-5
PBBEs (PolyBromoBiphenylEthers) (all)	n.a.	n.a.
PBBs (PolyBromoBiphenyls) (all)	n.a.	59536-65-1
Selenium and -compounds	Se	7782-49-2
Tellurium and -compounds	Te	13494-80-9
Thallium and -compounds	Tl	7440-28-0
Organic Tin-compounds	n.a.	n.a.

Substance	Formula	cas-number
Tungsten and -compounds	W	7440-33-7
Cyanides	CN-	57-12-5
Formaldehyde	HCOH	50-00-0
PAHs (Polycycl.arom.hydrocarbons)	n.a.	n.a.
PAHs, oxidized (Polycycl.arom.hydrocarbons)	n.a.	n.a.
Phenol and Phenolic compounds	C6H5OH	108-95-2
Phthalate (all)	n.a.	n.a.
Toluene	C6H5CH3	108-88-3
Xylenes	C6H4(CH3)3	1330-20-7
CHCs ChloronatedHydroCarbons (all others)	n.a.	n.a.
Epichlorohydrine (Monomer)		106-89-8
Tri-(2,3-dibroompropyl)fosfaat	n.a.	126-72-7
Tri--(aziridinyl)fosfineoxide	n.a.	5455-55-1
PCBs (PolyChloroBiphenyls) (all)	n.a.	1336-36-3
PCTs (PolyChloroTerphenyls) (all)	n.a.	11126-42-4
Ugilec 141)	n.a.	76253-60-6
Ugilec 121 or 21 } substidude for PCBs/PCTs	n.a.	unknown
DBBT)	n.a.	99688-47-8
HBFCs (HydroBromoFluorCarbons) (all)	n.a.	n.a.
Packaging		
PVC and -blends		

Annex M
(Informative)

Survey of insulation paths[211]

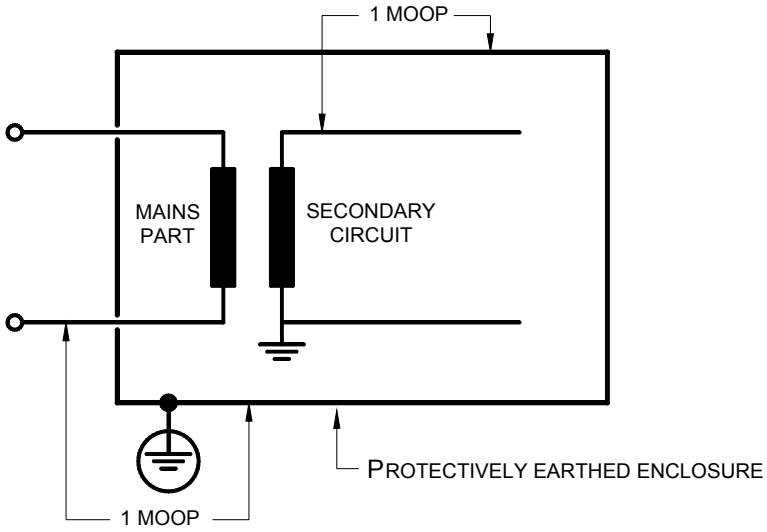

Figure M1 – Insulation example #1

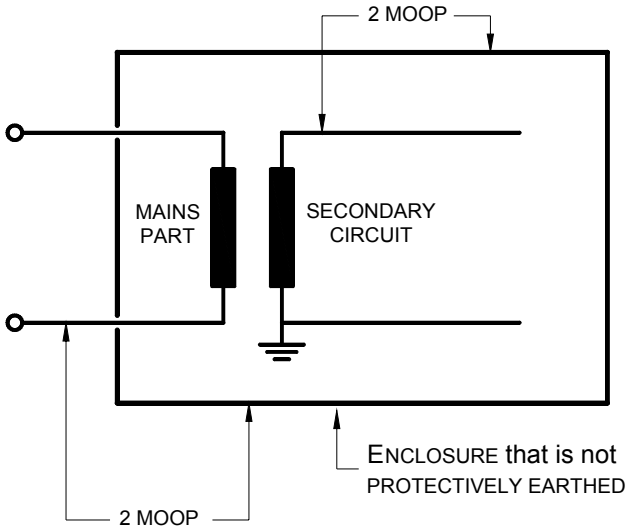

Figure M2 – Insulation example #2

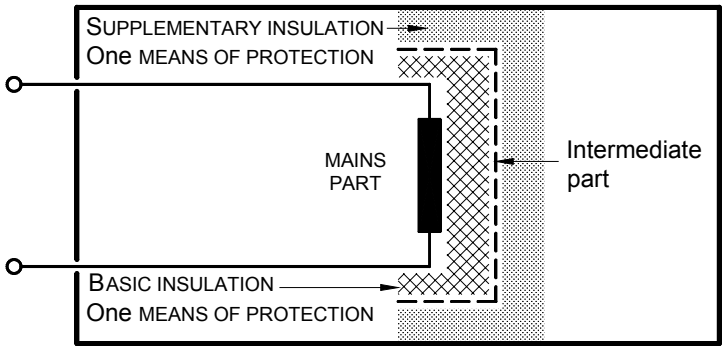

Figure M3 – Insulation example #3

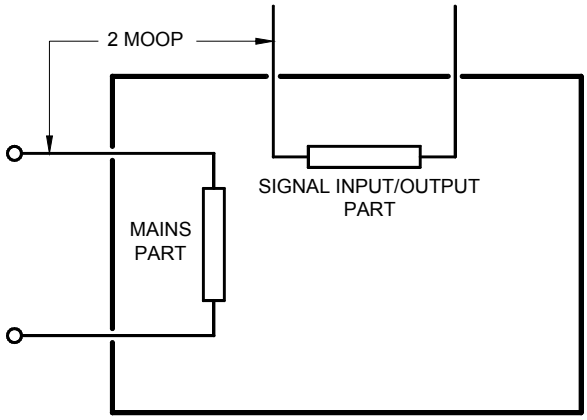

Figure M4 – Insulation example #4

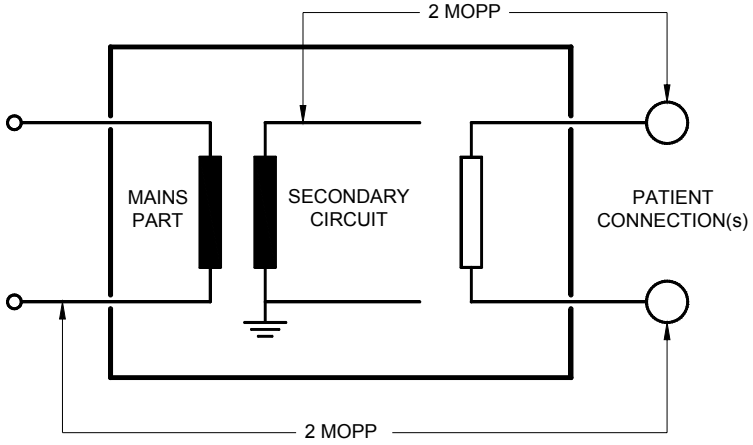

Figure M5 – Insulation example #5

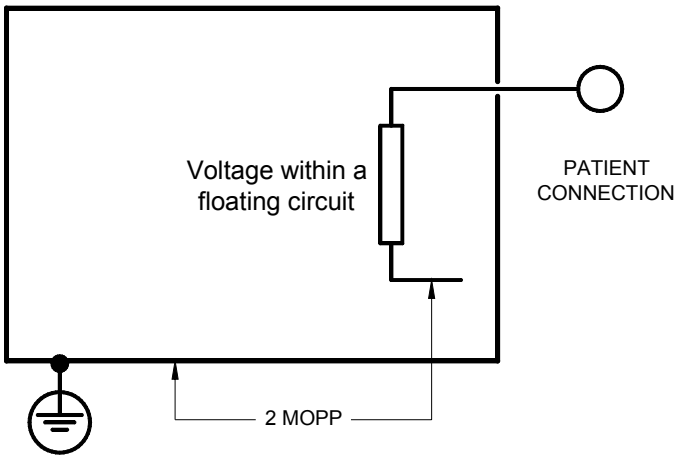

Figure M6 – Insulation example #6

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INDEX OF DEFINED TERMS

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INDEX OF ABBREVIATIONS AND ACRONYMS

