IEC TR 60601-4-3

Edition 2.0 2018-12

TECHNICAL REPORT

colour inside

Medical electrical equipment – Part 4-3: Guidance and interpretation – Considerations of unaddressed safety aspects in the third edition of IEC 60601-1 and proposals for new requirements

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

ICS 11.040.01

ISBN 978-2-8322-6278-8

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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FOREWORD

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IEC TR 60601-4-3, which is a technical report, 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.

This second edition cancels and replaces the first edition of IEC 60601-4-3 published in 2015. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition: addition of 47 new recommendations.

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

Enquiry draft	Report on voting
62A/1236/DTR	62A/1258A/RVDTR

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

This document has been drafted in accordance with the ISO/IEC Directives, Part 2.

Terms used throughout this document that have been defined in Clause 3 of IEC 60601-1:2005 and IEC 60601-1:2005/AMD 1:2012, IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012, IEC 60601-1-11:2010, IEC 60601-1-11:2015 and IEC 60601-1-12:2014 are printed in SMALL CAPITALS.

A list of all parts in the IEC 60601 series, published under the general title *Medical electrical equipment*, can be found on the IEC website.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

A bilingual version of this document may be issued at a later date.

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

INTRODUCTION

At the Sydney meeting in November 1993, IEC subcommittee (SC) 62A established a procedure under which working group (WG) 14 would develop recommendations regarding problems of interpretation or application of IEC 60601-1. WG 14 is made up of experts with particular expertise in testing according to the requirements of IEC 60601-1. Many of the experts on WG 14 are employed by test laboratories with a long history of applying IEC 60601-1 to MEDICAL ELECTRICAL EQUIPMENT. While the National Committee members of SC 62A nominate these experts, their recommendations were not to be formally adopted through any official voting procedure. To reinforce this process, the subcommittee specifically directed that the following note appear on every page of the resulting informational circular:

IMPORTANT NOTE: Per the 62A decision at Sydney (see RM3755/SC62A, August 1994), the 62A Secretary is circulating this recommendation, prepared by 62A/WG 14, regarding problems of interpretation or application of IEC 60601-1 to all P-Member NCs.

This recommendation/interpretation is the result of considerations by a group of nominated experts and has not been formally adopted through any National Committee voting procedure. Distribution is only for information.

At the November 2000 meeting of SC 62A in Tokyo, the subcommittee discussed ways and means for achieving a wider distribution of the WG 14 recommendations. At the conclusion of this discussion, the subcommittee instructed the Secretariat to develop a technical report (TR) based on the published recommendations of WG 14. This technical report is intended to convey the results of WG 14's work to interested parties such as MANUFACTURERS and test laboratories while retaining the informative nature of the material.

This second edition of IEC TR 60601-4-3 contains 143 recommendations, numbered 101 to 243. All these recommendations are based upon IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, and IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012, IEC 60601-1-11:2010, IEC 60601-1-11:2015 and IEC 60601-1-12:2014.

The numbering starts with 101 instead of just 1 to ensure that these WG 14 recommendations (101 to 243) will not accidentally be confused with previous issued WG 14 recommendations 1 to 63, which are based on IEC 60601-1:1998 and published in IEC TR 62296:2009.

This document may be amended from time to time as WG 14 prepares additional recommendations.

MEDICAL ELECTRICAL EQUIPMENT –

Part 4-3: Guidance and interpretation – Considerations of unaddressed safety aspects in the third edition of IEC 60601-1 and proposals for new requirements

1 Scope

This part of IEC 60601, which is a Technical Report, contains a series of recommendations developed by an expert working group of IEC subcommittee 62A in response to questions of interpretation of IEC 60601-1:2005 and related collateral standards in the IEC 60601 series.

This document is primarily intended to be used by:

– MANUFACTURERS of MEDICAL ELECTRICAL EQUIPMENT;

– test laboratories and others responsible for assessment of compliance with IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012, IEC 60601-1-11:2010, IEC 60601-1-11:2015 and IEC 60601-1-12:2014;

– those developing subsequent editions of IEC 60601-1.

The recommendations in the first edition of IEC TR 62296 were considered in preparing the third edition of IEC 60601-1. Similarly, it is expected that these recommendations within IEC 60601-4-3 will be considered when preparing future revisions of IEC 60601-1 and related collateral standards in the IEC 60601 series.

The object of this document is to make the recommendations/interpretations available to those interested in the application of the third edition of IEC 60601-1 and applicable collateral standards.

NOTE There might be other acceptable solutions which are not reflected in this document. The reader is reminded that, although a majority of the National Committee members of IEC/SC 62A have approved publication of this document, the contents remain the opinion of the expert members having participated in the drafting of the document. These recommendations/interpretations are the result of considerations by this group of nominated experts and have not been formally adopted through any National Committee voting procedure. Distribution is only for information.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE For improved reading and easy understanding of the recommendation section of each issue, the referenced standards are written as follows:

a) Written IEC 60601-1:2005, meant only Edition 3.0 from 2005.

b) Written IEC 60601-1:2005/AMD1:2012, meant only Amendment 1:2012.

c) Written IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, meant Edition 3.0 and Amendment 1:2012 combined.

d) Written IEC 60601-1 (in undated form), meant IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 (in the year 2018 the latest edition of IEC 60601-1).

If an edition is not explicitly specified, all editions referenced in this normative references clause applies.

IEC 60332-1-2, *Tests on electric and optical fibre cables under fire conditions – Part 1-2: Test for vertical flame propagation for a single insulated wire or cable – Procedure for 1 kW pre-mixed flame*

IEC 60332-2-2, *Tests on electric and optical fibre cables under fire conditions – Part 2-2: Test for vertical flame propagation for a single small insulated wire or cable – Procedure for diffusion flame*

IEC 60529:1989, *Degrees of protection provided by enclosures (IP Code)*
IEC 60529:1989/AMD1:1999
IEC 60529:1989/AMD2:2013

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012

IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests*

IEC 60601-1-8:2006, *Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*
IEC 60601-1-8:2006/AMD1:2012

IEC 60601-1-11:2010, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*[1]

IEC 60601-1-11:2015, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

IEC 60601-1-12:2014, *Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment*

IEC 60747-5-5:2007, *Semiconductor devices – Discrete devices – Part 5-5: Optoelectronic devices – Photocouplers*

IEC 60950-1:2005, *Information technology equipment – Safety – Part 1: General requirements*

IEC 62133, *Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications*[2]

IEC 62304:2006, *Medical device software – Software life cycle processes*
IEC 62304:2006/AMD1:2015

ISO 8820-3:2010, *Road vehicles – Fuse-links – Part 3: Fuse-links with tabs (blade type) Type C (medium), Type E (high current) and Type F (miniature)*

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[1] This publication was withdrawn and replaced by IEC 60601-1-11:2015.

[2] This publication was withdrawn and replaced by IEC 62366-1:2015.

ISO 14971:2000, *Medical devices – Application of risk management to medical devices*[3]

ISO 14971:2007, *Medical devices – Application of risk management to medical devices*

UL 1642:2012, *Standard for lithium batteries*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012, IEC 60601-1-11:2010, IEC 60601-1-11:2015 and IEC 60601-1-12:2014 apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

4 Recommendations

4.1 Template used for recommendations prepared by SC 62A

The recommendations in this document are presented in tabular form using the following table structure.

Recommendation number	NNN [a]
Clause(s) number (only) [b]	
Source/problem [c]	
Discussion/comment [d]	
Submitter proposed recommendation [e]	
Recommendation [f]	

[a] The numbering of the recommendations in the Technical Report starts with 101 instead of just 1 to ensure that these recommendations will not accidentally be confused with previously issued recommendations 1 to 63, which are based on the second edition of IEC 60601-1.

[b] The clause, subclause or requirement to which the question is related. If no standard is listed, the reference is to IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012. In case of a collateral standard, please specify: IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012, IEC 60601-1-11:2010, IEC 60601-1-11:2015 and IEC 60601-1-12:2014.

[c] A description of the problem as submitted to SC 62A.

[d] Additional discussion or commentary provided by the submitter.

[e] The submitter's proposed resolution to the problem, if one exists.

[f] The final recommendation developed by SC 62A.

[3] This publication was withdrawn and replaced by ISO 14971:2007.

