

Particular requirements for safety of medical supply units



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British Standard

ICS 11.040.01

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National foreword

This British Standard is the English language version of EN 793:1997.

The UK participation in its preparation was entrusted by Technical Committee CH/44, Anaesthetic machines, breathing attachments, medical gas pipeline systems and hose assemblies, to Subcommittee CH/44/2, Medical gas supply systems, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this committee can be obtained on request to its secretary.

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English version

Particular requirements for safety of medical supply units

Prescriptions particulières relatives à la sécurité des
gaines techniques à usage médical

Besondere Anforderungen für die Sicherheit von
medizinischen Versorgungseinheiten

This European Standard was approved by CEN on 30 October 1997.

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Foreword

This European Standard has been prepared by Technical Committee CEN/TC 215, Anaesthetics and respiratory equipment, the secretariat of which is held by BSI.

For special national conditions for clauses 6.1bb) and 6.2aa) see annex AA.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association and supports essential requirements of EU Directive(s).

For relationship with EU Directives, see informative annex ZA which is an integral part of this standard.

Annex AA is a normative part, and annexes BB, CC and ZA are informative parts, of this standard.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 1998, and conflicting national standards shall be withdrawn at the latest by May 1998.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

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Introduction

This Particular Standard amends EN 60601-1:1990 *Medical electrical equipment, Part 1: General requirements for safety*.

As stated in EN 60601-1:1990 the requirements of this Particular Standard take priority over those of EN 60601-1:1990.

As in EN 60601-1:1990 the requirements are followed by the relevant tests. The structure of this Particular Standard corresponds to that of EN 60601-1:1990 and the sections, clauses and subclauses refer to those of EN 60601-1:1990.

Clauses, subclauses, tables and figures additional to those in EN 60601-1:1990 are numbered beginning at "101". Additional annexes are lettered beginning at "AA" except for annex "ZA".

Additional items in lettered lists are lettered beginning "aa)".

Rationales for some of the requirements of this standard are given in annex CC. Such requirements are indicated by the letter "R" after the clause number.

Section one – General

1 Scope

Clause 1 of EN 60601-1:1990 applies with the following addition:

This standard applies to medical supply units as defined in 3.4.

1.3 Particular Standards

This Particular Standard amends EN 60601-1:1990. The requirements of this Particular Standard take priority over those of EN 60601-1:1990.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references subsequent amendment to or revisions of any of these apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

Appendix L of EN 60601-1:1990 applies with the following additions:

EN 737-1, *Medical gas pipeline systems — Part 1: Terminal units for compressed medical gases and vacuum*

prEN 737-2, *Medical gas pipeline systems — Part 2: Anaesthetic gas scavenging disposal systems — Basic requirements*

prEN 737-3, *Medical gas pipeline systems — Part 3: Pipelines for compressed medical gases and vacuum — Basic requirements*

EN 737-4, *Medical gas pipeline systems — Part 4: Terminal units for anaesthetic gas scavenging systems*

EN 739:1998, *Low-pressure hose assemblies for use with medical gases*

EN 1441, *Medical devices — Risk analysis*

EN ISO 3744, *Acoustics — Determination of sound power levels of noise sources using sound pressure — Engineering method in an essentially freefield condition over a reflecting plane*
(ISO 3744:1994)

EN 60598-1, *Luminaires — Part 1: General requirements and tests*
(IEC 598-1:1992, modified)

EN 60601-1:1990, *Medical electrical equipment — Part 1: General requirements for safety*

EN 60601-1-2, *Medical electrical equipment — Part 1: General requirements for safety — Electromagnetic compatibility — Requirements and tests*

EN 60669-1, *Switches for household and similar fixed electrical installations — Part 1: General requirements*
(IEC 669-1:1993, modified)

IEC 79-4, *Electrical apparatus for explosive gas atmospheres — Part 4: Method of test for ignition temperature*

IEC 884-1, *Plugs and socket-outlets for household and similar purposes — General requirements*

3 Terms and definitions

Clause 2 of EN 60601-1:1990 applies with the following additions:

3.1 equipment

single self-contained unit or combination of units provided with one or more permanently fixed connections to the building services, e.g. electricity, medical gas(es), liquid(s) or anaesthetic gas scavenging systems

3.2

junction point

connection point between the medical supply unit and the fixed building services

3.3

medical gas

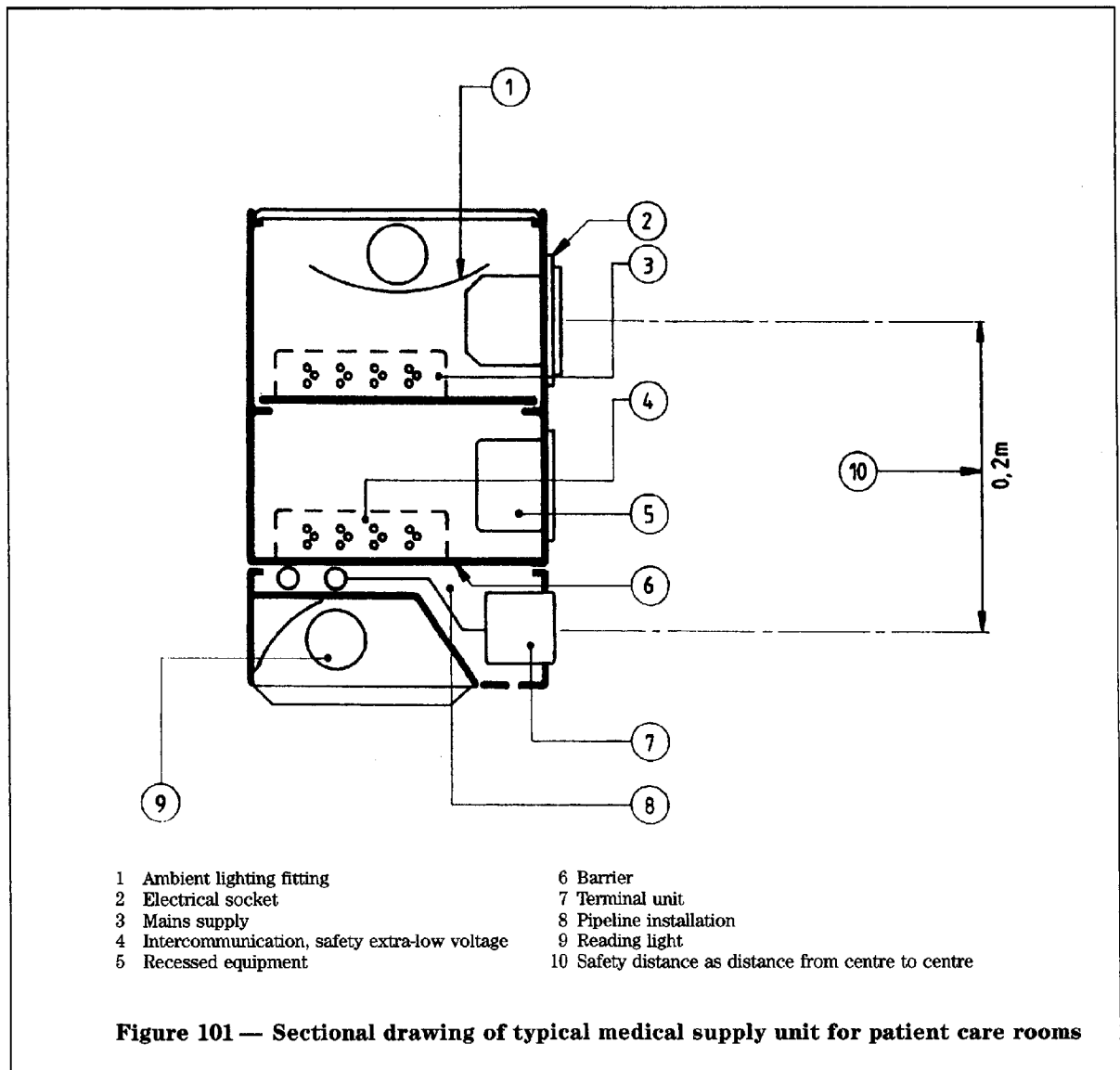
any gas or mixture of gases intended to be administered to patients for therapeutic, diagnostic or prophylactic purposes, or for surgical tool applications