Abbreviation	Term
a.c.	Alternating current
CO_2	Carbon dioxide
CASE	Computer aided software engineering
d.c.	Direct current
DICOM	Digital imaging and communication in medicine
FDDI	Fibre distributed data interface
HL7	Hospital level 7
IP	Internet protocol
IT	Information technology
LDAP	Light weight directory access protocol
LED	Light emitting diode
MAR	Mean Angle Resolvable
MD	Measuring device, see 8.7.4.4
ME	MEDICAL ELECTRICAL, see 3.63 and 3.64
MOOP	MEANS OF OPERATOR PROTECTION, see 3.60
MOP	MEANS OF PROTECTION, see 3.58
MOPP	MEANS OF PATIENT PROTECTION, see 3.59
MSO	MULTIPLE SOCKET-OUTLET, see 3.67
NOX	Nitrogen oxide
OTS	Off the shelf
PEMS	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEM, see 3.92
PESS	PROGRAMMABLE ELECTRONIC SUBSYSTEM, see 3.93
PTC	Positive Temperature Coefficient device
PVC	Poly-Vinyl-Chloride
r.m.s.	Root mean square
SELV	Safety extra-low voltage
SI	System international
TCP	Transport connection protocol
TENS	Transcutaneous electronic nerve stimulator
UPS	Uninterruptible power supply

EDITING NOTES FOR THE SECOND COMMITTEE DRAFT

[1] SEC: FIRST COMMITTEE DRAFT FOR VOTE

Version 34

2002-03-13

Version	Date	Working Group	Description
0	2000-11-20	Secretary	Second CD with revisions, drafting notes, and boxed notes deleted and all changes accepted.
1	2001-04-17	Secretary	Initial pass at resolving editorial comments. Comment 40, 120, 140, 180, 220, 230, 240, 250, 260, 270, 280, 290, 310, 350, 400, 410, 430, 440, 450, 500, 510, 520, 540, 660, 670, 710, 720, 730, 740, 750, 810, 820, 900, 950, 1040, 1050, 1960, 1070, 1080, 1450, 1570, 1580, 1590, 1600, 1750, 1780, 1800, 1810, 1870, 1930, 1980, 1990, 2010, 2030, 2410, 2420, 2450, 2640, 2750, 2800, 2860, 2910, 2920, 3010,3040, 3100, 3250, 3260, 3270, 3410, 3480, 3540, 3700, 3720, 3730, 3780, 3810, 3820, 3830, 4210, 4260, 4370, 4380, 4490, 4500, 4530, 4660, 4680, 4820, 4830, 5030, 5110, 5190, 5210, 5490, 5580, 6030, 6040, 6180, 6200, 6230, 6240, 6390, 6470, 6610, 6680, 6690, 6790, 6820, 6900, 6950, 7060, 7120, 7330, 7350, 7910, 7950, 8410, 8520, 8560, 8570, 8580, 8590, 8980, 8990, 9740, 9750, 9760, 9790, 9820, 9830, 9840, 9860, 9870, 9900, 9910, 9920, 9930, 9940, 10260, 10350, 10760, 10860, 10870, 10880, 10910, 10970, 10980, 10990, 11000, 11030, 11090, 11170, 11180, 11200, 11280, 11290, 11300, 11360, 11370, 11440, 11480, 11500, 11620, 11630, 11660, 11690, 11720, 11820, 11910, 11920, 11960, 11970, 12010, 12040, 12050, 12060, 12070, 12260, 12300, 12350, 12410, 12420, 12490, 12510, 12530, 12540, 12550, 12560, 12770, 12650, 12670, 12840, 12860, 12990, 13000, 13010, 13020, 13030, 13060, 13070, 13080,13110, 13410, 13460, 13470, 13480, 13490, 13500, 13520, 13540, 13570, 13680, 13690, 13700, 13720, 13760, 13770, 14010, 14030, 14080, 14090, 14120, 14130, 14280, 14310, 14450, 14490, 14510, 15600, 14640, 14660, 14680, 14690, 14700, 14710, 14730, 14740, 14940, 14990, 15010, 15020, 15060, 15070,15130, 15220, 15340, 15380, 15420, 15430, 15590, 15660, 15670, 15710, 15730, 15800,16320, 16360, 16470, 16590, 16600, 16610, 16630, 16640, 16670, 16750, 16780, 16880, 16890, 16900, 17020, 17090, 17110, 17130, 17140, 17150, 17310, 17320, 17330, 17400, 17440, 17450, 17610, 17630, 17640, 17650, 17660, 17670, 17780, 17790, 17800, 17810, 17820, 17900, 17910, 17920, 17930, 17940, 17950, 17970, 17980, 18230, 18280, 18330, 18350, 18420,18450, 18460,18580, 18600, 18690, 18700, 18850, 18860, 18880, 18900, 18990, 19000, 19030, 19050, 19080, 19100, 19120, 19140, 19150, 19160, 19270, 19280, 19290, 19320, 19370, 19390, 19400, 19420, 19460, 19480, 19620, 19640, 19650,

1	2001-04-17	Secretary	19660, 19700, 19710, 19750, 19780, 19790, 19810, 19860, 19870, 19880, 19900, 19910, 19930, 19980, 19990, 20000, 20030, 20040, 20050, 20060, 20070, 20080, 20100, 20110, 20120, 20130, 20140, 20150, 20180, 20250, 20260, 20270, 20280, 20290, 20340, 20350, 20370, 20380, 20490, 20630, 20680, 20690, 20700,20760, 20770, 20790, 20810, 20820, 20830, 20840, 20880, 20910, 20850, 20960, 20970, 21000, 21010, 21030, 21050, 21060, 21070,21170, 21190, 21200,21220, 21230, 21360, 21380, 21390, 21460, 21470,21500, 21570, 21580, 21590, 21600, 21610, 21640, 21650, 21660, 21670, 21680, 21690, 21700, 21710, 21730, 21740, 21750
2	2001-05-03	Secretary	Implement comments 2820, 5420, 6210, 9080, 11230, 13560, 14820, 16470
3	2001-05-04	CAG	Implement comments 300, 320, 360, 380, 420, 750, 1970, 2320, 2330, 2560, 2980, 2950, 2960, 2970, 3430, 12810, 12820, 15545
4	2001-05-19	WG 22	Implement comments 2830, 2840, 3710, 5995, 6370, 6380, 14910, 14950, 14960, 14970, 15980, 15000, 15030, 15040, 15050, 15080, 15090, 15110, 15120, 15170, 15180, 15240, 15270, 15280, 15290 (part), 15310, 15320, 15330, 15350, 15360, 15380, 15410, 15440, 15450, 15460
5	2001-05-24	WG 15	Implement comments 1660, 3020, 3210, 3230, 3790, 3860, 3870, 3890, 3900, 3940, 3950, 3960, 3970, 3980, 3990, 4000, 4030, 4040, 4060, 4080, 4090, 4110, 4140, 4160, 6270, 6280, 14170, 14180, 19340
6	2001-06-01	WG 14	Implement comments 4180, part of 4200, 4220, 4240, 4350, 4360, 4440, 4450, 4460, 4510, 4550, 4560, 4570, 8150
7	2001-06-11	SEC	Implement comments 4330, 8070, 14605 and Issue Sheet 0209
8	2001-08-06	62B/C	Implement comments 12660, 12690, 12700, 12710, 12720, 12770, 12780, 12790, 14160, 14162
9	2001-08-20	WG 17	Implement comments 1530, 2190, 2470, 3030, 3050, 3070, 3080, 3550, 5370, 10480, 10530, 10550, 10580, 10590, 10610, 10620, 10630, 10650, 10660, 10665, 10670, 10680, 10690, 10700, 10705, 10710, 10730, 10750, 10770, 10780, 10810, 10820, 10950, 10960, 11032, 11035, 11060, 11070, 11080, 11100, 11150, 11160, 11190, 11210, 11220, 11240, 11250, 11260, 11310, 11360, 11450, 11460, 11470, 11510, 11520, 11530, 11540, 11550, 11590, 11610, 11620, 11680, 11700, 11740, 11750, 11879, 11880, 11890, 11930, 11940, 11950, 12155, 15625, 16200
10	2001-09-19	WG 14	Implement comments 8150, 8220, 8280, 8300, 13320, 14590, 21040
11	2001-10-10	WG 15	Implement 14240, 14260, 14490, 14510, 16010, 19070, 19340, 19360, 19380, 19390, 19400, 19410, 19420, 19430, 19440, 19450, 19460, 19470, 19520, 19530, 19560, 19570, 19580, 19590, 19600, 19610, 19710, 19730, 20400