4.2 Recommendation sheets

4.2.101 Total PATIENT LEAKAGE CURRENT of a ME SYSTEM

Recommendation number	101
Clause(s) number (only)	16.6.3
Source/problem	There is no measuring circuit or measurement method given in IEC 60601-1 for measurement of the total PATIENT LEAKAGE CURRENT of ME SYSTEMS. Input: PATIENT can be simultaneously monitored for a physiological parameter by the ME EQUIPMENT "1" and for other physiological parameter by the ME EQUIPMENT "2". The ME EQUIPMENT "1" and "2" belong to the same ME SYSTEM. The total PATIENT LEAKAGE CURRENT of the ME SYSTEM in question should be measured, but how should the measurement be performed?
Discussion/comment	–
Submitter proposed recommendation	–
SC 62A recommendation	Q1: Shall the total PATIENT LEAKAGE CURRENT of the ME SYSTEM be measured "from" and "to" all PATIENT CONNECTIONS of all APPLIED PARTS (in the ME SYSTEM) of the same type connected together? NOTE Those APPLIED PARTS belong to several individual ME EQUIPMENTS of the ME SYSTEM. SC 62A answer to Q1: No, measure only "from" (i.e. to earth) not "to" all PATIENT CONNECTIONS of the same type of APPLIED PARTS of the ME SYSTEM connected together. Reason: SINGLE FAULT CONDITION tests with SUPPLY MAINS on APPLIED PART or with SUPPLY MAINS on SIP/SOP (represent "to" measurement) are N/A for a ME SYSTEM (see 16.1 and 16.6.3). Q2: Is it adequate that the total PATIENT LEAKAGE CURRENT of the ME SYSTEM in question is measured according to 8.7.4.7 h) separately for each individual ME EQUIPMENT belonging to the ME SYSTEM? SC 62A answer to Q2: No, this is not adequate. Individual tests of each item of ME EQUIPMENT or non-ME EQUIPMENT is anyway required and those individual measurements do not replace the ME SYSTEM tests of the total PATIENT LEAKAGE CURRENT. In addition: It is not explicitly written in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, but SC 62A recommends measuring the total PATIENT LEAKAGE CURRENT in an ME SYSTEM by combining all APPLIED PARTS of the same type of the whole ME SYSTEM together and measuring against earth. See also Annex A, subclause 16.6.3.

4.2.102 Pollution degree for MOPP

Recommendation number	102
Clause(s) number (only)	8.9, 8.9.1.1
Source/problem	IEC 60601-1 does not include requirements for MOPP in regards to pollution degrees 1 and 3.
Discussion/comment	There are no clear requirements in regards to pollution degree relative to MOPP.
Submitter proposed recommendation	Use Table 12 for MOPP as provided for pollution degrees 1, 2 and 3. NOTE Pollution degree 4 is not allowed as a MOP.
SC 62A recommendation	It is recommended to use Table 12 for MOPP for pollution degrees 1, 2 and 3. NOTE Pollution degree 4 is not allowed.

4.2.103 Transients on DC mains

Recommendation number	103
Clause(s) number (only)	8.9, 8.9.1.1
Source/problem	Transients on DC mains (e.g. ambulance power source).
Discussion/comment	The tables are based on AC mains transients. What about ME EQUIPMENT that operates from a DC mains such as an ambulance?
Submitter proposed recommendation	Apply Tables 12 through 16 as provided for ME EQUIPMENT connected to the DC mains.
SC 62A recommendation	It is recommended to apply Tables 12 through 16 for ME EQUIPMENT connected to the DC mains. Examples: a) pure external battery power: no MAINS TRANSIENT VOLTAGE exists; b) if the external DC power is derived out of an AC MAINS VOLTAGE (e.g. 230 V AC), use the concept already described in IEC 60601-1; c) if the external DC power is locally generated by a local generator (i.e. not derived out of MAINS VOLTAGE 230 V AC), for example by a generator of the ambulance, then use transient level Table 10, line 50 V RMS for primary DC circuit.

4.2.104 Altitude factor for DEFIBRILLATION-PROOF APPLIED PARTS

Recommendation number	104
Clause(s) number (only)	8.9, 8.9.1.1
Source/problem	Use of AIR CLEARANCE altitude multiplication factor for DEFIBRILLATION-PROOF APPLIED PARTS
Discussion/comment	Should the AIR CLEARANCE multiplication factor based on altitude (reference Table 8) be used for 8.9.1.15? It was mentioned that IEC 60601-2-4 could be referenced, but many APPLIED PARTS marked DEFIBRILLATION-PROOF are not in themselves defibrillators. The group felt that since the AIR CLEARANCE multiplication factor pertains to transients, it should apply. DEFIBRILLATION-PROOF TYPE CF APPLIED PARTS testing is conducted in IEC 60601-1 for three primary reasons, which include: 1) to ensure that the defibrillator energy at APPLIED PARTS does not transfer excessive energy to parts of ME EQUIPMENT that OPERATORS or other persons could touch during cardiac defibrillation; 2) to ensure that the ME EQUIPMENT does not lose more than 10 % of the total defibrillation energy across a 100 Ω resistor (see Figure 11); 3) to ensure that the ME EQUIPMENT remains functional (cardiac defibrillation recovery) within a specified period of time; As item 1) above directly relates to the CREEPAGE DISTANCE and AIR CLEARANCE requirement for 8.9.1.15 and is relative to the protection of OPERATORS rather than PATIENTS, the AIR CLEARANCE multiplication factors for altitude would be taken from Table 8 column heading "Multiplication factor for MOOP". However, these multiplication factors cause a large increase in the AIR CLEARANCE and it is doubtful that this is really necessary.
Submitter proposed recommendation	Apply the AIR CLEARANCE multiplication factor based on altitude to 8.9.1.15. Also, bump the CREEPAGE DISTANCE requirements to equal those of the AIR CLEARANCE according 8.9.1.4.
SC 62A recommendation	1) For DEFIBRILLATION-PROOF APPLIED PARTS, a minimum of 4,0 mm CREEPAGE DISTANCE and 4,0 mm AIR CLEARANCE are required. 2) For use in higher altitudes, the AIR CLEARANCE needs be corrected by a multiplication factor. According to Figure A.12, the MANUFACTURER has the choice to use MOPP instead of MOOP. The MOPP multiplication factor is less than the MOOP multiplication factor. The MOPP multiplication factor is sufficient. 3) Figure A.12 should be normative. This should be implemented in a future amendment of IEC 60601-1. 4) CREEPAGE DISTANCE requirements should be at least equal to those of the AIR CLEARANCE.

4.2.105 Defibrillation energy protection for MOOP/MOPP

Recommendation number	105
Clause(s) number (only)	8.9, 8.9.1.1
Source/problem	APPLIED PART separation MOP type.
Discussion/comment	Is APPLIED PART separation, for example in 8.9.1.15 for DEFIBRILLATION-PROOF APPLIED PARTS, considered a MOPP or MOOP? What about MAXIMUM MAINS VOLTAGE on APPLIED PARTS? Where the separation provides MOPP, such as during MAXIMUM MAINS VOLTAGE on APPLIED PARTS or DEFIBRILLATION-PROOF APPLIED PARTS and when measuring energy from other APPLIED PARTS, then that is a MOPP, whereas when the separation provides MOOP, such as DEFIBRILLATION-PROOF APPLIED PARTS and when verifying the energy at the ENCLOSURE or at SIP/SOP, then that is a MOOP.
Submitter proposed recommendation	Consider how the separation is being used. If for MOOP, then use the requirements for MOOP; if for the MOPP, then use the MOPP.
SC 62A recommendation	Consider how the separation is being used. If for MOOP, then use the requirements for MOOP; if for MOPP, then use the requirements for MOPP. However, Figure A.12 should be regarded as normative; consequently MOPP requirements are considered as satisfying both MOOP and MOPP requirements.

4.2.106 Overvoltage categories III and IV

Recommendation number	106
Clause(s) number (only)	8.9, 8.9.1.1
Source/problem	ME EQUIPMENT connected to overvoltage categories other than II.
Discussion/comment	IEC 60601-1 tables are based on overvoltage category II, except MOOP secondary which is overvoltage category I under certain conditions as defined in 8.9.1.12. What about overvoltage categories I, III, IV? ME EQUIPMENT meant for connection to another overvoltage category will need to meet requirements outside of the tables provided in IEC 60601-1.
Submitter proposed recommendation	Use IEC 60664 (all parts) or IEC 61010 (all parts) for requirements of CREEPAGE DISTANCE, AIR CLEARANCE and DIELECTRIC STRENGTH for ME EQUIPMENT connected to SUPPLY MAINS of overvoltage category III or IV.
SC 62A recommendation	Subclause 8.9.1.11 deals with this issue; therefore, there is no need for a recommendation.