3.4

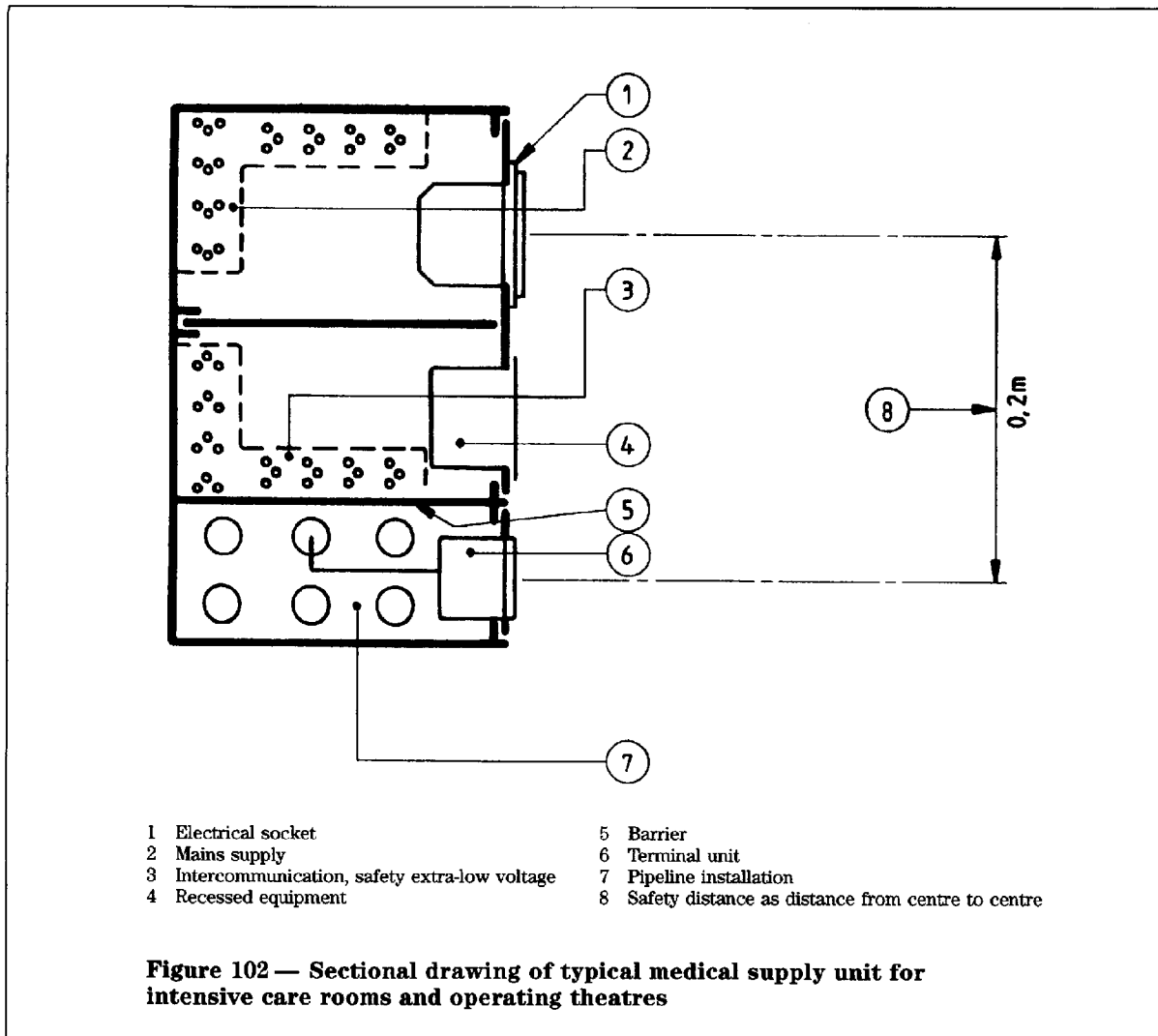
medical supply unit

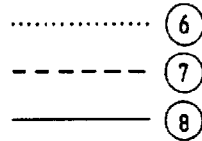
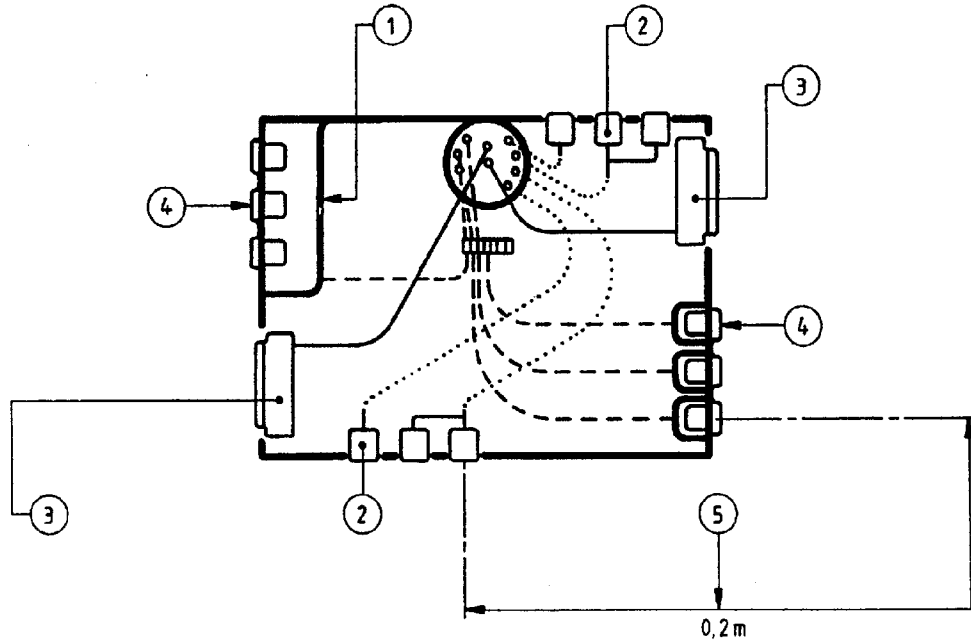
prefabricated permanently installed equipment of Class I, Type B for application in medical areas such as general wards and special purpose areas, e.g. operating theatres, induction rooms, recovery wards, intensive care of therapy units and other intermediate care areas. It is intended to supply electric power and/or medical gases and/or liquids

NOTE Medical supply units can include medical electrical equipment or systems or parts of such equipment or systems which might be applied to diagnosis, therapeutics and communications. Medical supply units can consist of modular sections for electrical supply, lighting for therapy or illumination, communication, supply of medical gases and liquids, anaesthetic gas scavenging systems. Typical examples of medical supply units are given in Figures 101, 102 and 103.