12	2001-10-31	WG 22	Implement comments 2830, 3710, 15140, 15150, 15160, 15190, 15200, 15210, 15220, 15260, 15390, 15400, 15420, 15460,15500, 15510, 15530, 15540, 15475, 15500, 15510, 15540, 20390, 20420, 20430, 20440, 20450, 20480, 20490, 20500, 20510, 20520, 20595, 20600, 20620, 21410, 21420, 21430, 21450, 21460, 21470, 21480, 21490
13	2001-11-02	WG 5	Implement comments 780, 990, 1000, 2720, 3120, 3140, 4750, 4760, 4770, 4790, 4800, 4810, 4890, 4900, 4910,, 4920, 4990, 5050, 5070, 5080, 5090, 5100, 5120, 5130, 5150, 5160, 5350, 5360, 5400, 5410, 5520, 5650, 5710, 5720, 5730, 5740, 5760, 5780, 5790, 5800, 5830, 5900, 5970, 5980, 5990, 6050, 6070, 6100, 6170, 6290, 6300, 6310, 6320, 6330, 6340, 6350, 6360, 16170.
14	2001-11-13	SEC	Secretary implement comments 1740, 8890, 21250, 21260
15	2001-12-20	WG 18	Implement comments 1480, 1850, 1910, 1940, 1950, 2580, 3160, 4440, 5290, 6130, 6140, 12870, 12880, 12900, 12930, 12940, 12960, 12970, 13120, 13140, 13150, 13160, 13170, 13190, 13200, 13210, 13240, 13250, 13260, 13270, 13280, 13290, 13300, 13310, 13360, 13380, 13400, 13510, 13530, 13415, 13465, 13580, 13590, 13600, 13610, 13630, 13640, 13710, 13730, 13890, 13900, 13950, 13970, 13980, 13990, 14000, 14020, 14040, 14050, 14300, 14330, 14340, 14360, 14370, 14380, 14390, 14470, 14610, 14650, 14670, 14720, 14790, 14810, 14830, 14860, 14880, 16030, 16060, 16080, 16100, 16110, 16120, 16130, 16140, 16150, 16180, 16270, 16280, 16300, 16310, 16370, 16400, 16460, 16500, 16510, 16520, 16530, 16540, 16545, 20670, 21280, 21290, 21320, 21330, 21340, 21370
16	2002-01-04	WG 20	Implement comments 1300, 1330, 1340, 1680, 1690, 2020, 2220, 2230, 2250, 2990, 5390, 6360, 17520, 17530, 17550, 17570, 17580, 17590, 17620, 17700, 17730, 17740, 17750,17570, 17580, 17590, 17620, 17700, 17730, 17740, 17750, 17760, 17770, 17830, 17850, 17860, 17870, 17880, 18010, 18020, 18030, 18050, 18140, 18150, 18160, 18170, 18180, 18190, 18240, 18250, 18260, 18290, 18310, 18320, 18370, 18430, 18440, 18450, 18460, 18500, 18510, 18520, 18340, 18550, 18560, 18570, 18590, 18620, 18660, 18680, 18710, 18740, 18760, 18790, 18830, 18840, 18910, 18930, 18960, 19010, 19020, 19250, 20740, 20770, 20850, 20860, 20870, 20940
17	2002-01-07	SEC	Resolve IS0222, IS0233, IS0238, IS0239 and IS0240; implement comments 8310, 1040, 1050, 1060, 1070, 1080, 17420, 17460, 17470

18	2001-01-16	WG 16	Implement comments 830, 890, 940, 970, 1090, 1100, 1120, 1130, 1140, 1170, 1180, 1220, 1240, 1270, 1350, 1380, 1420, 1540, 1830, 1900, 2040,2090, 2110, 2160, 2660, 2680, 2760, 2790, 3320, 3570, 3600, 3620, 3630, 3660, 2680, 4670, 4710, 5140, 5180, 5200, 5220, 5230, 5260, 5270, 5280, 5300, 5380, 5430, 5450, 5460, 5470, 5700, 6090, 6400, 6440, 6460, 5610, 6530, 6540, 6560, 6060, 6700, 6740, 6770, 6830, 6840, 6850, 6870, 6910, 6920, 6960, 6970, 6980, 6990, 7000, 7020, 7080, 7100, 7110, 7140, 7150, 7170, 7180, 7190, 7230, 7250, 7260, 7270, 7280, 7290, 7300, 7310, 7320, 7340, 7360, 7370, 7380, 7390, 7400, 7410, 7420, 7430, 7440, 7450, 7460, 7470, 7480, 7490, 7500, 7510, 7520, 7530, 7540, 7580, 7590, 7610, 7620, 7740, 7760, 7770, 7780, 7790, 7875, 7890, 7900, 7910, 7930, 7950, 7990, 8020, 8040, 8330, 8350, 8360, 8370, 8380, 8420, 8450, 8460, 8470, 8480, 8500, 8530, 8540, 8550, 8600, 8610, 8620, 8630, 8640, 8650, 8670, 8680, 8700, 8710, 8720, 8730, 8750, 8760, 8770, 8780, 8790, 8810, 8820, 8830, 8840, 8850, 8880, 8910, 8920, 8940, 8950, 8960, 8970, 9010, 9020, 9030, 9040, 9050, 9060, 9090, 9100, 9120, 9130, 9140, 9150, 9160, 9170, 9180, 9190, 9210, 9220, 9240, 9250, 9260, 9270, 9280, 9300, 9310, 9320, 9330, 9340, 9390, 9400, 9440, 9490, 9520, 9540, 9550, 9580, 9670, 9680, 9690, 9700, 9710, 9730, 9770, 9780, 9840, 9990, 10000, 10060, 10070, 10080, 10090, 10110, 10120, 10140, 10150, 10160, 10170, 10180, 10190, 10220, 10230, 10250, 10270, 10380, 10390, 10410, 10420, 10440, 10460, 19820, 19830, 19850, 19920, 19940, 19960, 19970, 20020, 20160, 20170, 20190, 20200
19	2002-1-18	WG 17	Implement comments 1605, 1610, 1640, 3050, 3340, 3350, 3360, 3510, 3520, 3530, 12020, 12030, 12090, 12100, 12120, 12160, 12170, 12180, 12200, 12210, 12230, 12300, 12310, 12370, 12380, 12390, 12400, 12460, 12470, 12500, 12510, 12520, 12580, 15560, 15830, 15870, 15900, 15910, 16190, 16200, 16210, 16240, 16260 and three batches of corrections from WG 16.
20	2002-01-23	WG 11	Implement comments 590, 600, 630, 670, 770, 800, 840, 860, 870, 910, 920, 930, 960, 980, 1020, 1260, 1360, 1370, 1470, 1510, 1650, 1820, 1835, 1865, 1885, 2400, 2460, 2500, 2510, 2520, 2550, 2690, 2730, 2770, 2780, 2880, 3110, 3150, 3190, 3310, 3370, 3380, 3490, 14140, 16570, 16660, 16680, 16700, 16720, 16730, 16770, 16780, 16800, 16810, 16850, 16860, 16870, 16910, 17010, 17030, 17120, 17170, 17190, 17230, 17240, 17250, 17260, 17270, 17280, 17330, 17380, 17390, 19670, 19690, 21510, 21520, 21530, 21540, 21550, and comment 16570.
21	2002-01-23	WG 13	Implement comments 5910, 19200, 19201, 20730
22	2002-01-24	SEC	Implement “ME EQUIPMENT” and “ME SYSTEM” changes, convert to new structure, implement comments 14045, 14142, 14144, 14146, 14148, 14164, 15555, 20330, 20640, 21630.
23	2002-01-25	SEC	Remove revision marking, add new Annex J, minor editorial corrections. Print for CAG