4.2.107 Pollution degree related to different micro/macro environments

Recommendation number	107
Clause(s) number (only)	8.9 8.9.1.1
Source/problem	Application of pollution degree classifications.
Discussion/comment	Pollution degree initially is a micro environment exactly at the barrier concerned. However, there is a relation between the micro and macro environments under certain conditions. Normally one environment is applied. Based on the design of the ME EQUIPMENT or ME SYSTEM, more than one pollution degree can be applicable to different parts.
Submitter proposed recommendation	–
SC 62A recommendation	The answer can be found in IEC 60601-1:2005/AMD1:2012, Annex M.

4.2.108 Warnings versus ALARM SIGNALS

Recommendation number	108
Clause(s) number (only)	7.8.1, Table 2
Source/problem	A red indicator light signifies a "warning" but if it is not flashing in accordance with IEC 60601-1-8 requirements, it means that it is not an alarm. What is the difference between a warning and an alarm? Warnings are not alarms and generally do not require response by the OPERATOR. Potential conflicts include: – a constant yellow light could be a "caution" or a "low priority alarm"; – if a response from the OPERATOR is required – surely it is an alarm not a warning or caution.
Discussion/comment	A warning is normally something that alerts the OPERATOR but no immediate action is required but further action can be hazardous – for example a red light on a door to indicate that entering the room can be hazardous (lasers, X-ray, etc.). It might then be appropriate to initiate an alarm if the door is opened when the red light is on.
Submitter proposed recommendation	The meaning in Table 2 should not state "immediate response" or "prompt response" but just state "warning" for red and "caution" for yellow. The note in 7.8.1 should be made normative and state that flashing lights are only allowed for alarms.
SC 62A recommendation	It is recommended to use IEC 60601-1:2005, and IEC 60601-1:2005/AMD1:2012 Table 2, for warnings or cautions that are similar to a safety sign. A typical example would be an indicator accompanied by natural language describing the HAZARD or HAZARDOUS SITUATION. Where the ME EQUIPMENT needs to notify the OPERATOR of a situation that requires attention (e.g. immediate or prompt OPERATOR action is needed or when OPERATOR awareness is needed – see IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012, Table 1) to control RISK, an ALARM SYSTEM and ALARM SIGNALS are recommended (see IEC 60601-1-8:2006, Clause 4). NOTE Colour definitions of warnings, cautions, proper operation and alarms are according to IEC 60073, and IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 7.8.1. If the red light is flashing, it is an alarm signal. The response of the OPERATOR as currently addressed in IEC 60601-1:2005 Table 2, related to the meaning of warnings and cautions seems to be in conflict with definition 3.141 of IEC 60601-1:2005/AMD1:2012 for ALARM CONDITION. This should be clarified in a future revision of IEC 60601-1.

4.2.109 Single Y1 capacitor for MOPP

Recommendation number	109
Clause(s) number (only)	8.5.1
Source/problem	Is a single Y-capacitor between a secondary circuit and an APPLIED PART acceptable?
Discussion/comment	This issue is addressed in IEC 60601-1:2005/AMD1:2012.
Submitter proposed recommendation	–
SC 62A recommendation	The issue is already addressed in IEC 60601-1:2005/AMD1:2012.

4.2.110 WORKING VOLTAGE > 14 140 V peak

Recommendation number	110
Clause(s) number (only)	8.8.3, Table 6; 8.9
Source/problem	Solid insulation is only tested and separation distances are only measured if the WORKING VOLTAGE is less than 14 140 V peak or is specified in a particular standard. What tests should be done if there is no particular standard?
Discussion/comment	SC 62A is aware only of ME EQUIPMENT operating at voltages greater than 14 140 V having particular standards that describe what to do.
Submitter proposed recommendation	–
SC 62A recommendation	Usually, particular standards address the issue. For example, see IEC 60601-2-2, IEC 60601-2-22, IEC 60601-2-28, IEC 60601-2-36, IEC 60601-2-44, IEC 60601-2-54. If no particular standard exists for the EUT, then the particular standards that deal with high voltage insulation in the most similar way should be used as guidance.

4.2.111 CREEPAGE DISTANCE and AIR CLEARANCE for dental equipment

Recommendation number	111
Clause(s) number (only)	IEC 80601-2-60
Source/problem	This particular standard attempts to address the issue: "it is not possible to meet the requirements of IEC 60601-1 due to the small size of the dental electric motor" by allowing the minimum possible CREEPAGE DISTANCES and AIR CLEARANCEs obtained from IEC 60664 (all parts), which is a horizontal safety standard series that does not consider "PATIENTS". The allowable AIR CLEARANCEs are in fact less than those of IEC 60601-1 for MOOP. This would seem not to be acceptable following the rationale of IEC 60601. Firstly, apart from implications concerning the safety of dental equipment, the concern is that some MANUFACTURERS of ME EQUIPMENT having no particular standards will refer to particular standards that are for devices similar to their device and so can use IEC 80601-2-60 to demonstrate safety. Note that 8.9 of IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 is one of the many subclauses that do not allow consideration of RISK ASSESSMENT for making decisions of this nature; so this is major change in the rationale of IEC 60601 (all parts). Also, the impulse test method for determining the overvoltage category of secondary circuits and subsequent rationale for determining compliance limits for AIR CLEARANCEs proposed is a subject to be addressed in IEC 60601-1 and so this proposal should be addressed in a future revision of IEC 60601-1. The definition of PERMANENTLY INSTALLED should surely additionally state "and is not normally moved" or a similar phrase. Making ME EQUIPMENT PERMANENTLY INSTALLED does not necessarily decrease the RISK of PROTECTIVE EARTH CONDUCTOR damage. The alternative is to include mains cord restraint mechanical strength tests. The new dialysis machine standard attempts to get around the problem introduced by the home healthcare equipment standard, not allowing CLASS I equipment unless permanently installed, by a method that introduces additional problems in that dialysis equipment can be easily moved around the treatment room whilst "permanently installed", with the significant increase in RISK of mains cord earth conductor damage.
Discussion/comment	–
Submitter proposed recommendation	–
SC 62A recommendation	SC 62A refers to the particular standard and to the fact that the particular standard overrules IEC 60601-1. Definition of PERMANENTLY INSTALLED: The issue should be addressed in a future revision of IEC 60601-1.

4.2.112 Short-circuiting of one constituent part of DOUBLE INSULATION

Recommendation number	112
Clause(s) number (only)	8.1 b), first dash note 8.4.2 8.7.2, third dash Annex A, Subclause 8.7.2
Source/problem	Should short-circuiting of either constituent part of DOUBLE INSULATION be tested when we measure the leakage current, especially earth leakage current?
Discussion/comment	According to the reference subclause, it is not obvious whether SINGLE FAULT CONDITION of short-circuiting either part of DOUBLE INSULATION (DI) should be tested in terms of LEAKAGE CURRENT testing, or not. It is always incorrect that EARTH LEAKAGE CURRENT for the above SINGLE FAULT CONDITION is 2x because the applied voltage is 2x from Annex A, subclause 8.7.2, because power supplies complying with IEC 60950-1 (3,5 mA limit) can be used after isolating the transformer which has 1-MOP ONLY (between the primary and secondary coils) connected to the SUPPLY MAINS. Assuming that the SINGLE FAULT CONDITION should be tested by 8.1 b), 8.4.2 does not describe EARTH LEAKAGE CURRENT limit.
Submitter proposed recommendation	–
SC 62A recommendation	The issue is clearly addressed in 8.7.2, second and third dashes.

4.2.113 Instability in transport position

Recommendation number	113
Clause(s) number (only)	9.4.3.1
Source/problem	Compliance is unclear (contradictive) because it says: "prepare as described in 9.4.2.2" (NORMAL USE) directly followed by: "The MOBILE ME EQUIPMENT is placed in its transport position". There is no mentioning of the instructions. The text which follows within brackets implies that one shall follow the instructions, but it is unfortunate that the text is not as clear as in 9.4.2.1.
Discussion/comment	In 9.4.2.1, it is clear that the ME EQUIPMENT is set up in transport position as described in the instruction. Only if such information is missing, is the ME EQUIPMENT set up according to 9.4.2.2. The same would reasonably apply for 9.4.3.1.
Submitter proposed recommendation	This can be fixed either by using the same wording as in 9.4.2.1 or simply by changing the reference in 9.4.3.1 from 9.4.2.2 to 9.4.2.1.
SC 62A recommendation	It is recommended to change the reference in the 9.4.3.1 compliance paragraph from currently 9.4.2.2 to 9.4.2.1.