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- | | |
|-----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1 Barrier | 5 Safety distance measured on the surface as distance from centre to centre |
| 2 Terminal units | 6 Flexible hoses |
| 3 Recessed equipment, low current electro installation, intercommunication safety extra-low voltage | 7 Mains installation |
| 4 Electrical socket | 8 Low current installation |

Figure 103 — Sectional drawing of typical non-rigid medical supply unit

6.2 Marking on the inside of equipment and equipment parts

Add the following:

aa) Junction points and pipelines for medical gases shall be marked in accordance with prEN 737-3. Colour coding, if used, shall be in accordance with prEN 737-3.

See annex AA for special national conditions.

bb) Junction points and pipelines for anaesthetic gas scavenging systems shall be marked in accordance with prEN 737-2. Colour coding, if used, shall be in accordance with prEN 737-2.

cc) Junction points and pipelines for liquids shall be marked with the name of the liquid in accordance with Table 101 or the equivalent in the national language.

NOTE Colour coding, if used, should be in accordance with national standards if available.

6.8 Accompanying documents

Clause 6.8 of EN 60601-1:1990 applies with the following amendments:

6.8.2 Instruction for use

a) General information

Add the following:

- Instructions for use shall state which parts of the equipment are capable of bearing additional loads. The safe working load shall be stated.
- Instructions for use shall state that in any health care facility, terminal units of only one type (i.e. with the same set of dimensions for probe and socket) should be used for the same liquid.
- If flexible hoses and hose assemblies are used for medical gas supply, anaesthetic gas scavenging and liquid supply for operator adjustable systems, e.g. ceiling pendants, the instructions for use shall include a procedure for and the frequency of inspection and replacement.
- If flexible hoses are used for medical gas supply for operator adjustable systems, e.g. ceiling pendants, the instructions for use shall state that the following tests given in prEN 737-3 shall be carried out following modification or replacement of the flexible hose:
 - test for leakage
 - test for obstruction
 - test for particulate contamination
 - test of gas identity
- If flexible hoses are used for anaesthetic gas scavenging for operator adjustable systems, e.g. ceiling pendants, the instructions for use shall state that the following tests given in prEN 737-2 shall be carried out following modification or replacement of the flexible hose:
 - test for leakage
 - test of flow and pressure drop

- If flexible hoses are used for liquid supply for operator adjustable systems, e.g. ceiling pendants, the instructions for use shall state that the following test, given in 59.103.2b), shall be carried out following modification or replacement of the flexible hose:

- test for leakage

- If live parts of the electrical system can be touched during maintenance of the piping systems, the manufacturer shall state the precautions required for safe maintenance when safety covers have been removed.

b) Responsibility of the manufacturer

Replace with the following:

The manufacturer/supplier shall provide evidence that the following production tests have been performed for each unit and that the specified requirements are met:

- i) Impedance of protective earthing in accordance with 18f) of EN 60601-1:1990;
- ii) Earth leakage current in accordance with 19.3 and 19.4 of EN 60601-1:1990;
- iii) The following requirements and tests:
 - requirements as in 59.101.1, 59.102.1 and 59.103.1;
 - flow and pressure drop in accordance with 59.101.2a) and 59.102.2a);
 - no cross-connections in accordance with 59.101.2b), 59.102.2b) and 59.103.2a);
 - leakage in accordance with 59.101.2c), 59.102.2c) and 59.103.2b);
 - pressure tests in accordance with 59.101.2d) and 59.102.2d).

Add the following:

aa) Specifications for installations and use

Medical supply units shall be installed, tested and used in compliance with prEN 737-2, prEN 737-3 and the manufacturer's instructions.

NOTE An IEC document is in preparation on this subject. (See IEC 64/747/FDIS:1995 in annex BB)

6.8.3 Technical descriptions

Add the following:

aa) Disclosure by the manufacturer

- The manufacturer shall provide evidence that the noise levels of clause 26 are not exceeded.
- The manufacturer shall specify the flow and pressure drop characteristics of the medical supply unit both for medical gases and anaesthetic gas scavenging, if fitted.
- The manufacturer shall submit upon request evidence of the residual hydrocarbon content on the inner surface of the medical gas pipes.

NOTE The maximum permissible level of residual hydrocarbon content on the inner surface of medical gas pipes is under consideration by CEN/TC 133.



7 Power input

Clause 7 of EN 60601-1:1990 applies.

Section two — Environmental conditions

8 Basic safety categories

Clause 8 of EN 60601-1:1990 applies.

9 Removable protection means

Not used. Replaced by subclause 6.1z).

10 Environmental conditions

Clause 10 of EN 60601-1:1990 applies.

11 Not used

12 Not used

Section three — Protection against electrical shock hazards

13 General

Clause 13 of EN 60601-1:1990 applies with the following addition:

Lighting fixtures, built in or mounted on medical supply units shall comply with EN 60598-1.

14 Requirements related to classification

Clause 14 of EN 60601-1:1990 applies.

15 Limitation of voltage and/or energy

Clause 15 of EN 60601-1:1990 applies.

16 Enclosures and protective covers

Clause 16 of EN 60601-1:1990 applies.

17 Separation

Clause 17 of EN 60601-1:1990 applies.

18 Protective earthing, functional earthing and potential equalization

Clause 18 of EN 60601-1:1990 applies with the following additions:

- aa) Terminal units for compressed medical gases and vacuum and for anaesthetic gas scavenging systems do not require to be connected to the earth terminal.
- bb) All earth conductors of circuits from the existing mains supply shall be connected in the medical supply unit with a bus-bar.

19 Continuous leakage currents and patient auxiliary currents

Clause 19 of EN 60601-1:1990 applies with the following amendments:

19.3 Allowable values

Add to examples of such equipment in Note 3 of table IV of EN 60601-1:1990:

- “Medical supply units”

20 Dielectric strength

Clause 20 of EN 60601-1:1990 applies.

Section four — Protection against mechanical hazard

21 Mechanical strength

Clause 21 of EN 60601-1:1990 applies with the following addition:

21.101

21.101.1 Dynamic forces

Medical supply units shall be subjected to an impact as described in 21.101.2. After the impact, the live parts shall not become accessible, terminal units shall neither mechanically malfunction nor leak and existing protective devices shall remain intact.

21.101.2 Impact resistance test

A bag of 0,5 m width approximately half-filled with sand to give a total weight of 200 N suspended so as to give a pendulum length of 1 m, shall be released from a horizontal deflection of 0,5 m so as to hit the medical supply unit, mounted according to the manufacturer's instructions. The test configuration is shown in Figure 104. The test shall be repeated at at least one more position.