23	2002-01-28	CAG	Added new rationale for subclause 8.6.9, corrected note on Tables 7 and 8, replacement of text in lines 5809-5811 of Version 23 with text provided by R. Mellish.
24	2002-02-01	WG 17	Implement comments 11710, 11760, 11770, 11810, 11990, 12020, 12030, 12090, 12120, 12150, 12160, 12179, 12220, 12230, 12330, 12340, 12360, 12480, 15620, 15630, 15740, 15750, 15790, 20230, 20240, 20320.
25	2002-02-01	SEC	Second cut for the CAG
26	2002-02-02	WG 17	Revise former Clause 22 on instability
27	2002-02-09	SEC	Review and update normative reference and bibliography. Implement Edit Team 1 changes.
28	2002-02-10	SEC	Implement Edit Team 4 changes, changes from ad hoc group on RISK MANAGEMENT, new rationale for scope, and introduction to CDV.
29	2002-02-12	SEC	Implement Edit Team 3 changes and question resolutions from Edit Team 1.
30	2002-02-14	SEC	Implement Edit Team 2 changes
31	2002-02-27	SEC	Add new informative annex from WG 16 and miscellaneous corrections.
32	2002-03-01	SEC	Add WG 16 material on PATIENT CONNECTION and new rationale. Other minor editorial corrections. Version for final CAG review
33	2002-03-13	SEC	Final edits including change to the threshold test in 15.3.1.4.
34	2002-03-13	SEC	Freeze for 1CDV

[2] WG 11: The definition of AUXILIARY MAINS SOCKET-OUTLET has been merged with MULTIPLE PORTABLE SOCKET-OUTLET to create a new term "MULTIPLE SOCKET-OUTLET." See comment 910.

[3] WG 18: The definitions for CATEGORY AP and CATEGORY APG EQUIPMENT were restored as part of the response to UK comment 21280 requesting that Annex F in 2CD be made normative instead of informative. "Equipment" deleted as part of CAG editing process. See also "Category APG".

[4] WG 16: The definition of CONDUCTIVE CONNECTION was deleted and the term is no longer used as a defined term.

[5] WG 18: The definition of "DUTY CYCLE" was modified in response to comment 5290.

[6] WG 11: The definition of EMERGENCY TROLLEY was deleted in conjunction with comment 1360.

[7] CAG: The definition of ENCLOSURE was modified in partial response to comment 2300.

[8] WG 16: The condition referred to in Table IV of the 2nd edition as "MAINS VOLTAGE on APPLIED PART", and treated in that edition as a SINGLE FAULT CONDITIUON, is treated in this edition as a special test condition.

[9] WG 18: The definition of FIRE-PROOF ENCLOSURE was deleted in response to Japan comment 1480.

[10] WG 17: The definition of FIXED GUARD was deleted in response to comment 1530.

[11] WG 16: The definition of FIXED MAINS SOCKET OUTLET is used only in the definition of MAINS PLUG. The definition was folded into the definition for MAINS PLUG. See comment 1540.

[12] WG 18: The definitions for FLAMMABLE ANAESTHETIC MIXTURE WITH AIR and FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE were restored as part of the response to UK comment 21280 requesting that Annex F be made normative instead of informative.

[13] WG 15: The definition was extended to include animals in response to comment 1660.

[14] WG 18: WG 18, who was the last to use the term, deleted the definition of LIVE. See comment 1850.

[15] CAG: The term "labeling" was replaced by "marking or ACCOMPANYING DOCUMENTS" in response to comment 1970.

[16] WG 16: The new term "MAXIMUM MAINS VOLTAGE" replaces "REFERENCE SUPPLY VOLTAGE" from 2CD. The meaning is the same.

[17] WG 17: Definition revised in response to comments 2190, 2200, and 2210.

[18] WG 20: The definitions was changed from, "Any material, component or ACCESSORY that is in contact with a PATIENT and is intended for one time use on the PATIENT." to the present text in response to comments 2220, 2230 and 2250.

[19] CAG: The paragraph, "Medical electrical equipment may have more than one enclosure. All connections between such separate enclosures are considered as parts of the medical electrical equipment and subject to the requirements of this standard." was deleted in response to comment 2300 from Japan.

[20] WG 17: The definition of MOVABLE GUARD was deleted in response to comment 2470.

[21] WG 22: This new definition was added as part of the response to comment 15460 as the tem NETWORK/DATA COUPLING is used in two normative subclauses as well as in the rationale.

[22] SEC: User was added as a synonym for OPERATOR in response to comment 2560.

[23] SEC: The majority of NCs responding to box note 3 preferred the definition as it appeared in 1CD without "accordance with the instructions for use."

[24] WG 16: The defined term "PATIENT CIRCUIT" is no longer used.

[25] SEC: This definition was moved to the correct order in response to comment 3680.

[26] CAG: The new definition was added in response to comments 2890 and 2895.

[27] WG 16: The term "REFERENCE SUPPLY VOLTAGE" was changed to "MAXIMUM MAINS VOLTAGE' with the same meaning.

[28] WG 17: The definition was modified in response to comment 3070, which suggested the definition, was not specific enough.

[29] WG 18: "SHORT-TIME OPERATION" was deleted because it was not used. See comment 3160.

[30] WG 15: "Means of protection" was changes to "means for reducing the RISK resulting from…" and the word "external" in "single external abnormal condition" was deleted in response to comment 3210.

[31] WG 15: This definition was modified in response to comment 3230.

[32] WG 17: The term was change from SAFETY FACTOR to TENSILE SAFETY FACTOR in response to comment 3080, which requested to make clear that this term applies only to mechanical aspects.

[33] CAG: This note was added in response to comment 3430.

[34] WG 15: The bullet "The HAZARDS listed in 45.1 shall be considered" was deleted in response to comment 3860. The second sentence in the following bullet, "The SINGLE FAULT CONDITIONS listed in 42.5 are the subject of specific requirements and tests." was also deleted using the same logic.[35] WG 22: The phrase "considered acceptable" was replaced with "presumed to be acceptable unless there is OBJECTIVE EVIDENCE to the contrary" based on U.S. comment 3900.

[36] WG 15: This requirement was modified in response to U.K. comment 4000 and the NC response to box note 7 in 2CD.

[37] WG 15: This clarifying requirement was added at the request of WG 16 to avoid having to insert a redundant statement about parts identified in this subclause in many other places in the document.

[38] WG 15: This compliance requirement was added in response to comment 14170.

[39] WG 14: This subclause was extensively revised in response to comment 4350 ad 4360.

[40] WG 14: Wiring was added at the suggestion of WG 16 because the NCs agreed to the proposal in Box Note 14 to remove the separate test for wiring. Subsequently WG 16 amended 17.1 to be valid also for wiring and asked WG 14 to make a similar change to this subclause.

[41] WG 18: The sentence, *"The tests of this standard for motors and transformers are considered to be comprehensive and no other tests are required."* was modified in response to comment 4440.

[42] CAG: This reference to Clause 16 for ME SYSTEM components was added by the CAG editing team as part of the general review of the application of systems requirements in the standard,

[43] WG 14: The requirement was modified in response to comment 4180 because not all MEDICAL ELECTRICAL EQUIPMENT is intended to be mains powered.