4.2.114 Delay time for conducting leakage current tests after humidity preconditioning treatment

Recommendation number	114
Clause(s) number (only)	8.7.1
Source/problem	IEC 60601-1:1988 required that LEAKAGE CURRENT measurement be conducted starting 1 h after the humidity preconditioning treatment. It appears that IEC 60601-1:2005 does not specify a delay time?
Discussion/comment	8.7.1 b) – at operating temperature and following the humidity preconditioning treatment, as described in 5.7. Is this a gap in IEC 60601-1? What would be the appropriate delay time?
Submitter proposed recommendation	–
SC 62A recommendation	After humidity preconditioning treatment, LEAKAGE CURRENT testing should be conducted immediately after the DIELECTRIC STRENGTH test has been completed (no delay time).

4.2.115 DEFIBRILLATION-PROOF TYPE B APPLIED PARTS

Recommendation number	115
Clause(s) number (only)	8.5.5
Source/problem	DEFIBRILLATION-PROOF testing on operating tables in IEC 60601-2-46. IEC 60601-1 requires that if the APPLIED PART (the table top) has conductive parts, it shall be possible to connect these parts to potential equalization (where locally so required). Defibrillation-proof testing is performed also without connection to protective earth and potential equalization. The former exclusion (energy on the ENCLOSURE) as present in Clause 17 in edition 1 of IEC 60601-2-46 and in 201.8.5.5.1 in draft edition 2 is not present in the published edition 2 (IEC 60601-2-46:2010). How is defibrillation-proof testing performed on a table with Type B defibrillation-proof rating and conductive APPLIED PART?
Discussion/comment	–
Submitter proposed recommendation	–
SC 62A recommendation	Test should be performed according to applicable standards. It has to be clearly distinguished between the APPLIED PART and ENCLOSURE parts. The defibrillation energy measurement should not be conducted from surfaces which are APPLIED PARTS, but only from surfaces which are ENCLOSURE parts. If hazardous electrical energy appears on the ENCLOSURE, which might be conductively connected to the DEFIBRILLATION-PROOF TYPE B APPLIED PART, then this is a FAIL. The operating table top surface is the APPLIED PART, so the defibrillation energy measurement should not be conducted from that surface as well. Measurements should be done from parts, which are not the APPLIED PART, for example the operating table legs. Consequently, if the operating table legs are not isolated from the operating table top surface (=APPLIED PART), this design fails.

4.2.116 Instability excluding transport position

Recommendation number	116
Clause(s) number (only)	9.4.2.2, compliance paragraph
Source/problem	The second sentence leads to various interpretations on the floor surface used, leading to non-repeatable test results.
Discussion/comment	The hardness of the material and the friction between wheels and floor surface has a significant impact on test results. The base material is not critical but it shall be hard and flat and thus concrete is a good example. The top material is however critical. It seems the intention of IEC 60601-1 was to state vinyl flooring as the top material, simulating the vast majority of hospital flooring. With this in mind it seems there is a typo in the text. Moving the end-bracket from the end of the sentence to after "floor" would rectify the problem making the vinyl floor normative.
Submitter proposed recommendation	Change the wording within brackets to read: "(e.g. concrete floor)"
SC 62A recommendation	To better ensure test repeatability the following is recommended: "*The test floor surface is to be hard and flat (e.g. concrete floor) covered with 2 mm to 4 mm thick vinyl flooring material.*"

4.2.117 DIELECTRIC STRENGTH of two serial MOPP barrier parts

Recommendation number	117
Clause(s) number (only)	8.8.3 Table 6
Source/problem	The fact that each MOPP of 2 MOPPs shall withstand 1 500 V can be misinterpreted that 3 000 V total would be sufficient for 2 MOPP in the form of DOUBLE INSULATION and that 4 000 V is required only for 2 MOPP in the form of REINFORCED INSULATION. The rationale states that each individual MOPP has to meet the 1 500 V. There is no requirement for a MOPP to pass a 2 500 V test.
Discussion/comment	Is a recommendation required to clarify that DIELECTRIC STRENGTH test is to be applied first with 1 500 V each and then followed by 4 000 V total?
Submitter proposed recommendation	–
SC 62A recommendation	We suggest two options to meet the requirements of IEC 60601-1: Option 1: If a 2 MOPP barrier is clearly divided in two individual serial 1 MOPP barriers (without any bypass), each one should be tested with minimum of 1 500 V. However, due to the fact that both barriers together should reach the 4 000 V level, one of the two barriers should comply with a higher test voltage of 2 500 V. In the case that 1 MOPP complies with a DIELECTRIC STRENGTH test voltage higher than 1 500 V (e.g. 1 900 V) but less than 2 500 V, the other 1 MOPP barrier should be able to withstand the rest up to a total 4 000 V for both MOPPs together, i.e. here 2 100 V (1 900 V + 2 100 V = 4 000 V). When option 1 is applicable and is used, a DIELECTRIC STRENGTH test of the total 2 MOPP barrier with 4 000 V should not be required. Option 2: a) Each single 1 MOPP should be tested with minimum 1 500 V, **and** b) The whole 2 MOPP should be tested with 4 000 V.

4.2.118 Overheating transformer

Recommendation number	118
Clause(s) number (only)	15.5.1.1
Source/problem	The text in the heading of Table 31 (contrary to edition 2) includes a tolerance of ± 5 °C. This implies that the 25 °C is a test condition only but the temperature to be compared to the limits in Table 31 shall be the temperature rise plus the specified ambient. Also, the rationale (last paragraph) indicates this is the case. The rationale implies that SINGLE FAULT CONDITION and overload would be hard to do in a chamber. This in turn implies that NORMAL CONDITION testing would not be hard to do in a chamber, which seems a bit strange. To use temperature rise plus the specified ambient is logical because the ambient is normally not different at SINGLE FAULT CONDITION compared to NORMAL CONDITION. However, if this is the intention of IEC 60601-1, it is much more stringent versus edition 2 where we (and several other test laboratories) have always used temperature rise + 25 °C during SINGLE FAULT CONDITION and overload testing.
Discussion/comment	One standard committee member proposed in May 2009 that transformers with protective device should be tested at 25 °C while impedance protected transformers should be tested at specified ambient. Irrespective of test conditions, which is the correct temperature to add to the measured temperature rise? Is an interpretation/recommendation needed to clarify the test conditions and the temperature to be added to the measured temperature rise?
Submitter proposed recommendation	–
SC 62A recommendation	Annex A, subclause 15.5.1.1, clarifies that the results of overload and short-circuit tests are based on exactly 25 °C ambient temperature. If the ambient temperature deviates in the laboratory from 25 °C but remains in the range of 20 °C to 30 °C, a necessary adjustment of the measured values back to 25 °C should be done. In addition, a future revision of IEC 60601-1 should reconsider if it would be more appropriate to adjust the measurement result to real allowed ambient temperature instead of 25 °C.

4.2.119 Test equipment for recurrent tests according to IEC 62353 testing used within IEC 60601-1 type approval testing

Recommendation number	119
Clause(s) number (only)	8.7, 8.6.4
Source/problem	Maintenance test equipment (i.e. test equipment for recurrent test) used for type approval tests according to IEC 60601-1. The question is: Are there accuracy and test method concerns if maintenance test equipment is used for a different purpose in the field of IEC 60601-1 type approval testing? The maintenance test equipment is usually designed for – periodic safety checks when the medical device is already on the market, – MANUFACTURER production line end tests, and – interim tests of the production line. However, maintenance tests are not suitable for test laboratories performing initial tests (type approval tests) according to IEC 60601-1 for approval purposes due to the following reasons. – The PATIENT LEAKAGE CURRENT measurement with mains voltages on the APPLIED PART shall be conducted with a resistor used in series with the MD. The resistor for BF 230 V shall be modified according to IEC TR 62296 recommendation number, which is usually not implemented. – Such devices uses a "normalized voltage" of their input voltage instead of 110 % of the RATED (label) medical device voltage. For example: If the available power socket has 220 V, measurement will be done with 242 V instead of 264 V, which is based on the label of the medical device (240 V) plus 10 %. – Sometimes, the second isolated power for e.g. mains on the APPLIED PART is not 110 % of the RATED input voltage (264 VAC). – In other cases, the test equipment measures with 100 % of the voltage and calculates the 110 % value only. – Sometimes, such test equipment cannot select between 50 Hz and 60 Hz measurements. – Accuracy is not adequate, and therefore CTL sheet 251A (B) not fulfilled. NOTE The LEAKAGE CURRENT measurement according to 8.7.4.4 requires to use a voltage measuring instrument (not the measuring device) which is able to indicate true RMS values of frequencies up to 1 MHz. To indicate such high frequencies is usually only possible by using an oscilloscope. Using a multimeter might not be sufficient, because those are often limited to kHz frequencies. – Such automatic test equipment is not able to select single tests and therefore cannot wait until the ME EQUIPMENT is within a special mode (e.g. standby mode). – Perhaps 3rd edition test setups cannot be implemented. – Such devices work with internally relays. The contacts of the relays-switch are not visible from the outside. The contacts of such relays are oxidised after some period of use due to flashovers during switching high currents. This leads to contact resistance, which influences the correct detection of leakage currents.