NOTE The occurrence of cracks in mouldings does not constitute failure of the test.

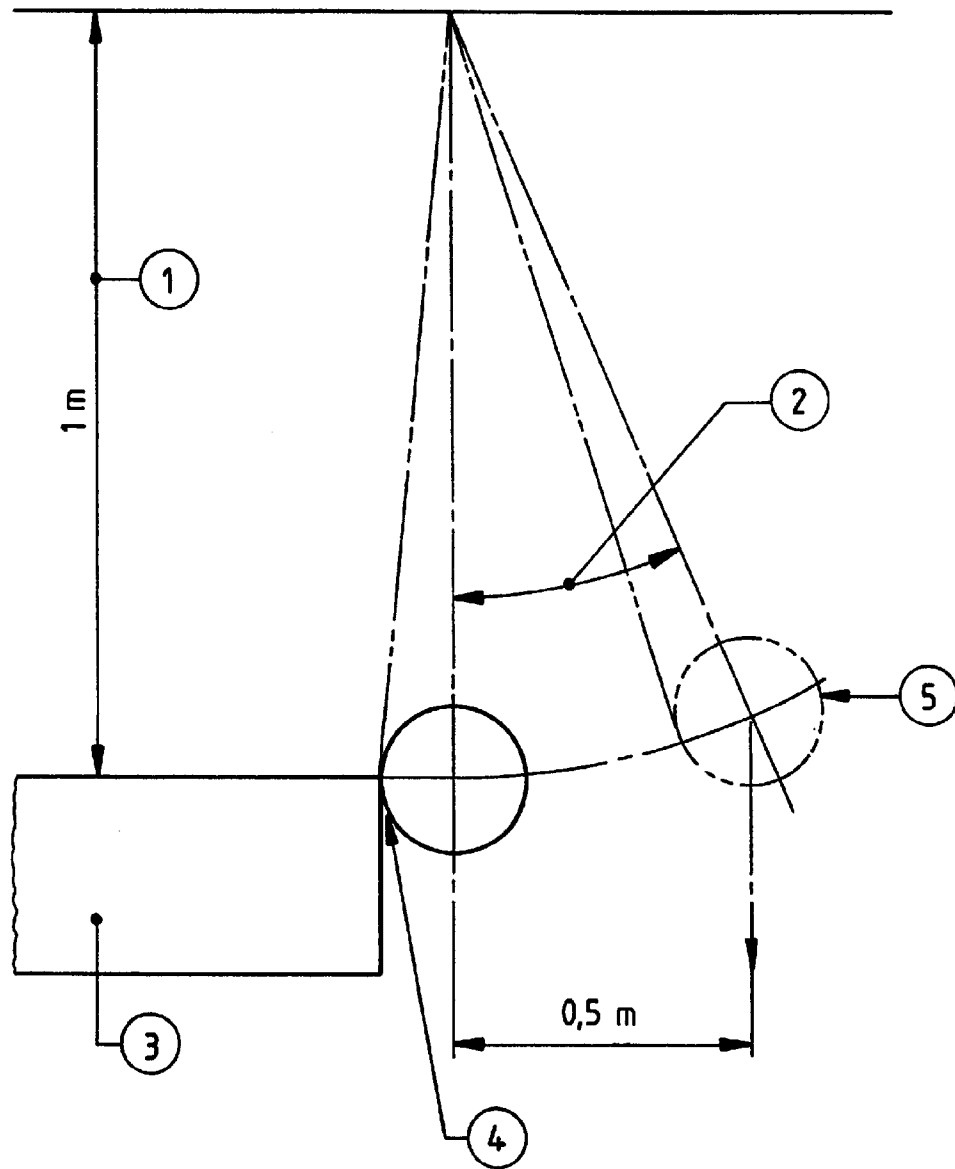
21.101.3 Static forces

Parts of medical supply units designed for additional loads shall be subjected to a test load of twice the safe working load specified by the manufacturer as described in 21.101.4.

The medical supply units and their supports designed for additional loads shall not be permanently deformed nor deflect by more than 10° with reference to the non-load bearing surfaces.

21.101.4 Static load test

The test load shall be uniformly distributed over the medical supply unit according to the manufacturer's specification.



- 1 Length of pendulum
- 2 Deflection
- 3 Mounted medical supply unit
- 4 Most vulnerable point (example)
- 5 Bag of weight 200 N

Figure 104 — Impact resistance test



22 Moving parts

Clause 22 of EN 60601-1:1990 applies.

23 Surfaces, corners and edges

Clause 23 of EN 60601-1:1990 applies.

24 Stability in normal use

Clause 24 of EN 60601-1:1990 applies.

25 Expelled parts

Clause 25 of EN 60601-1:1990 applies.

26 Vibration and noise

Add the following:

26.101 Within the frequency spectrum, individual peak noise levels shall not be in excess of 35 dB(A).

Except for noise caused by therapeutic or diagnostic measures or by adjustment of the medical supply unit (e.g. by lifting or lowering), during operation at 1,1 times the rated voltage at nominal frequency, the medical supply unit shall not produce acoustic energies in excess of 30 dB(A).

The manufacturer shall provide evidence that specified sound levels are not exceeded when measured according to EN ISO 3744.

27 Pneumatic and hydraulic power

Clause 27 of EN 60601-1:1990 applies.

28 Suspended masses

Clause 28 of EN 60601-1:1990 applies.

Section five — Protection against hazards from unwanted or excessive radiation

29 X-radiation

Clause 29 of EN 60601-1:1990 applies.

30 Alpha, beta, gamma, neutron radiation and other particle radiation

Clause 30 of EN 60601-1:1990 applies.

31 Microwave radiation

Clause 31 of EN 60601-1:1990 applies.

32 Light radiation (including lasers)

Clause 32 of EN 60601-1:1990 applies.

33 Infra-red radiation

Clause 33 of EN 60601-1:1990 applies.

34 Ultraviolet radiation

Clause 34 of EN 60601-1:1990 applies.

35 Acoustical energy (including ultrasonics)

Clause 35 of EN 60601-1:1990 applies.

36 Electromagnetic compatibility

Replace clause 36 with the following.

EN 60601-1-2 shall apply with the following amendments to all components incorporated into the medical supply unit which can generate magnetic (inductive) interferences.

36.101 Magnetic (inductive) interferences

Medical supply units shall be designed to minimize the emission of magnetic flux. The peak-to-peak values of the magnetic flux generated by the medical supply unit at a distance of 0,75 m shall not exceed the values for specific applications as follows:

- electromyogram application: $0,1 \times 10^{-6}$ Tesla
- electroencephalogram application: $0,2 \times 10^{-6}$ Tesla
- electrocardiogram application: $0,4 \times 10^{-6}$ Tesla

These applications shall be labelled in accordance with clause 6.1aa).

NOTE 1 In addition to the components determined by systems or appliance, various other electrical components are installed by users in medical supply units, such as components in peripheral systems or appliances e.g. peripheral nurse call systems, computers, etc.

NOTE 2 An example of a test method is described in DIN VDE 0107/11.89.