[44] WG 14: This requirement was added in response to comment 4220.

[45] WG 14: In response to UK comment 4460, the test condition, "*For reference tests (if the results are dependent on the ambient condition), one set of atmospheric conditions specified in Table 1 is recognized.*" was deleted. The following are the contents of Table 1 in 2CD.

Temperature	Relative humidity	Atmospheric pressure
23 °C ± 2 °C	50 % ± 15 %	860 hPa to 1 060 hPa (86 kPa to 106 kPa) (645 mm Hg to 795 mm Hg)

[46] WG 14: This additional wording was added in response to comment 4240. As an editorial change, the Secretary substituted “lease favourable” for the term “worst”, which means “least advantageous or desirable.” This was done for consistency with other parts of the subclause.

[47] WG 14: Requirement 5.6 *h)* of 2CD was deleted in response to comment 4510. The requirement read, "*Measurement of voltages and currents shall be carried out with instruments adequate for the values to be measured."* This was requirement 4.7 *h)* in the 2nd Edition.

[48] WG 14: In response to comment 4550 and 4560, WG 14 deleted "*not being IPX7 or IPX8 (see IEC 60529)*" from this test condition.

[49] WG 14: This requirement was added in response to 4570.

[50] CAG: In comment 470, France reminds us that only documents which are available to the public may be referenced in the normative reference section of an IEC standard (see ISO/IEC Directives, Part 2, subclause 6.2.2). This is understood to mean that an FDIS can be referenced but not earlier stage documents. Therefore, the references to IEC 60601-1-6 and IEC 60601-1-8 have been removed from the normative section to the bibliography and the requirement replaced with a more general reference to the RISK MANAGEMENT PROCESS. A note informing the reader that a collateral standard on the subject has also been added wherever one of these references is found.

[51] WG 5: After the revision of 7.1.2 as a result of various NC comments, the resulting material seemed more appropriate as a major subclause of 7 rather than a part of 7.1. The material was moved to 7.5.

[52] WG 5: “Relevant end-user packaging” was added in response to comment 5050.

[53] WG 5: This specification was changed from “separable part” to “detachable component” to use terminology consistent with the EU Medical Devices Directive.

[54] WG 5: The exclusion that allows marking in the ACCOMPANYING DOCUMNETATION or on the end-user packaging is equally applicable to ACCESSORIES as it is to the equipment itself. This was added in response to comment 5090.

[55] WG 5: The requirement, “If applicable, safety signs for particular HAZARDS, as adopted in ISO 3864, shall be used.” was deleted as unnecessary after the revision of 7.1.2.

[56] WG 17: This requirement was moved from 25.6 of 2CD in response to comment 5370 because it is a pure marking requirement.

[57] CAG: The requirement, “A terminal for the connection of a POTENTIAL EQUALIZATION CONDUCTOR shall be marked with Symbol IEC 60417-5021 (see Table D1, Symbol 8). See also 8.6.7.” was deleted because the exact same requirement statement is in 8.6.7 along with other requirements for proper handling of POTENTIAL EQUALIZATION CONDUCTORS.

[58] WG 16: The requirement, “A PROTECTIVE EARTH TERMINAL shall be marked with Symbol IEC 60417-5019 (see Table C1, Symbol 6) unless the PROTECTIVE EARTH TERMINAL is in an APPLIANCE INLET according to IEC 60320-1.” Was deleted in response to comment 5380 because a PROTECTIVE EARTH TERMINAL will not be on the outside of MEE.

[59] SEC: Swedish comment 5420. The deletion of the words "requiring soldering" was agreed for 2CD but did not get implemented.

[60] WG 16: The words “For example…” do not form a complete sentence. It is not clear what the “reference” shall refer to. Change to “…by reference to information in the ACCOMPANYING DOCUMENTS.”

[61] WG 16: The subclauses that were 6.2 h) and k) in the 2nd edition have been combined into one, in response to comments 5440 and 5450 on the 2CD

[62] WG 20: The requirement to including markings for hazardous materials was added in response to comment 5390.

[63] SEC. These units for pressure of gasses were added in response to comment 5620.

[64] WG 5: Table 2 was deleted in response to comment 4750. Table 2 is reproduced here.

Table 2
Safety warning signs and caution symbols

Level	Safety sign or symbol	Meaning
Warning	ISO 3864, subclause 8.3[a)] (see Table C1, Symbol 29)	Warning: Designates a possible dangerous situation. Non-observance may lead to death or injuries.
Caution	Symbol ISO 7000-0434 (see Table C1, Symbol 10)	Caution: Designates a possibly harmful situation. Non-observance may lead to damage to the product or the ENVIRONMENT.

[a)] Safety signs may be found in ISO 3864. The appropriate symbol or text is placed centrally on the background. Where a symbol is not available to indicate a particular desired meaning, the meaning may be obtained preferably by using the general warning sign together with a text on a supplementary sign or alternatively by using a text in place of a symbol on the warning sign.

[65] WG 5: In response to comment 5740, “push-button” was replaced by “control”. The term “push-button” is too limited and should be made more general.

[66] WG 22: The new requirement for identification of PEMS was added in response to comment 5995.

[67] WG 5: The identification requirements where moved to the general requirements for ACCOMPANYING DOCUMENTS and revised per comment 5990.

[68] SEC: The term “HAZARD” was changed to “unacceptable RISK” as a result of a review of the use of the term HAZARD in response to comment 05. Many substances may pose a potential source of HARM, but only those that constitute an unacceptable RISK as demonstrated through biocompatibility testing in Clause 38 need to be documented.

[69] WG 20: This requirement was added in response to comment 1340.

[70] WG 5: The installation of some equipment may be so complex that only specially trained service personnel can safely perform the installation. In this case, it is not necessary or even prudent to require all the installation instructions be provided to the responsible organization. See comment 6070.

[71] WG 16: The new subclause was added in response to comment 6090.

[72] WG 5: The requirement to place environmental conditions on the labeling is a duplicate of that in 7.2.15. WG 5 deleted the requirement here and replaced it with a reference to the subclause where the requirement appears.

[73] SEC: This new dash was added in response to comment 10210. In addition, the reference in 18.1 *b)* was changed from ACCOMPANYING DOCUMENTS to “technical description.” When consider this last point, It should be remembered that the 2nd edition used the term ACCOMPANYING DOCUMENTS but directed the reader to the subclause on the technical description.

[74] CAG: This requirement was implied in 15.4.9, which check compliance by inspection of the technical description.

[75] WG 15: The requirement that the technical description include "A list of any deviations from the requirements of this Standard together with their justification (see 4.3)." was deleted in response to comments 6270, 6280 and box note 7.

[76] WG 5: This note was added in response to comment 6290 as some authorities set criteria for biomedical technicians who maintain and may repair equipment.

[77] SEC: The term "HAZARD" was changed to "unacceptable RISK" as a result of a review of the use of the term HAZARD in response to comment 05.

[78] WG 22: The paragraph was replaced in response to 6380.

[79] WG 15: In response to comment 5520, the marking requirement was deleted and in response to comment 5540, this requirement was added to the technical description.

[80] WG 20: This new subclause was added in response to comment 6360.

[81] WG 16: The requirement in 9.3 of 2CD on INTERNALLY POWERED ME EQUIPMENT was deleted because if INTERNALLY POWERED ME EQUIPMENT can also be connected to a SUPPLY MAINS it should generally be obvious which requirements apply and which do not. There is a general requirement for testing "under the least favourable working conditions."

[82] WG 16: The requirement in 11.4 b) of 2CD was moved to 8.11.1 i) in response to comment 6910.

[83] WG 16: Arising from the discussion of the comments on box note 11, WG 16 identified a need for additional explanation of how one determines whether a MEANS OF PROTECTION is a MEANS OF OPERATOR PROTECTION or a MEANS OF PATIENT PROTECTION. A reference to 4.4 is needed.