Recommendation 119 *(continued)*

	– The verification of the MD (1 kΩ // 10 kΩ // capacitor) is not possible from the outside before each measurement. Therefore, the test expert shall trust the calibration label, even if it is 11 months old. Consequently, one can never be sure if the test result is correct until the next calibration is successfully finished. Concretely, this means there exists a high probability of "recall" of all tested medical device by a test laboratory in a 11-month period, i.e. the test laboratory shall contact e.g. 100 medical manufacturers and request a retesting of their product free of charge (image damaged). – Sometimes, it is questionable if "T RMS" measurements will be conducted. – Not all switch conditions of IEC 60601-1 are possible, for example testing during stand-by. – Testing with a MD independent from waveform and frequency according to 8.7.3 e) is not possible. – Such devices are not suited to test high power (16 A). – Such devices are not suited to test 3 phase systems such as X-ray. – Such devices are not suited for testing ME SYSTEMS (IEC 60601-1-1) with two POWER SUPPLY CORDS or with one POWER SUPPLY CORD, which contains two protective earth conductors. – Tests according to 8.5.1.2 and 8.5.1.3 (protective impedance) are not possible. – During measurement of mains voltages at a floating F-type APPLIED PART, the internal intermediate circuits which have a connection to the SIP/SOP are not earthed as required by IEC 60601-1 (8.7). – The protective earth of the installation will be used as protective earth reference pole of the test set-up. This could lead to wrong test results for CF devices (PATIENT LEAKAGE CURRENT = 10 μA) if the protective earth of the installation building is not "clean". – Sometimes, DC/AC values are not distinguished. – Canada requires 40 A protective earth test. Such devices do not carry out protective earth tests with 40 A. Sometimes, it works with 10 A only (those required in IEC 60601-1 are 25 A). If the input fuses are very high, due to high input power (MRI 200 A per phase), then the protective earth test shall be conducted with, for example, 1,5 times the rated input current.
Discussion/comment	The above overview shows many concerns if maintenance test equipment would be used for type approval tests according IEC 60601-1. However, SC 62A is of the opinion that IEC 60601-1 is already clear enough related to the accuracy of the test equipment and the correct test method. Test laboratories within the CB-scheme are not concerned because, if they use not-suited test equipment, this would be detected, for example during IECEE audits or during IECEE proficiency tests.
Submitter proposed recommendation	Issue a recommendation not to allow recurrent test equipment for IEC 60601-1 type approval tests as long as no objective evidence of suitability related to all IEC 60601-1 requirements, for example those listed in the above overview, is given.
SC 62A recommendation	SC 62A is not responsible for dealing with suitable test equipment and possible testing errors based on selection of unsuitable test equipment.

4.2.120 Tolerances of apparatus

Recommendation number	120
Clause(s) number (only)	9.4.2.4.3, 15.3.5 a), 15.3.5 b), 15.3.5 c)
Source/problem	Linear dimension tolerances; for threshold and rough handling apparatus
Discussion/comment	Key dimensions are 10 mm (when using IEC 60601-1:2005/AMD1:2012), 20 mm, and 40 mm. No tolerances are specified. Tolerance allowed by CB decision 251B, year 2009: For linear dimensions: 1 mm up to 25 mm, ±0,1 mm 25 mm and higher mm, ±0,5 % for 10 mm, tolerance of ±0,1 mm for 20 mm, tolerance of ±0,1 mm for 40 mm, tolerance of ±0,2 mm Our group (SC 62A, WG 17/MT 29) recognized that there would be metric board sizes and slightly different American board sizes. Perhaps we should have put intended tolerances in clauses. As this was not done, we would like to suggest that there be a recommendation to specify tolerances that were intended.
Submitter proposed recommendation	Tolerances intended: the greater of ± mm or ± 5 % tolerance. for 10 mm, tolerance ± 1 mm for 20 mm, tolerance ± 1 mm for 40 mm, tolerance ± 2 mm
SC 62A recommendation	9.4.2.4.3 specifies tolerances as specified in IEC 60601-1:2005/AMD1:2012, which is ±0,5 mm for a 10 mm threshold. SC 62A recommends the following proposal: ±5 % should be applied as the tolerance of values from 15.3.5 a), 15.3.5 b), and 15.3.5 c) of IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012. NOTE Due to humidity reasons, a very small tolerance is not practical.

4.2.121 FUNCTIONAL EARTH CONDUCTOR and ESSENTIAL PERFORMANCE

Recommendation number	121
Clause(s) number (only)	8.1 a) last dash 8.1 b) last dash 8.6.9
Source/problem	This comment is not necessarily related to electrical HAZARDS. It concerns contradiction in the two clauses. If 8.1 a) last dash overrides 8.1 b) last dash, there seems little point in allowing functional earth connections at all, since they can often be used to prevent loss of ESSENTIAL PERFORMANCE. If a mains earth connection complies with IEC 60601-1:2005, subclauses 8.6.2, 8.6.3 and 8.6.5, for the requirements for a protective earth, then failure of this connection should not be a NORMAL CONDITION but a SINGLE FAULT CONDITION. Note this might not be related to "electrical hazards" and so should not be confined to Clause 8. Further, concerning 8.6.9, the internal FUNCTIONAL EARTH CONDUCTORS should not be green/yellow so as not to be confused with PROTECTIVE EARTH CONDUCTORS (note that IEC 60950 (all parts) does not allow green/yellow).
Discussion/comment	–
Submitter proposed recommendation	Allow disconnections of mains earth connections that comply with IEC 60601-1:2005, 8.6.2, 8.6.3 and 8.6.5, for the requirements for a protective earth to be a SINGLE FAULT CONDITION. Allow internal FUNCTIONAL EARTH CONDUCTORS to be not green/yellow.
SC 62A recommendation	If a FUNCTIONAL EARTH CONDUCTOR is used as a RISK CONTROL measure to achieve ESSENTIAL PERFORMANCE, then it should be constructed in a way which allows a break of the FUNCTIONAL EARTH CONDUCTOR to be regarded as a SINGLE FAULT CONDITION. Mechanical construction aspects (see 8.10.2) are required. The current carrying capacity requirement (see 8.6.4 for protective earth) does not apply. Subclause 8.6.9 does not require that internal FUNCTIONAL EARTH CONDUCTOR to be green yellow, because it speaks about the POWER SUPPLY CORD.

4.2.122 AC motors

Recommendation number	122
Clause(s) number (only)	8.5.4
Source/problem	Resonance voltage on start capacitors on motors subclause 8.5.4 and CREEPAGE DISTANCE and AIR CLEARANCE values related to slot insulations in motors. From 8.5.4, it is clear that the measured U_c (voltage at cap) shall be used as the U (WORKING VOLTAGE) when establishing the test voltage (same as in edition 2). There is no similar statement regarding U_c for isolation distances (same as in edition 2). In practice, test laboratories have strictly applied the U_c only for DIELECTRIC STRENGTH on motors and not for isolation distances in motors. The relaxation of CREEPAGE DISTANCE allowed per 57.10 a) in edition 2 is no longer present in edition 3. If U_c shall be applied as well for AIR CLEARANCE and CREEPAGE DISTANCE, without any relaxation of creepage, very few motors will pass testing to IEC 60601-1 since they are mostly designed for industrial applications and house-hold appliances. Shall U_c be applied for AIR CLEARANCE? Shall U_c be applied for CREEPAGE DISTANCE?
Discussion/comment	Since withstand voltage is related/based on clearance, it is perhaps logical that the U_c shall be applied also for AIR CLEARANCE. However, if applied to CREEPAGE DISTANCE, many motors previously complying with edition 2 will now fail.
Submitter proposed recommendation	The measured U_C is used for DIELECTRIC STRENGTH but not for AIR CLEARANCE and CREEPAGE DISTANCE.
SC 62A recommendation	Requirements for motors are not fully given in IEC 60601-1, so it is unaddressed in IEC 60601-1. It is recommended: DIELECTRIC STRENGTH: WORKING VOLTAGE according to 8.5.4, seventh dash, should be applied. CREEPAGE DISTANCE: The MAINS VOLTAGE (not the resonance voltage) should be applied as WORKING VOLTAGE for motors. For slot insulation of motors, a reduction to 50 % of the values of Table 12 or Table 16 for CREEPAGE DISTANCES shall be allowed, with a minimum of 2 mm at 250 V. The 50 % reduction of CREEPAGE DISTANCE for all types of motors should be used, not just AC motors with resonance voltage. AIR CLEARANCE: The MAINS VOLTAGE to the motor (not the resonance voltage) as WORKING VOLTAGE for motors should be used, and Table 12 or Table 13 should be used. Apply rule 8.9.1.4 (CREEPAGE DISTANCE never less than AIR CLEARANCE) and 8.9.1.5 (altitude factor). NOTE The solution is partly based on IEC 60601-1:1988.