Section six — Protection against hazards of ignition of flammable anaesthetic mixtures

37 Locations and basic requirements

Clause 37 of EN 60601-1:1990 applies.

38 Marking, accompanying documents

Clause 38 of EN 60601-1:1990 applies.

39 Common requirements for category AP and category APG equipment

Clause 39 of EN 60601-1:1990 applies.

40 Requirements and tests for category AP equipment, parts and components thereof

Clause 40 of EN 60601-1:1990 applies.

41 Requirements and tests for category APG equipment, parts and components thereof

Clause 41 of EN 60601-1:1990 applies.

Section seven — Protection against excessive temperatures and other safety hazards**42 Excessive temperatures**

Clause 42 of EN 60601-1:1990 applies with the following amendments:

Add the following:

42.101 The maximum temperatures of lighting fixtures and their exposed components shall not exceed the maximum temperature stated in EN 60598-1.

43 R Fire prevention

Clause 43 of EN 60601-1:1990 applies with the following amendment:

43.2 Replace with the following.

In order to reduce the risk to patients, other persons or the surroundings due to fire, ignitable material, under normal and single fault condition, shall not, at the same time, be subjected to conditions in which:

- the temperature of the material is raised to its minimum ignition temperature and
- an oxidant is present.

Determine the minimum ignition temperature in accordance with IEC 79-4 using the oxidizing conditions present under the normal and single fault condition.

Compliance is checked by determining the temperature the material is raised to under the normal and single fault condition.

If sparking can occur under normal or single fault conditions, the material subjected to the energy dissipation of the spark shall not ignite under the oxidizing conditions present.

Compliance is checked by observing if ignition occurs under the most unfavourable combination of normal conditions with a single fault.

44 Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization and disinfection

Clause 44 of EN 60601-1:1990 applies.

45 Pressure vessels and parts subject to pressure

Clause 45 of EN 60601-1:1990 does not apply.

46 Human errors

Not used.

47 Electrostatic charges

Not used.

48 Material in applied parts in contact with the body of the patient

Clause 48 of EN 60601-1:1990 does not apply.

49 Interruption of the power supply

Clause 49 of EN 60601-1:1990 applies.

Section eight — Accuracy of operating data and protection against hazardous output**50 Accuracy of operating data**

Not used.

51 Protection against hazardous output

Clause 51 of EN 60601-1:1990 applies.

Section nine — Abnormal operation and fault conditions, environmental tests**52 Abnormal operation and fault conditions**

Clause 52 of EN 60601-1:1990 applies.

53 Environmental tests

Clause 53 of EN 60601-1:1990 applies.

Section ten — Constructional requirements**54 General**

Clause 54 of EN 60601-1:1990 applies.

55 Enclosures and covers

Clause 55 of EN 60601-1:1990 applies.



5

56 Components and general assembly

Clause 56 of EN 60601-1:1990 applies with the following amendments:

56.1 General

Add the following:

- aa) Sockets for potential equalization conductors, if provided, shall be recessed.

Compliance shall be tested by inspection.

57 Main parts, components and layout

Clauses 57.1a) to m) of EN 60601-1:1990 are replaced by the following:

57.1 Isolation from the supply mains

Medical supply units shall not include externally accessible master switches or fuses capable of isolating a complete electrical circuit.

Mains socket outlets shall not be provided with mains switches.

NOTE Unintentional operation of mains switches or mains fuses if integrated in the medical supply unit could endanger the patient.

57.2 Mains connectors, appliance inlets and the like

Clause 57.2 of EN 60601-1:1990 applies with the following amendments:

Add the following:

- aa) Sockets for x-ray equipment shall be in accordance with IEC 884-1.

57.6 Mains fuses and over-current releases

Clause 57.6 of EN 60601-1:1990 does not apply: see clause 57.1 in this standard.

58 Protective earthing – terminals and connections

Clause 58 of EN 60601-1:1990 applies with the following amendments:

58.2 Add the following:

Two examples are given in Figure 105.

Add the following:

58.101 Conductors

Protective earth conductors shall each have a cross-section of at least 2,5 mm² of copper and shall be individually fixed to the protective earth terminal.

Potential equalization conductors, if provided, shall each have a cross-section of at least 4 mm² of copper and shall be individually detachable from the potential equalization sockets.

Add the following:

58.102 Bus bar

All protective earth conductors, of circuits from the existing mains supply shall be connected in the medical supply unit to a bus bar with a conductance equivalent to at least that of 16 mm² copper.

The bus bar for protective earth conductors shall also be equipped with a terminal for connection to a protective earth conductor of at least 16 mm² cross-section. Facilities for potential equalization conductors shall be connected to the bus bar of protective earth conductors if there is no bus bar for potential equalization: see Figure 106 for an example. All terminals shall be secured against unintentional loosening.

The medical gas pipeline shall not be used as a bus bar.

NOTE A metal section of the medical supply unit of equivalent conductance can be used as a bus bar.

59 Construction and layout

Clause 59 of EN 60601-1:1990 applies with the following amendments:

59.1 Internal wiring

- e) Separation of circuits

Replace with the following:

NOTE Conductors of different mains circuits of the same voltage do not require mechanical separation. In diagnostic and medical care facilities at least one separate circuit which can have more than one mains socket outlet should be provided for each bed. A separate circuit should be provided for each haemodialysis machine and x-ray equipment. In general wards one mains circuit can serve more than one bed.

Add the following:

- aa) **Intercommunication circuits**

If wiring for intercommunication, such as nurse call systems, wiring for radio transmission, telephone wiring, signal wiring for biophysical parameters, other data transmission conductors etc. are ducted together with mains cables or gas pipes in medical supply units, electrically safe operation under single fault condition shall be ensured.

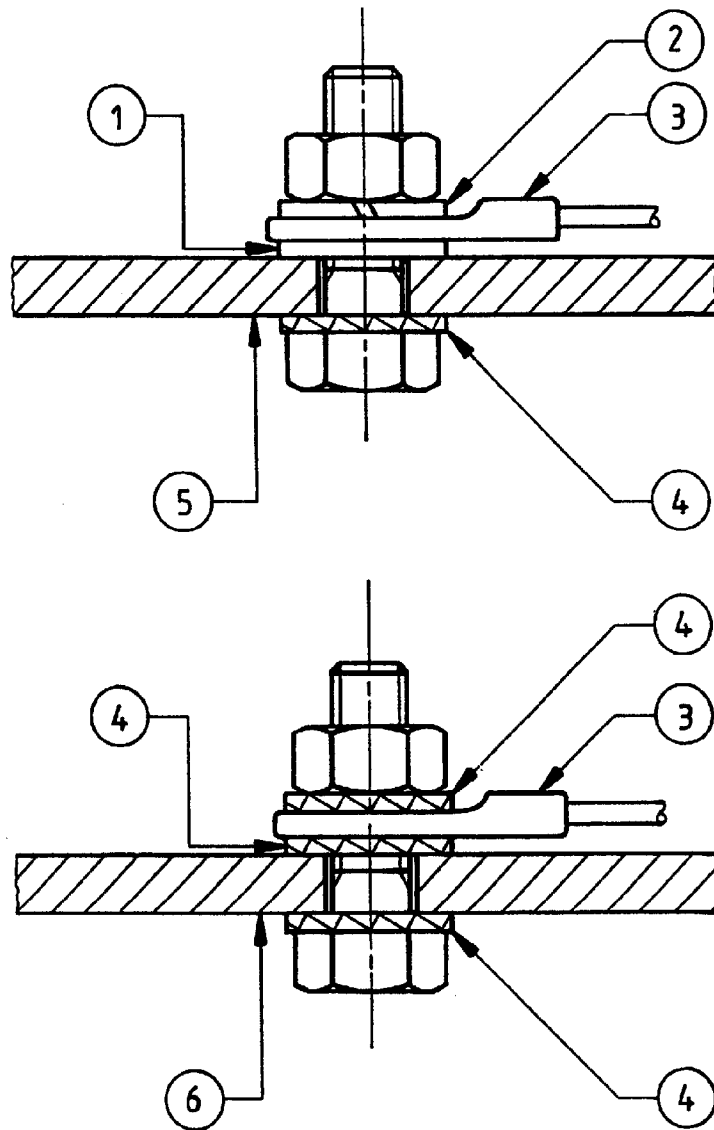
NOTE This can be achieved, for example, by double insulation of wiring for intercommunication facilities or separation by metallic partitions or a distance of at least 50 mm. For an example see Figure 101.