[84] WG 16: WG16 developed two different revised versions of this paragraph: one eliminating the term "CONDUCTIVE CONNECTION" in response to comment 1250, and one eliminating the phrase "remote from the PATIENT" in response to comment 7150. Unfortunately each version depended on retention of the other phrase. The purpose of the phrase "remote from the PATIENT" was to make clear that the requirement applies to a connector at one end of a lead having its other end connected to the PATIENT, and not to a connector that is disconnected from the PATIENT. The present wording is intended to preserve this meaning while avoiding both the phrases that were the subjects of adverse comments.

[85] WG 16. The requirement, "For insulation between two isolated parts or between an isolated part and an earthed part, the reference voltage (*U*) is equal to the arithmetic sum of the highest voltages between any two points within both parts." Was determined to be incorrect. It was deleted and similar wording was inserted in Annex A. See comment 7260.

[86] WG 16: The requirement, "For insulation providing protection against unintended external voltages, the reference voltage (*U*) is equal to the REFERENCE SUPPLY VOLTAGE." Was deleted as unnecessary. See comment 7270.

[87] WG 16: The test condition, "*the MEDICAL ELECTRICAL EQUIPMENT shall not be energized*" was deleted in response to comment 7300 because how can you check for recovery if the equipment is de-energized.

[88] CAG: This paragraph was revised to overcome the editorial and technical problems identified in the editing stage, particularly that even the first test at 25 A would be impossible if the PROTECTIVE EARTH CONNECTION had a high impedance. The intent of the test has been retained.

[89] WG 16: The requirement, "The measured values shall not exceed the allowable values given in 14.3." was deleted as redundant in response to comment 7760. Paragraphs c) to g) were moved to other parts of this clause.

[90] WG 16: Changes introduced in response to comment 8360, but low frequency limit chosen as 0,1 Hz, rather than 3 Hz as proposed in the comment, because the rationale refers to 0,1 Hz as the lowest frequency to which the a.c. limits apply.

[91] WG 16. This paragraph was moved from 14.1 *d)* of 2CD and edited per comment 7780.

[92] WG 16: This paragraph was moved from 14.1 *c)* of 2CD and edited per comment 7770.

[93] WG 16: The informative statement, "*To achieve this, it may be pressed against the insulating material with a pressure of approximately 0,5 N/cm^2."* Was deleted and the content moved to the rationale. See comment 8420.

[94] WG 16: Comment 8450 is accepted in principle. The larger foil will be specified where the area likely to be contacted is larger than the area of the foil generally used, i.e. 20 x 10 cm.

[95] WG 16. This paragraph was moved from 14.1 *e)* of 2CD and edited per comment 7790.

[96] WG 16. This paragraph was moved from 14.1 *f)* of 2CD and edited per comment 7800.

[97] WG 16: This text was moved from 14.1 *g)* of 2CD.

[98] WG 16: The test requirement, "*In this case the value of the test voltage shall be determined from Table 4 or Table 5 using a reference voltage* (U) *equal to the measured peak-to-peak voltage divided by* $2\sqrt{2}$." Was deleted as being superfluous. See comment 8540.

[99] WG 16: Subclause 15.3, Insulation of conductors in the MAINS PART, was deleted in response to Box Note comment 32210. See also comment 8910.

[100] WG 16: The requirement, "Parts of natural or synthetic rubber used as SUPPLEMENTARY INSULATION in CLASS II EQUIPMENT shall be resistant to ageing and be so arranged and dimensioned that CREEPAGE DISTANCES are not reduced below the values specified in Clause 8.9 whatever cracks may occur." was deleted as being superfluous in response to comment 9020.

[101] WG 16: The reduction for slot insulation, "For slot insulation of motors a reduction to 50 % of the values of Table 7 through Table 10 for CREEPAGE DISTANCES shall be allowed, with a minimum of 2 mm at 250 V." was deleted in response to comment 9120.

[102] WG 16: This table and the next table have been re-drawn with the voltage axis vertical for consistency with the tables of dielectric strength test voltages and the other tables of CREEPAGE DISTANCES and AIR CLEARANCES. The following is the table as it existed before the reformatting:

Reference voltage d.c.	**15**	**36**	**75**	**150**	**300**	**450**	**600**	**800**	**900**	**1 200**	
Reference voltage a.c.	**12**	**30**	**60**	**125**	**250**	**400**	**500**	**660**	**750**	**1 000**	
Spacings between parts of opposite polarity of MAINS PART	0,4	0.5	0,7	1	1,6	2.4	3	4	4.5	6	AIR CLEARANCES
	0,8	1	1,3	2	3	4	5,5	7	8	11	CREEPAGE DISTANCES

[103] WG 16: The following is the table as it existed before the reformatting (See the note to the previous table):

Reference voltage – d.c.	**15**	**36**	**75**	**150**	**300**	**450**	**600**	**800**	**900**	**1 200**	
Reference voltage – a.c.	**12**	**30**	**60**	**125**	**250**	**400**	**500**	**660**	**750**	**1 000**	
Spacings providing one MEANS OF PROTECTION	0,8	1	1,2	1,6	2,5	3,5	4,5	6	6,5	9	AIR CLEARANCES
	1,7	2	2,3	3	4	6	8	10,5	12	16	CREEPAGE DISTANCES
Spacings providing two MEANS OF PROTECTION	1,6	2	2,4	3,2	5	7	9	12	13	18	AIR CLEARANCES
	3,4	4	4,6	6	8	12	16	21	24	32	CREEPAGE DISTANCES

[104] WG 16: The following notes were deleted from the table:

NOTE 1 Values for two means of protection are obtained by doubling the values in the table.

NOTE 2 The Material Groups refer to values obtained in accordance with IEC 60112, as follows

Material Group I	600 ≤ CTI
Material Group II	400 ≤ CTI < 600
Material Group IIIa	175 ≤ CTI < 400
Material Group IIIb	100 ≤ CTI < 175

NOTE 3 If the material group is not known, group IIIb should be assumed.

[a)] Linear interpolation is permitted between the nearest two points, the calculated spacing being rounded to the next higher 0,1 mm increment.

[105] WG 16: The sentence, “Operation of a protective device shall not be considered as a HAZARD.” was deleted in response to comment 9670.

[106] WG 16: The paragraph, “The AIR CLEARANCES requirements shall not apply to the air gap between the switching contacts of THERMOSTATS, THERMAL CUT-OUTS, OVER-CURRENT RELEASES, switches of microgap construction and the like, or to the air gap between the current-carrying parts of such devices where the clearance varies with the movement of the contacts and where adequacy of ratings has been proved.” was deleted in response to comment 9680.

[107] WG 16: The paragraph, “When assessing CREEPAGE DISTANCES and AIR CLEARANCES, the effect of insulating linings of metal ENCLOSURES or ACCESS COVERS shall be taken into consideration.” was deleted as superfluous in response to comment 9690.

[108] WG 16: The following legends were deleted and the text, with edits, moved to 8.9.4.

[109] CAG: In response to comment 9980, the CAG decided to combine the material on reliability of components in Clause 4. Therefore, the requirements for rating of components (17.1 of 2CD) and reliability of components (17.2 of 2CD) are covered already in Clause 4. This text is duplicative and was deleted.

[110] WG 16: In response to comment 4360, WG14 has decided to delete lines 1158-1159. For consistency, lines 3053-3054 will be deleted. Deleted text form 2CD read, “17.2 *b)* the requirements and tests of this Standard and, where necessary for the application, any additional applicable safety requirements of the relevant IEC component standard.”

[111] WG 16: In response to comment 4350, WG14 has decided to delete the first sentence in lines 1169-1170. For consistency, the same words in lines 3056-3057 will be deleted. Deleted text read, “Components approved by a recognized testing authority, for compliance with applicable safety requirements, need not be retested.”