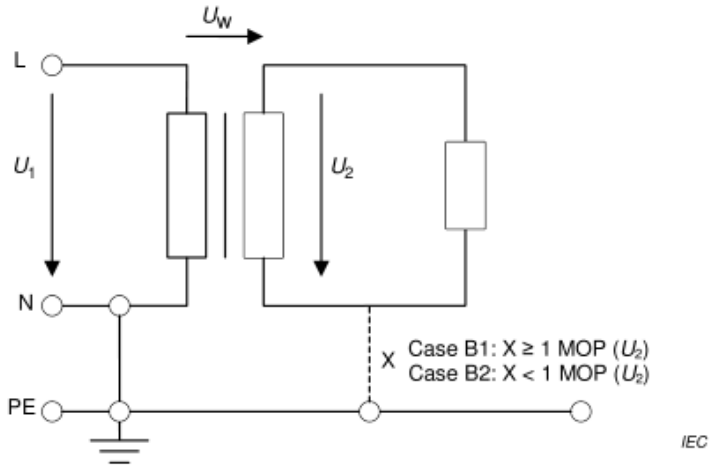
4.2.123 Operational insulation

Recommendation number	123
Clause(s) number (only)	8.1
Source/problem	In the IECEE Test Report Form (TRF) IEC60601_1G:2010-12, only MOP (MOOP or MOPP) are defined. How shall the operational insulation be recorded in the insulation diagram and table?
Discussion/comment	–
Submitter proposed recommendation	OP Insulation shall show up in the insulation diagram (e.g. with an addition comment that is not relied on for safety).
SC 62A recommendation	IEC 60601-1 does not have a definition for the term "operational insulation" = functional insulation barrier. However, for better understanding of the insulation diagram and the design of the ME EQUIPMENT, SC 62A supports that it could make sense to document the "operational insulation" in the TRF, for example at the insulation diagram.

4.2.124 WORKING VOLTAGE measurement

Recommendation number	124
Clause(s) number (only)	8.5.4
Source/problem	IEC 60601-1 does not describe how to measure WORKING VOLTAGE on floating parts. How shall WORKING VOLTAGE measurement be performed on floating parts?
Discussion/comment	–
Submitter proposed recommendation	Use procedure of IEC 60950-1:2005, 1.4.9 (excerpted below).
SC 62A recommendation	It is recommended to measure WORKING VOLTAGE according to the procedure in IEC 60950-1:2005, 2.10.2: Case A (estimated to cover > 95 % of all cases): If a transformer winding or other part is not connected to a circuit that establishes its potential relative to earth, it should be assumed to be earthed at the point by which the highest WORKING VOLTAGE is obtained. In real practice, it can be achieved by using a PEN (protective earth connected to neutral) line in the installation, or an earth connection by a SIP/SOP, or an earth potential by the PATIENT – APPLIED PART. Case B (estimated to cover < 5 % of all cases): Two different possibilities exist (see Figure 1 below): B1) The floating circuit (U_2) is isolated by 1 MOP (based on the floating circuit voltage U_2) to earth. The WORKING VOLTAGE (U_w) of the MAINS barrier is the highest voltage of one side of the barrier concerned for which the WORKING VOLTAGE is determined, i.e. either U_1 or U_2 whichever is higher. B2) The floating circuit (U_2) is not at least isolated by 1 MOP (based on the floating circuit voltage U_2) to earth: for the measurement of the WORKING VOLTAGE (U_w) of the MAINS barrier, both sides have to be earthed for U_w measurement to get repeatable worst case results.

Recommendation 124 *(continued)*

Recommendation (continued)	
	 **Figure 1 – WORKING VOLTAGE measuremnent**

4.2.125 Defibrillation test

Recommendation number	125
Clause(s) number (only)	8.5
Source/problem	Defibrillation tests on conductive TYPE B APPLIED PARTS, e.g. an operating table.
Discussion/comment	IEC 60601-1 requires that, if the APPLIED PART (the table top) has conductive parts, these parts shall be possible to connect to a POTENTIAL EQUALIZATION CONDUCTOR (where locally so required). The defibrillation test is performed also without connection to protective earth and the POTENTIAL EQUALIZATION CONDUCTOR. The former exclusion (energy on the ENCLOSURE) as present in Clause 17 in edition 1 of IEC 60601-2-46 and in 201.8.5.5.1 in draft edition 2 is not present in the published edition 2 (IEC 60601-2-46:2010). If tested as described in IEC 60601-1, there will be a short-circuit of the test voltage which would normally be a failure. How is defibrillation test performed on a table with Type B defibrillation-proof and conductive APPLIED PART?
Submitter proposed recommendation	I have no proposal.
SC 62A recommendation	The issue belongs to the committee responsible for the particular standard. Please contact the expert group responsible for IEC 60601-2-46 or rephrase the question without any link to a particular standard. See in addition recommendation 4.2.115.

4.2.126 Oil containers for moving parts

Recommendation number	126
Clause(s) number (only)	15.4.9
Source/problem	There is a fixed equipment with multiple movement and axis, where components under questions are moved in such a way that they can be compared with PORTABLE equipment. Do motors, gear boxes of such fixed equipment fall under this subclause? If yes, does it apply also for FIXED equipment with multiple movements where these parts move around? What is the understanding of "partially sealed"?
Discussion/comment	–
Submitter proposed recommendation	The recommendation shall make clear how to handle such components.
SC 62A recommendation	15.4.9 c) applies. 15.4.9 a) and b) do not apply if strictly following the wording of IEC 60601-1, because the described ME EQUIPMENT is neither PORTABLE nor MOBILE. However, the safety relevant aspects behind these items make sense. Therefore, it is recommended to follow the RISK MANAGEMENT approach, which refers back to International Standards in ISO 14971:2007, 3.2 and then to apply 15.4.9 a) and b) but ignoring the words PORTABLE and MOBILE. NOTE See as well the RISK MANAGEMENT requirement in 13.2.6 about leakage and liquids.

4.2.127 PERMANENTLY INSTALLED ME EQUIPMENT in the HOME HEALTHCARE ENVIRONMENT

Recommendation number	127
Clause(s) number (only)	3.84 of IEC 60601-1:2005, 7.5.1 of IEC 60601-1-11:2010 and IEC 60601-1-11:2015
Source/problem	We had a home care product in protection class I with the typical Schuko mains plug. The installation in the home is always done by the MANUFACTURER'S own personnel. In order to comply with the requirements for permanent connection, the MANUFACTURER used a metal locking device that was screwed into the wall (one screw on each side of the wall socket outlet). This way, the plug could not be detached without the use of a tool and thus IEC 60601-1 was fulfilled when reading it to the letter rather than understanding what I believe is the intent of IEC 60601-1. Of course the quality of the protective earth connection between the wall socket outlet and plug does not become better simply because the plug cannot be pulled out. Right or wrong, we did not accept the design. The MANUFACTURER decided instead during installation to exchange the wall socket outlet to a correct installation box with a cord anchorage and cord guard. Because the product was MOBILE they also added a steel wire, shorter than the mains cord, to relieve the cord from strain. We accepted this design. However, there can be severe strain when a 100 kg MOBILE equipment is moved so the fixing shall be very well dimensioned. I think IEC 60601-1 is too vague in the definition of PERMANENTLY INSTALLED.