- bb) **Double insulation**

If mains conductors are installed together with medical gas pipelines, these conductors shall be double-insulated.

- cc) **Maintenance**

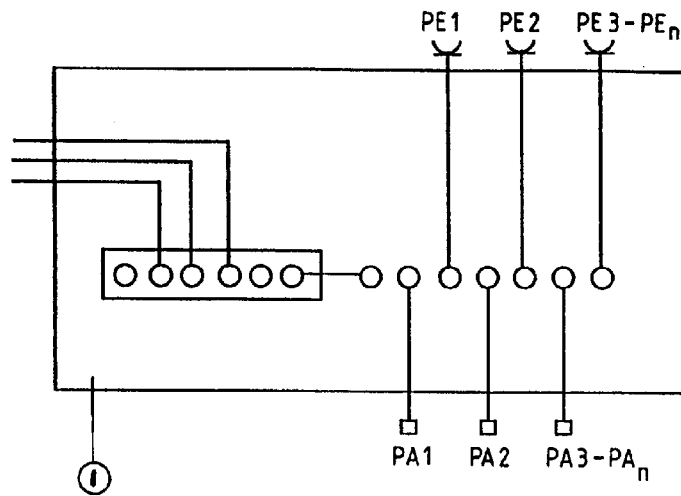
The design features shall either ensure that in case of maintenance on the piping system no live parts of the electrical system can be touched, or the manufacturer shall indicate on the removable safety covers and in accompanying documents how by other precautions safe maintenance can be assured. See clause 16d) of EN 60601-1:1990.



- 1 Cupal washer Cu/Al (Copper surface uppermost)
- 2 Spring washer
- 3 Cable bracket
- 4 Lock washer
- 5 Supply unit section (e.g. aluminium)
- 6 Supply unit section (e.g. ferrous)

Figure 105 — Typical examples for protection measures against loosening and corrosion of potential equalization and earth-conductor facilities

S



I Medical supply unit
PE connection of main plug sockets
PA potential equalization sockets

NOTE There should be no additional potential equalization detachable bridge.

Figure 106 — Example of the terminal device for medical supply units in accordance with IEC 364-5-54

59.3 Add the following:

If pulse relays are fitted, they shall comply with EN 60669-1 and EN 60601-1:1990 clause 57.10.

Add the following new subclauses

59.101 Medical gas supply construction

59.101.1 Requirements

a) Medical gas pipelines shall be made of materials according to prEN 737-3.

NOTE 1 Pure copper is recommended for compressed medical gases and vacuum.

NOTE 2 The dimensions of pipes which supply terminal units for compressed medical gases and vacuum should permit the system to function in accordance with prEN 737-3.

NOTE 3 Pipes to pressure gauges and other measuring and control equipment can have small cross-sections.

Interconnections of pipes shall be in accordance with prEN 737-3. Cutting ring connections and compression joints shall not be used.

b) **R** Flexible hoses and hose assemblies shall not be used within medical supply units except for the operator adjustable portions (e.g. on ceiling pendants).

If flexible hoses and hose assemblies are used, means shall be provided to allow periodic inspection and replacement.

If flexible hoses are used, they shall comply with EN 739:1998 except for clauses 5.4.2.1, 5.4.7, 5.4.8 and 5.4.9. The minimum bursting pressure of hoses used for all services except vacuum shall be not less than 8000 kPa at 23 °C and not less than 6400 kPa at 40 °C. Evidence shall be provided by the manufacturer.

If flexible hoses are accessible to the operator for removal, they shall be incorporated in hose assemblies which comply with EN 739:1998 except for clauses 5.4.2.1, 5.4.7, 5.4.8 and 5.4.9. The minimum bursting pressure of hoses used for all services except vacuum shall be not less than 8000 kPa at 23 °C and not less than 6400 kPa at 40 °C. Evidence shall be provided by the manufacturer.

If flexible hoses are used, the accompanying documents for the medical supply unit shall include a procedure for, and the frequency of, inspection and replacement of the flexible hoses and shall specify the tests to be carried out following such replacement [see clause 6.8.2a)].

If hose assemblies are used, they shall comply with EN 739:1998 except for clause 5.4.2.1, and the accompanying documents for the medical supply units shall include a procedure for, and the frequency of, inspection and replacement of the hose assemblies [see clause 6.8.2a)].

c) During the design phase, constructional provisions shall be made so that piping is not exposed to temperatures above 50 °C and flexible hoses, if used, are not exposed to temperatures above 40 °C caused e.g. by lighting facilities, transformers, etc.

d) Control knobs and spindles of flow control valves, if fitted, shall be captive, such that they cannot be disengaged without the use of a tool.

e) The electrical compartment within a medical supply unit shall be separated from the liquid and gas compartment by a partition wall. Liquid compartments in horizontal mountings shall be located below electrical compartments.

f) Terminal units for oxidizing medical gases, for anaesthetic gas scavenging systems and for liquids shall be located at least 0,2 m from any mains socket outlet.

NOTE The effect of thermal expansion should be taken into account.

59.101.2 Production tests

The compressed medical gases and vacuum systems shall be tested at ambient temperature to ensure the following:

a) That the medical gas supply system meets the manufacturer's specified flow and pressure drop performance [see clause 6.8.3aa)].

b) That there are no cross-connections between pipelines for different gases.

NOTE Test procedures for cross-connections are given in prEN 737-3.

c) That when pressurized with clean, oil free, dry air or nitrogen at the nominal distribution pressure specified in prEN 737-3, the leakage from the portion of the pipeline for each compressed medical gas and vacuum included in the medical supply unit shall not exceed the value of 0,296 ml/min (0,03 kPa l/min) times the number of terminal units connected to that portion of pipeline.

NOTE For the vacuum supply, the test can be carried out at 400 kPa positive pressure.

d) That each portion of pipeline can withstand a pressure of two times the nominal distribution pressure specified in prEN 737-3.

e) That pipelines are made of copper and interconnections are in accordance with prEN 737-3.