[112] WG 16: This requirement has been extended to apply to hand-held parts other than control devices following email discussion within WG16, which was prompted by an enquiry to the Secretary about the applicability of the corresponding requirement in the second edition.

[113] WG 16: The requirement, “For fixing of wiring in the APPLIED PART and the MAINS PART, see 17.4.” was deleted as redundant in response to comment 10140.

[114] WG 16: The compliance paragraph for *b)* was removed in response to comment 10160.

[115] WG 16: The examples from this paragraph were moved to the rationale in response to 6910.

[116] WG 11: This requirement was moved to 16.9.2.1 *a)*.

[117] WG 11: The requirement, “This requirement does not apply to EMERGENCY TROLLEYS, on which however the number of such sockets shall be limited to 4.” was moved to Section10 of 1CD and the deleted by WG 11 for reasons given in the rationale. See comment 1360 and 10320, 10330 and 10340.

[118] WG 17: This paragraph was revised in response to comment 10480.

[119] WG 17: The phrase " as long as this continuous activation allows the OPERATOR to have adequate control of positioning without endangering the PATIENT or the OPERATOR" was added here and in 20.3.1.a) in response to comment 10665.

[120] WG 17: This paragraph was replaced by text provided in comment 10770 as amended by comment 10780.

[121] WG 17: Paragraph c) in 2CD was deleted in response to comment 10810.

[122] CAG: This requirement was editorial moved from the last bullet in this list.

[123] WG 17: The requirement that all doors and drawers be closed was replaced by "as specified in NORMAL USE" in response to comment 11250.

[124] WG 17: A new paragraph was added to comment 11320 requesting that the test surface be specified.

[125] WG 17: The reference to "horizontal" in the title was removed by WG 17 in response to comment 11180. The exclusion for patient support surfaces and the accompanying note were added in response to comment 11190. The Secretary also removed the reference to "horizontal" in the body of the paragraph.

[126] WG 17: The first and second paragraphs of f) in 2CD were deleted in response to comment 11260. The remainder was deleted during the reordering of the subclause because it became redundant.

[127] WG 17: Paragraph c) in 2CD was deleted in response to comment 11360.

[128] WG 17: The requirement was change to make it clear that any movement is unacceptable. See comments 11450, 11460 and 11470.

[129] WG 17: The additional requirement was added in response to comment 11610.

[130] WG 17: The requirement was shortened to refer only to Clause 18 of IEC 60065: 2001, which allows testing according to either, that clause of IEC 61965. In keeping with the philosophy of qualification of components in 4.6, only parts that meet the applicable safety requirements of a relevant IEC standard are allowed. See comment 11710.

[131] WG 17: The missing compliance paragraph was added in response to comment 11700.

[132] WG 17: Subclause 25.6 was moved to 7.2.16 in response to comment 5370. A cross-reference was retained.

[133] WG 17: This paragraph was moved from 26.5 of 2CD.

[134] WG 17: The requirement, “Any moving part shall also comply with the requirements of Clause 20.” was deleted in response to comment 12030.

[135] WG 17: The clarification the TENSILE SAFETY FACTORS in the table are for the start of life of the ME EQUIPMENT and the minimum requirement at end of the useful life were added in response to comment 12150.

[136] WG 17: The third paragraph of 26.6 in 2CD was moved to this location.

[137] WG 17: The requirement, “require the use of a TOOL to be reset or replaced; and” was deleted during the revision of this paragraph.

[138] WG 17: This requirement was moved from 26.4.3 of 2CD.

[139] WG 17: This subclause was deleted in response to comment 12590. However, the text was distributed to other parts of the document, primarily to 9.8.1.

[140] SEC: This clause, which contained only informative material, was deleted in response to comment 12630 and 12640. The old text read, Requirements for protection of the PATIENTS, OPERATORS, other persons and sensitive devices in the vicinity from unwanted or excessive radiation emitted by the ME EQUIPMENT are found in this section and 44.5.”

[141] 62A/B: The exposure limit was change from 130 nC/kg to "an air kerna exceeding 4,7 µGy in 1 h averaged over any area of 10 cm^2 of which no linear dimension exceeds 5 cm at a distance of 5 cm" in response to comment 12690.

[142] 62A/B: This extra statement was added in response to comment 12660.

[143] SEC: This reference to the RISK MANAGEMENT PROCESS was inserted in place of the reference to “No general requirement” in response to the comment 14045 generalized to all such occurrences.

[144] 62B/C: The requirements for laser barriers and laser fibre optics were added in response to comment 12780.

[145] WG 18: The sentence, “The maximum temperature of a part is determined by measuring the temperature rise of the part and adding it to the difference between the ambient temperature at the time the measurements are made and the maximum allowed ambient temperature (as defined in 7.9.3.1).” was moved to the paragraph on test criteria. See comment 13310.

[146] WG 18: The table entry “Other thermoplastic insulation and materials supporting LIVE parts” was deleted in response to comment 12930.

[147] WG 18: This and the following new subclause were added in response to comment 13120.

[148] WG 18: The new heading was added in response to comment 13140.

[149] WG 18: Option 7 was deleted in response to comment 13730.

[150] SEC: This text, which was formally in 45.2.14 of 2CD, was moved by the Secretary to implement an agreement between the conveners of WG 18 and 15 to implement the realignment of subclause 45.2. See comment 14540.

[151] WG 15: WG 15 changed “an electrical component” to “a component” because other factors, such as mechanical friction, could raise the temperature of a material to its ignition temperature.

[152] WG 18: The paragraph was revised to eliminate the use of the term BASIC INSULATION and align with the terminology adopted by WG 16. The intent is that the requirement be equivalent to that in the 2nd Edition with one MOPP being equal to BASIC INSULATION and two MOPP being equal to DOUBLE INSULATION. See comment 14720.

[153] WG 18: This subclause was extensively revised based on the principle in IEC 61010 with the addition of risk management to selecting the elements. See comment 13400.

[154] WG 18: This subclause was added in consequence of accepting UK comment 21280 to make Annex F normative.

[155] WG 18: The compliance paragraph of this subclause was revised to align with other in the clause in response to comment 13980.

[156] WG 18: The minimum number of repetitions of the cleaning procedure was set to one in response to comment 14020. However, the manufacturer is still required to consider if multiple cleaning/disinfections of the product would have an impact on safety over the useful life of the equipment.

[157] CAG: See comments 470 and 14135.

[158] CAG: In comment 470, France reminds us that only documents which are available to the public may be referenced in the normative reference section of an IEC standard (see ISO/IEC Directives, Part 2, subclause 6.2.2). This is understood to mean that an FDIS can be referenced but not earlier stage documents. Therefore, the references to IEC 60601-1-6 and IEC 60601-1-8 have been removed from the normative section to the bibliography and the requirement replaced with a more general reference to the RISK MANAGEMENT PROCESS. A note informing the reader that a collateral standard on the subject has also been added wherever one of these references is found.

[159] WG 15: The title and requirement were replaced in response to comment 14180.

[160] WG 18: The ambient temperature of 25 C was eliminated and replaced with a reference to 11.1.3 in response to comment 14300.

[161] WG 18: The requirement was modified to name ‘other components and materials’ in response to comment 14340.

[162] WG 18: The requirement, “For MEDICAL ELECTRICAL EQUIPMENT with heaters: The walls, ceiling or floor of the test corner or supply cord exceed 175 ºC.” was deleted because the requirements in 2CD subclause 35.2 were modified. See comments 13260 and 14340.

[163] WG 18: The requirement, “Temperatures exceeding the maximum values shown in Table 16, during the tests of 45.2.17.1 *c*), 45.2.17.1 *d)* and 45.2.17.2 and 45.2.17.3. These temperatures apply for an ambient temperature of 25 °C.” in response to comment 14340.

[164] WG 18: This requirement was extensively revised in response to comment 14370.

[165] WG 18: The requirement and test relating to 13.2.14.2 to 13.2.14.4 were moved to a new General subclause under 13.2.14.