Recommendation 127 *(continued)*

Discussion/comment	SC 62A discussion: This answer applies only to the home care environment, not to the hospital environment. The SC 62A interpretation of the wording of IEC 60601-1:2005 and IEC 60601-1-11:2010 and IEC 60601-1-11:2015 concludes that the solution of securing a mains plug with two screws would fulfil the requirement of IEC 60601-1. NOTE 1 The design described above has a fuse inside of the ME EQUIPMENT in the neutral line, which is not allowed for permanently installed equipment. IEC 60950-1 allows to fuse the neutral only if adequate warnings are used. However, the issue itself clearly falls within the responsibility of IEC 60601-1-11. Therefore, SC 62A has forwarded this issue to the expert group responsible for IEC 60601-1-11 for their decision. NOTE 2 See IEC 60601-2-16 for specialized unique plug allowed under certain condition with class I ME EQUIPMENT. Example locking type receptacle.
Submitter proposed recommendation	–
SC 62A recommendation	Having considered the question at their January 2013 meeting in London, UK, IEC/SC 62A-ISO/TC 121/SC 3 Joint Working Group (JWG) offered the following opinion. 1) This concern can better be addressed by the particular standard for this type of ME EQUIPMENT if it is felt that a CLASS II SUPPLY MAINS connection is not feasible. The recommended connection would be for the particular standard to specify a type of suitable locking sturdy plug that is not commonly found in the home healthcare setting which would require a suitably trained electrician to install the protective earth enabled connection point in the HOME HEALTHCARE ENVIRONMENT for the SERVICE PERSONNEL to use when installing the ME EQUIPMENT in the home. This would allow a secure assured protective earth and a heavy cord that would not likely be pulled from the socket but would allow for easy transfer of the MOBILE equipment. 2) However, if one company shows that this ME EQUIPMENT can be put on the market without a CLASS I SUPPLY MAINS connection, it would seem that a CLASS II SUPPLY MAINS connection would eliminate many reasonably foreseen RISKs as highlighted in the rationale of Clause 6 of IEC 60601-1-11:2010 and of IEC°60601-1-11:2015 and the state of the art would not be a CLASS I SUPPLY MAINS connection. 3) Until the year 2013 it is known that at least one MANUFACTURER of home use dialysis is going to 2-prong plugs to bring their product into compliance (i.e. it can be done for this class of equipment). 4) From a RISK MANAGEMENT viewpoint, unless the two screws are not connected to a "normal" mains receptacle, the HAZARDOUS SITUATION of NO protective earth in the receptacle has not been solved. 5) There are no grounded outlets in many countries (parts of Scandinavia and Japan, for instance). So any conventional outlet (mains receptacle) will have no protective earth unless it is custom installed. Plugging equipment that requires a protective earth to be SINGLE FAULT SAFE into an ungrounded outlet is an unacceptable RISK. That notwithstanding, if the installation process requires that the effectiveness of the ground in the receptacle is verified and the plug is then connected with 2 screws (needs a tool), the design would comply with the requirements in the standard. But it is reasonably foreseeable that the home user will move the equipment to a different location (a receptacle without a PE) and thereby create an unacceptable RISK. Any MANUFACTURER doing that is taking a significant (unacceptable) RISK, even though they are technically in compliance with the standard.

Recommendation 127 *(continued)*

SC 62A recommendation (continued)	SC 62A additional information: To fix a mains plug with screws to the wall is against the national electrical code in some countries. Separation from mains shall be ensured by suitable mains switches or DETACHABLE POWER SUPPLY CORD.

4.2.128 Polystyrene plate for LEAKAGE CURRENT tests

Recommendation number	128
Clause(s) number (only)	8.7.4.3 d) 1)
Source/problem	8.7.4.3 d) 1) Measuring arrangements. Background: 8.7.4.3 d) 1) Measuring arrangements – APPLIED PARTS: dielectric constant of approximately 1 and approximately 200 mm above an earthed metal surface. During an internal audit, we were questioned on how we ensured compliance to 8.7.4.3 d) 1) testing setup/requirements?
Discussion/comment	The question raised a number of additional questions related to whether the subclause requirement is really needed or not. So we made some calculations to see if dielectric constant or distance above an earthed metal surface has a significant impact on the measurement arrangement (read – adds significant capacitance to the measurement circuit). IEC 60601-1:2005, 8.7.4.4, allows the voltage measuring equipment to have an input capacitance of up to 150 pF, so we use this value as the limit for our calculations. Assumption: Large size APPLIED PART (10 cm × 20 cm) Calculation (1) – What if E r is much higher than 1? Calculation example: C stray = 150 pF, Distance to protective earth surface with same size: 200 mm, Result E r = 169 Calculation (2) – What if the distance is much less than 200 mm? Calculation example: C stray = 150 pF, E r = 1 Result: Distance to protective earth = 1,1 mm From the two examples, it can be concluded: a) General: The C stray has a reverse linear impact on the capacitive resistance and therefore as well a linear impact on the final measured leakage current. As long as the measuring equipment does not have more than 150 pF input capacitance, it does not have any significant impact on the final measured leakage current. The assumption here is that additional 150 pF as C stray of the test set up will as well not have any significant impact on the final leakage measurement. b) Example 1: IEC 60601-1 requires using an insulating surface with a dielectric constant of approximately 1. However, the calculation in example 1 shows that even a dielectric constant of 169 would not increase the C stray value above 150 pF. c) Example 2: IEC 60601-1 requires using a distance of 200 mm. However the calculation in example 2 shows that even a distance of only 1,1 mm would not increase the C stray value above 150 pF.

Recommendation 128 *(continued)*

Submitter proposed recommendation	Suggested revision to 8.7.4.3 d) 1) or its rationale to the following guideline: (1) Use a wood work bench well insulated from protective earth and without conductive protective earth layers. The stray capacitance to protective earth is therefore much lower than 150 pF as indicated in our calculations. (2) ESD protected work bench. Some labs use ESD protected work benches, which are provided with a conductive surface connected reference to protective earth by approximately 100 kΩ. The 100 kΩ resistor prevents excessive LEAKAGE CURRENT to PE, but in order to protect against hazardous LEAKAGE CURRENT to our lab-tech, the table shall be covered with insulation material. The thickness and relative permittivity is without relevance to the measurement. (3) Steel type work bench. In case of testing on a steel work bench connected to PE, the lab-tech shall ensure proper insulation material between the workbench and APPLIED PART. Such material could be a wood plate having a thickness larger than 8 mm, since the relative permittivity for wood is below 5. (C stray = 110 pF, d = 8 mm, E r = 5)
SC 62A recommendation	SC 62A is not aware of the origin of the test set-up as described in 8.7.4.3.d) 1). SC 62A recommends regarding tests conducted on an isolated surface as sufficient. However, for TYPE CF APPLIED PARTS, it is recommended to conduct the tests as required in 8.7.4.3 d) 1), in order to ensure reproducibility of test results for these sensitive measurements.

4.2.129 Push buttons

Recommendation number	129
Clause(s) number (only)	7.4.2
Source/problem	Push buttons usually do not have different 'working positions' (e. g. switches).
Discussion/comment	Is 7.4.2 applicable for push buttons? How to fill in verdict in Test Report Form (TRF)?
Submitter proposed recommendation	—
SC 62A recommendation	The issue is already addressed in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 7.4.2. A push button could be a control device/switch.

4.2.130 Temperature limit at the ENCLOSURE in SINGLE FAULT CONDITION

Recommendation number	130
Clause(s) number (only)	13.1.2
Source/problem	Table 23 applies for both NORMAL CONDITION and SINGLE FAULT CONDITION
Discussion/comment	13.1.2 states in the fourth dash that, for parts likely to be touched, Table 23 applies, i.e. same levels as in NORMAL CONDITION. It seems quite unclear what the allowed temperature on an ENCLOSURE is. ENCLOSUREs, in most cases, are likely to be touched at some point. On the other hand, to have the same limit as in NORMAL CONDITION seems very stringent compared to many other standards. Is this the intention of IEC 60601-1? The second dash implies that some deformation of an ENCLOSURE is allowed as long as it complies with 15.3.1. This is confusing because how can an ENCLOSURE be allowed to deform without a temperature higher than in NORMAL CONDITION? For comparison, IEC 61010-1 allows Total 105 °C (at ambient 40 °C) during SINGLE FAULT CONDITION. What is the temperature limit on an ENCLOSURE during SINGLE FAULT CONDITION testing if it is likely to be touched at some point/occasion? Does the fifth dash apply (other components and materials) when the ENCLOSURE is not likely to be touched?
Submitter proposed recommendation	Use fifth dash in 13.1.2 for temperatures on ENCLOSUREs during SINGLE FAULT CONDITION.
SC 62A recommendation	See Interpretation Sheet ISH 03 published in May 2013 as solution for this issue. Temperatures of ME EQUIPMENT parts that are not APPLIED PARTS but are likely to be touched, exceeding the allowable values in Table 23 when measured and adjusted as described in 11.1.3. The above standard requirement is clarified by the following: The above requirement is regarded as fulfilled in accordance with 4.5 for temperatures at the surfaces of the ENCLOSURE, if the following conditions are fulfilled: – the maximum allowed temperature on OPERATOR accessible surfaces in SINGLE FAULT CONDITION is 105 °C; and – the instructions for use contain a warning that, under some SINGLE FAULT CONDITIONS, the temperature of: (*indicate the surface of concern*) could get hot and there is a possible RISK of a burn if touched; and – if the RISK ANALYSIS demonstrates a need for a warning symbol on the ENCLOSURE, safety sign ISO 7010-W017:2011-05 () shall be used on or adjacent to the hot spot on the ENCLOSURE; and – the RISK ASSESSMENT demonstrates that the temperature attained in the SINGLE FAULT CONDITION is acceptable; and – the RISK ASSESSMENT demonstrates that applying the alternative RISK CONTROL measures in Interpretation Sheet ISH 03 results in a RESIDUAL RISK that is comparable to the RESIDUAL RISK resulting from applying the requirement of the standard. NOTE See ISO 13732-1 for consideration in a future revision of IEC 60601-1.