59.102 Anaesthetic gas scavenging system construction

59.102.1 Requirements

a) The construction of the anaesthetic gas scavenging system shall comply with prEN 737-2.

b) Flexible hoses shall not be used within medical supply units except for the operator adjustable portions (e.g. on ceiling pendants).

If flexible hoses are used, means shall be provided to allow periodic inspection and replacement.

If flexible hoses are used, the accompanying documents for the medical supply unit shall include a procedure for, and the frequency of, inspection and replacement of the flexible hoses and shall specify the tests to be carried out following such replacement [see clause 6.8.2a)].

c) each portion of the pipeline for gases under pressure shall withstand a pressure of two times the nominal operating pressure.

59.102.2 Production tests

The anaesthetic gas scavenging system installed on each medical supply unit shall be tested to ensure the following:

a) That the anaesthetic gas scavenging system meets the manufacturer's specified flow and pressure drop performance [see clause 6.8.3aa)].

b) That there are no cross-connections, between pipelines for different gases.

c) That when pressurized with clean, oil free, dry air or nitrogen at the nominal operating pressure specified in prEN 737-2, the leakage of the portion of the pipeline for the anaesthetic gas scavenging system included in the medical supply unit does not exceed the value of 2,96 ml/min (0,3 kPa l/min) times the number of terminal units connected to that portion of pipeline.

59.103 Liquid supply construction

59.103.1 R Requirements

a) Pipelines for potable water (warm or cold) and cooling water (warm or cold) shall be made of copper or stainless steel.

b) Pipelines for de-mineralized water (cold), distilled water, dialysing concentrate and dialysing permeate shall be made of corrosion resistant material.

NOTE Stainless steel with a corrosion resistance at least equivalent to CrNiMoTi 18 10 – ISO 683-13, Type 15 or appropriate PVC or appropriate polypropylene should be used for dialysing concentrate and dialysing permeate pipelines.

c) Flexible hoses shall not be used within medical supply units except for the operator adjustable portions (e.g. on ceiling pendants).

If flexible hoses are used, means shall be provided to allow periodic inspection and replacement.

If flexible hoses are used, the accompanying documents for the medical supply unit shall include a procedure for, and the frequency of, inspection and replacement of the flexible hoses and shall specify the tests to be carried out following such replacement [see clause 6.8.2a)].

The material of the flexible hoses selected for any liquid supply shall be compatible with the liquid contained in those hoses with regard to strength, long term stability and corrosion resistance under the operating conditions specified by the manufacturer.

Evidence shall be provided by the manufacturer.

d) Pipes and hoses for medical gases may be installed together with piping for liquids. If fitted together in horizontal mountings, gas pipes shall be located above liquid pipes.

NOTE 1 Pipelines for dialysing solutions should be installed in a single recirculating loop.

NOTE 2 Hot water or wet steam may be used for pasteurisation of pipelines for dialysing solutions. Means should be provided to protect other components from excessive temperature.

NOTE 3 Turbulence and dead spaces should be avoided by design.

e) Metallic pipe connections and branches to the terminal units shall be welded or brazed. Flaring and similar methods shall not be used. Cutting ring connections and compression joints for copper pipes shall not be used. To prevent oxide formation inside the pipes they shall be filled and rinsed with a suitable inert gas during welding or brazing. Pipe connections in pipelines for liquids shall be bonded by means of sleeves without changes in diameter.

f) The liquid supply system shall be designed and manufactured to minimize health risks due to substances leached from the system.

Evidence shall be provided by the manufacturer.

59.103.2 Production tests

Each liquid supply unit shall be tested to ensure the following:

- a) That there are no cross-connections between pipelines for different liquids.
- b) That when pressurized with clean, oil free, dry air or nitrogen at 1,5 times the operating pressure specified by the manufacturer, the leakage from the portion of the pipeline for each liquid included in the medical supply unit shall not exceed the value of 0,296 ml/min (0,03 kPa l/min) times the number of terminal units connected to that portion of pipeline.
- c) That the requirements of 59.103.1 are met.

59.104 Terminal unit construction

59.104.1 Terminal units for medical gases shall comply with EN 737-1.

59.104.2 Terminal units for anaesthetic gas scavenging systems shall comply with EN 737-4.

59.104.3 Terminal units for liquids

a) Terminal units for liquids shall comprise either:

– a flow control valve fitted with a check valve and at the outlet a hose insert for the following:

- potable water, cold
- potable water, warm
- cooling water
- cooling water, feed-back
- de-mineralized water
- distilled water

or

– a quick-connect socket and probe for the following:

- dialysing concentrate
- dialysing permeate

b) Control knobs and spindles of flow control valves, if fitted, shall be captive such that they cannot be disengaged without the use of a tool.

c) Quick-connect sockets and probes, if fitted, shall both be equipped with a check valve to ensure automatic closure during release.

d) If probes and sockets are used for dialysing concentrate and dialysing permeate, the probe shall be fitted on the medical supply unit.

e) R The materials shall be compatible with the liquids under the operating conditions specified by the manufacturer.

NOTE Stainless steel with a corrosion resistance at least equivalent to CrNiMoTi, 18 10 – ISO 683/13 type 15 should be used for terminal units for dialysing solutions.

Evidence shall be provided by the manufacturer.

f) The nominal internal diameters for quick-connect sockets and probes, if fitted, shall be as follows:

Dialysing concentrate:	4 mm
Dialysing permeate:	6 mm

g) If quick-connect sockets and probes are used for the discharge of dialysis solutions, they shall have different dimensions from all the others used.

h) Compliance with clauses 59.104.3a) to d) and f) and g) shall be checked by visual inspection.

Annexes A to K

Appendices A to K of EN 60601-1:1990 apply.

Annex AA (normative)**Special national conditions**

Special national condition: National characteristic or practice that cannot be changed even over a long period, e.g. climatic conditions, electrical earthing conditions. If it affects harmonization, it forms part of the European Standard. In the countries in which the relevant national condition applies these provisions are normative, for other countries they are informative.

Clause 6.1bb): Special national condition for Austria, Germany, Switzerland.

The requirement for colour coding to comply with EN 737-1 does not apply until the latest date of withdrawal of the special national conditions (dop + 10 years) subject to review taking into account e.g. the results of a forthcoming European study and the ongoing European standardization activities of the EN 1089 series.

Clause 6.2aa): Special national condition for Austria, Germany, Switzerland.

The requirement for colour coding to comply with prEN 737-3 does not apply until the latest date of withdrawal of the special national conditions (dop + 10 years) subject to review taking into account e.g. the results of a forthcoming European study and the ongoing European standardization activities of the EN 1089 series.