[166] WG 18: The text condition, “*For MEDICAL ELECTRICAL EQUIPMENT that is immersed in, or filled with, conducting liquid in NORMAL USE, the sample is immersed in or filled with the conducting liquid or water,*

as appropriate, for 24 h before the dielectric strength test is made" was moved to 5.4 e) in response to comment 14470.

[167] The particular requirement, "Starting, interrupting or locking of movements, particularly for MEDICAL ELECTRICAL EQUIPMENT (parts) supporting, lifting or moving masses (including PATIENTS) and suspension systems of masses in the vicinity of PATIENTS." was deleted and replaced by a complete reference for mechanical hazards. See comment 14530.

[168] WG 18: The paragraph, "MEDICAL ELECTRICAL EQUIPMENT shall be so designed that it remains SINGLE FAULT SAFE in NORMAL USE." was deleted in response to comment 14650.

[169] WG 15: The contents of subclause 45.2.15 of 2CD was moved to 4.5 in partial response 14540 to move requirements in 45.2 to more appropriate parts of the standard.

[170] WG 18: Paragraphs c) and d) were combined in response to comments 14790 and 14860, which observed they were very redundant.

[171] WG 18: This paragraph and the following test were moved from 45.2.17.2 d) 4) of 2CD in response to comments 14860. The Secretary edited the paragraph for readability.

[172] WG 22: This paragraph was replaced in response to comment 15050.

[173] WG 22: A new heading was added in response to comment 15030.

[174] WG 22: "Components of third-part origin and legacy systems" was added in response to the issue raised by the UK in comment 2830 about PENS that are created by adding a PESS in a non-medical piece of equipment where there is no possibility of applying all the procedures in this clause to that subsystem. An additional potential cause of a hazard due to these system elements was added to the note below as well as some rationale.

[175] WG 22: Examples were added in response to comment 15080.

[176] WG 22: Wording was modified in response to comment 15090.

[177] WG 22: This requirement was modified in response to comment 15160. The following requirement document tools and procedures in the requirements specification were deleted in response to comment 15180.

[178] WG 22: The requirement to document the " appropriate level of independence of the personnel performing the VERIFICATION" was added in response to comment 15270.

[179] WG 22: The introductory paragraph was moved to the rationale for this subclause in response to comment 15320.

[180] WG 22: The requirement was changed from "justify" the level on independence to "document the rationale" for the level of independence in response to comment 15360.

[181] WG 22: The following paragraph in 2CD, " All relevant documents in the DEVELOPMENT LIFE-CYCLE shall be revised, amended, reviewed and approved under a document control." was deleted when considering comment 15420 as it duplicates the requirement in 46.2 with the addition of "reviewed" to 46.2.

[182] WG 22: The title was changed in response to comment 15460.

[183] CAG: The heading for Clause 47 General and the information text that followed it were deleted in response to comment 15545. The following subclauses were renumbered.

[184] WG 17: A test for moulding stress was added from IEC 60950 in response to comment 15620 that asked that this section be aligned with IEC 60950.

[185] WG 17: The test, "*The rigidity of an ENCLOSURE or an ENCLOSURE part, and of any component thereon, is tested by application of an inward directed force of 45 N applied over an area of 625 mm^2 anywhere on the surface*" was replaced with a similar test from IEC 60950.

[186] WG 17: This paragraph was revised removing "appreciable" and adding "resulting in an unacceptable RISK, including" in response to comment 15625.

[187] CAG and WG 17: A problem with applying this test to some MOBILE ME EQUIPMENT was identified late in the editing process. There is no requirement for a minimum wheel size in this standard. That was removed between the 1st and 2nd Committee Drafts in response to a comment from France (62A/320/CC, Comment 951). However, the threshold requirement was retained. Both Japan and Sweden commented on the threshold test in the 2nd CD. Japan favoured deleting the test (comment 15850) and Sweden proposed adding a note that, "Equipment constructed so that it cannot pass the

threshold need only comply with a).” (Comment 15890). WG 17 accepted neither of the comments. However, a participant in the SC 62A Chairman Advisory Group (CAG) observed that there are a number of types of MOBILE ME EQUIPMENT (monitors, electrosurgery units, etc.) mounted on carts with wheels that may not pass this test. There is no OBJECTIVE EVIDENCE that these devices currently present an unacceptable RISK to PATIENTS, OPERATORS, or third parties from either shock damage to the equipment or tipping over when they encounter the obstruction. In any event, their stability when encountering an obstruction is tested in paragraph a). WG 17 discussed this issue by e-mail. It was decided to retain the test but limit it to MOBILE ME EQUIPMENT heavier than 45 kg. Lighter weight equipment presents less of a HAZARD. See also the rationale for 9.4 and 15.3.1.4.

[188] WG 18: The following test was deleted and replaced with the procedure in the standard in response to comment 16100.

“Single-operation THERMAL CUT-OUTS and OVER-CURRENT RELEASES shall be tested by verifying that ten samples operate within the rated parameters, if they are not approved to an appropriate IEC component standard.

All THERMAL CUT-OUTS or OVER-CURRENT RELEASES or equivalent circuits shall be made to operate a minimum of one time in application during SINGLE FAULT CONDITION testing.”

[189] WG 18: This paragraph and its test were added based on comment 16030.

[190] WG 17: Figure 36 of 2CD was deleted in response to comment 16240.

[191] WG 18: The IPX rating was change to at least IPX6 in response to comment 16270.

[192] WG 18: The example of “emergency rooms” and the requirement to evaluate the likelihood of liquids as part of risk management was added in response to comment 16280.

[193] SEC: This text was moved from 51.1 in 2CD in response to comment 16570.

[194] WG 18: The additional test condition for transformer insulation was added in response to comment 16370.

[195] SEC: US comment 16470. The text in this and the two preceding paragraphs should have been in the 2CD but were missed in the integration of the WG material.

[196] SEC: The remaining parts of Clause 51 in 2CD were moved forward to Clause 49 in response to comment 16570.

[197] WG 11: The introductory clause was deleted redundant. See comment 16620.

[198] SEC: The Secretary added a new heading to meet the drafting requirement, as hanging paragraphs are not allowed. See the ISO/IEC Directives, Part 2, 5.2.4.

[199] WG 20: The contents of 66.3.1.1 and 66.3.1.2 of 2CD were combined into a single subclause with edits and the old heading deleted.

[200] SEC: This and the following subheading were moved up one level to align with the other subclauses of this clause.

[201] WG 20: The contents of paragraph c) were move to other parts of the subclause or deleted as unnecessary. See comment 18260.

[202] CAG: This extra rational was added following the review of the WG 11 work to address a number of National Committee comments that requested that the elements of the standard “generalized” to address ME SYSTEMS issues.

[203] SEC: The wording was revised to align with the description in subclause 6.2 of ISO 14971 in response to comment 19070.

[204] WG 18: The new paragraph was moved from the rationale for Subclause 36.2 in the 2CD.

[205] WG 15: This rationale was moved from Clause 40, lines 7441 to 7462, of 2CD because it describes RISK CONTROL and is not particularly related to ESSENTIAL PERFORMANCE.

[206] WG 16: The rationale on earthing of TYPE B APPLIED PARTS has been consolidated and reworded to address the concern expressed by Israel in comment 3560. Please note that the response to comment 3560 was inadvertently left out of 72A/370A/CC.

[207] SEC: The text to which this rationale related was deleted in the 2CD in response to an NC comment. Therefore, this rationale (Examples of interference would include power supply transients, magnetic interference, mechanical interaction, vibration, thermal radiation and optical radiation.) no longer applies.

[208] WG 11: This paragraph was moved from the beginning of 61.2 of 2CD.

[209] WG 11: This paragraph was moved from 61.2.2 of 2CD.

[210] WG22: WG 22 added this additional guidance in response to German comments 15500 and 15510.

[211] WG 16: This informative annex was added in response to comment 6930.

[212] CAG: This bibliography entry and the reference in definition 3.3 were added in response to comment 750.