Annex BB Bibliography (informative)

EN 1089, *Transportable gas cylinders — Gas cylinder identification (excluding LPG)*

ISO 683-13, *Heat-treatable steels, alloy steels and free-cutting steels — Part 13: Wrought stainless steels*

IEC 364-5-54, *Electrical installations of buildings — Part 5: Selection and erection of electrical equipment — Chapter 54: Earthing arrangements and protective covers.*

IEC 64/747/FDIS: 1995, *Draft IEC 364-7-710 Electrical installations of buildings — Part 7: Requirements for special installations or locations — Section 710: Medical locations (64/819/RVD, rejected)*

DIN VDE 0107/11.89, *Electrical installations in hospitals and locations for medical use outside hospitals*

NFPA Publication 53 M, *Fire hazards in oxygen — enriched atmospheres¹⁾*

Annex CC (informative) Rationale

CC.3.6aa) A fault which is not detected can exist for a long time. Under these circumstances it is not acceptable to regard a further fault as a second fault which can be disregarded.

Such a first fault is regarded as a normal condition.

CC.43 Reports of fire caused by medical devices are unusual. However, when such fires occur in the hospital environment they can have tragic consequences.

The risk of a fire is fundamentally determined by the three elements which are necessary in order to start a fire:

- ignitable material (fuel):
- temperature equal to or above the minimum ignition temperature of the material, or sparks with energy dissipation equal to or above the minimum ignition energy of the materials;
- an oxidant.

Therefore, following the basic safety concepts of EN 60601-1, the objective in the design of the equipment is to ensure that under both normal and single fault conditions and under the oxidizing conditions to which the material may be exposed, the temperature of any material is not raised to its minimum ignition temperature or the spark energy does not exceed the material ignition energy level. Alternatively, contained ignition can occur provided it is self limiting so that no hazard is created, e.g. a fuse or a resistor within a sealed compartment.

Minimum ignition temperature for a large number of specific materials are well established in published literature, although usually only for ambient air and pure oxygen environments. The minimum ignition temperature can be critically dependent upon the concentration of oxidant present. If ignition temperatures for other materials or different oxygen concentrations are required, these can be determined using the methods and apparatus described in IEC 79-4. In considering the ignitable materials particular attention should be paid to materials which may accumulate during prolonged use, e.g. airborne particles of paper or cotton.

The risk of fire directly caused by sparking of electrical circuits is generally considered insignificant in medical equipment as temperature rise resulting from the power dissipation caused by a spark will not normally reach the ignition temperature of the solid materials generally used when following good design practice.

¹⁾ Available from the National Fire Protection Association, 1 Batterymarch Park, PO Box 9101, Quincy MA 02269-9101, USA.

However, if materials with a low ignition temperature and a very low thermal capacity, e.g. cotton wool, paper or organic fibre accumulations, are present then it may not be possible to determine the surface temperature attained during exposure to spark energy and specific tests, e.g. ignition tests, may be necessary to assume safety under these conditions.

In certain standards currently in use the requirements to minimize fire risk are based on limitation of temperature, electrical energy and oxidant concentration to absolute values.

The temperature value is based on the minimum hotplate ignition temperature for fire retardant cotton in 100% oxygen which is given in the American NFPA Publication 53 M as 310 °C. The assumption was therefore made that 300 °C was an acceptable temperature limit in medical equipment with oxygen enriched atmospheres.

The origin of the electrical energy values which have been used is less clear and it would seem that, in the absence of specific controlled tests, figures have been adopted from other published standards.

However, simple tests and detailed analysis of the known factors involved in causing an oxygen fire show that these figures can be either over-restrictive or potentially hazardous depending, in particular, on the manner in which the power may be dissipated and the proximity and type of any "fuel" present.

It is now generally accepted that there are no single or universally applicable ranges of temperatures, energy and concentration of oxidant which can ensure safety under all circumstances. Ultimately, electrical energy is only significant in respect of its ability to raise the temperature of ignitable materials and this in turn depends upon the particular configuration and the proximity of any ignitable materials.

Under single fault conditions in a typical electrical circuit the possible number of failure modes is very high. In this case full assurance of safety can only be possible by the use of appropriate hazard and safety analysis procedures, taking into consideration the three basic elements, i.e. material, temperature and oxidant. An appropriate design might limit the electrical energy in the circuit to ensure that temperatures remain below the minimum air ignition temperature under normal conditions and seal compartments or add forced ventilation to ensure that oxygen content does not exceed that of ambient air under a single fault condition.

Alternatively, it can be appropriate to limit the electrical energy to ensure temperatures below the minimum ignition temperature for a pure oxygen environment, even under single fault condition. The particular combination of material, oxidant and temperature determines whether a fire will occur, not a single value of any one of these variables.

CC.59.101.1b) Evidence will be provided e.g. to a Notified Body during CE conformity assessment and to a Competent Authority upon request.

CC.59.103.1 Evidence of such compatibility will be provided e.g. to a Notified Body during CE conformity assessment and to a Competent Authority upon request.

CC.59.104.3e) Evidence of such compatibility will be provided e.g. to a Notified Body during CE conformity assessment and to a Competent Authority upon request.

Annex ZA (informative) Clauses of this European standard addressing essential requirements or other provisions of EU Directives

This European Standard has been prepared under a mandate given to CEN/CENELEC by the European Commission and the European Free Trade Association and supports essential requirements of EU Directive 93/42/EEC.

WARNING: other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

The following clauses of this standard (see Table ZA.1) are likely to support requirements of Directive 93/42/EEC. Compliance with these clauses of this standard provides one means of conforming with the specific essential requirements of the Directive concerned and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and EU Directives

Clause/subclause of this European Standard	Corresponding Essential Requirement of Directive 93/42/EEC	Comments
All	1	
All	2	
All	3	
4 [3.6aa)]	9.3	
4 [3.6bb)]	6	
6.1a)	13.3 a)	
6.1g)	13.3 a)	
6.1k)	13.2 13.3 a)	
6.1l)	13.3 a)	
6.1y)	13.2, 13.3 a)	
6.1aa)	13.2, 13.3 a)	
6.2	7.6, 9.1	
6.8	7.1, 13.1, 13.4, 13.6a) b) c) d)	
6.8.2	13.1, 13.6a) b) c) d)	
6.8.2a)	13.4	
6.8.3	13.1	
6.8.2a)	13.4	
6.8.3	13.1	
Section 3	12.6	
Section 4	12.7.1	
21.101	4, 9.2	
21.101.2	9.2	
21.101.3	9.2	
26.101	12.7.2, 12.7.3	
36.101	12.5	
42	12.7.5	
42.101	12.7.5	
43	7.1, 9.3	
43.2	7.1, 9.3	
56.1	9.2, 12.6	
57.1	9.2, 12.6	
57.2	9.2, 12.6	
57.6	9.2, 12.6	

* 5 *

Table ZA.1 : Correspondence between this European Standard and EU Directives (continued)

Clause/subclause of this European Standard	Corresponding Essential Requirement of Directive 93/42/EEC	Comments
58.101	9.2, 12.6	
59.101.1	12.7.4	
59.101.1a)	7.1, 7.3	
59.101.2	7.3, 12.7.4	
59.101.2a)	7.3	
59.101.2c)	7.5	
59.102.2c)	7.5	
59.103.1a)	7.1, 7.3	
59.103.1b)	7.1, 7.3	
59.103.1c)	7.1, 7.3	
59.103.2b)	7.5	
59.104.1	9.1, 12.7.4	
59.104.2	9.1, 12.7.4	
59.104.3a)	9.1	
59.104.3e)	7.1, 7.3	
59.104.3g)	9.1	

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