4.2.131 Optic coupler requirements

<table>
<tr><td>Recommendation number</td><td>131</td></tr>
<tr><td>Clause(s) number (only)</td><td>4.8, 8.5, 8.8.2, 8.8.3, 8.9.1, 8.9.3</td></tr>
<tr><td>Source/problem</td><td>Optic couplers: Do the ME EQUIPMENT end-product standard's insulation requirements apply?</td></tr>
<tr><td>Discussion/comment</td><td>
According to 4.8 a), an optic coupler providing at least 1 MOP would need to comply with applicable optic coupler standard, IEC 60747-5-5:2007 (replaces optic clauses from IEC 60747-1, -2, -3). This standard has appropriate insulation requirements for MOOP, however it does not include the 0,4 mm single layer thickness requirement in 8.8.2 of IEC 60601-1:2005, nor does it require the 30 day cemented joint requirement in 8.9.3. It does require a partial discharge test for solid insulation, including cemented joints, and presumably there is aging/conditioning done prior to partial discharge. Presumably is not appropriate for the CR, CL, DS requirements considered necessary for MOPP.

According to Figure 5, which is associated with 4.8 a), there is a decision box at end that says after complying with component standard, "are additional end product requirements necessary?" I am not sure how the flow chart matches with the wording of 4.8, but it would seem it is always appropriate to consider any ME EQUIPMENT end-product requirements that might be appropriate for a general component used with ME EQUIPMENT.

Questions:

Assuming optic coupler provides at least 1 MOP, complies with IEC 60747-5-5:2007 and is being used within its ratings (as required by 4.8.a)),
1) for optic couplers providing at least 1 MOP (MOOP or MOPP), do we need to require the 30-day thermal cycling test in 8.9.3?
2) if optic coupler insulation is supplementary or reinforced (MOOP or MOPP) for > 71 V peak, is it necessary to verify the 0,4 mm thickness in 8.8.2?
3) if optic coupler is being used as MOOP, is it necessary to verify CR, CL, and DS?
4) if optic coupler is being used as MOPP, is it necessary to verify CR, CL, and DS?

For review, here is a comparison of the ME EQUIPMENT insulation requirements for an optic coupler providing 2 MOOP for mains voltage, versus 2 MOPP for mains voltage:
<table>
<tr><th>Insulation</th><th>2 MOPP</th><th>2 MOOP</th></tr>
<tr><td rowspan="5">RI (240 V RMS)</td><td>8 mm CR,</td><td>5 mm CR,</td></tr>
<tr><td>5 mm CL,</td><td>4 mm CL,</td></tr>
<tr><td>4 kV RMS DS,</td><td>3 kV RMS DS,</td></tr>
<tr><td>0,4 mm DTI[a],</td><td>0,4 mm DTI[a],</td></tr>
<tr><td>30 d thermal cycling for cemented joint</td><td>30 d thermal cycling for cemented joint</td></tr>
<tr><td colspan="3">[a] Perhaps represented by IEC 60747-5-5:2007 partial discharge testing with pre-conditioning.</td></tr>
</table>
</td></tr>
</table>

Recommendation 131 *(continued)*

	Incidentally, it is my understanding that IEC 60950-1:2005 requires IEC 60747-5-5:2007 compliance, and independently verifies the 0,4 mm thickness, but does NOT require the 30-day thermal cycling test (both of which are end product requirements within IEC 60950-1).
Submitter proposed recommendation	Assuming optic coupler complies with IEC 60747-5-5:2007 and is being used within its ratings, 1) for optic couplers providing at least 1 MOP (MOOP or MOPP), do we need to require the 30 days thermal cycling test in 8.9.3? NO, a partial discharge test and whatever aging/conditioning tests are required by the component standard are considered sufficient (it is my understanding that IEC 60950-1:2005 requires IEC 60747-5-5:2007 compliance, and does NOT require the 30 days thermal cycling test). 2) if the optic coupler insulation is supplementary or reinforced (MOOP or MOPP) for > 71 V peak, do we need to verify the 0,4 mm thickness in 8.8.2? NO, a partial discharge test and whatever aging/conditioning tests are required by the component standard are considered sufficient (it is my understanding that IEC 60950-1:2005 requires IEC 60747-5-5:2007 compliance and independently verifies 0,4 mm DTI thickness. Because of this, optic coupler industry sometimes includes 0,4 mm DTI information on its datasheets). 3) if the optic coupler is being used as MOOP, do we need to verify CR, CL, and DS? NO, IEC 60664-1 requirements are basis for both IEC 60747-5-5:2007 optic coupler and MOOP insulation requirements. 4) if the optic coupler is being used as MOPP, do we need to verify CR, CL, and DS? YES, this is consistent with 2nd edition practice, and recognizes that MOOP is not sufficient for MOPP.
SC 62A recommendation	For an opto-coupler providing MOOP and MOPP, it is recommended to test – AIR CLEARANCE at the outside of the opto-coupler, – CREEPAGE DISTANCE at the outside of the opto-coupler, – DIELECTRIC STRENGTH at the opto-coupler, and – compliance with IEC 60747-5-5:2007 or its predecessor standards (IEC 60747-1, IEC 60747-2, IEC 60747-3). NOTE The factor of 1,6 on insulation test voltage is only used for thermal cycling tests (8.9.3), as also in other safety standards (e.g. IEC 62368-1, IEC 60950-1). IEC 60747-5-5 applies different test methods. Because we regard IEC 60747-5-5 as equivalent to the thermal cycling test, the 1,6 factor is not required. This is the same approach used in IEC 62368-1:2010, 5.5.4. and 5.4.4.4. DTI (0,4 mm) and thermal cycling testing should not be required because compliance with the component standards addresses the RISK of pin holes and thermal effects on the insulating compound.

4.2.132 Eye-verification of tester before legibility test

Recommendation number	132
Clause(s) number (only)	7.1.2
Source/problem	IEC 60601-1 has special requirements for tester's eyes. Why was Jaeger card (N6) added with an "and" conjunction (in IEC 60050-1:2005/AMD1:2012)? How shall it be proved that the tester is able to read N6 of Jaeger test card, i.e. visit a doctor? Shall it be done before every test?
Discussion/comment	The 2nd Edition of IEC 60601-1 uses the term "normal vision". Because "normal vision" is an undefined term, the 3rd Edition tried to set up reproducible test requirements, which has consequently led to compliance criteria related to the tester's eyes. The compliance criteria in the 3.1 edition says: *The ME EQUIPMENT or its part is positioned so that the viewpoint is the intended position of the OPERATOR. If the intended position of the OPERATOR is not specified and the position is not obvious, 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 illumination is the least favourable level in the range of 100 lx to 1 500 lx.* *The observer has a visual acuity, corrected if necessary, of:* – *0 on the log Minimum Angle of Resolution (log MAR) scale or 6/6 (20/20); and* – *is able to read N6 of the Jaeger test card;* *in normal room lighting conditions (approximately 500 lx).* The following aspects are still not defined in the compliance criteria and remain unclear: 1) What does "*The observer has a visual acuity, corrected if necessary, of: 0 on the log Minimum Angle of Resolution (log MAR) scale or 6/6 (20/20)*" mean? 2) How should compliance be proven in practice? 3) Is it sufficient if the tester visits an eye-physician in his medical office before each test, under the condition that the lighting in the medical office is checked with a calibrated test equipment to be approximately 500 lx? 4) What does "approximately" mean? Does it mean for example 450 lx is not adequate? What about 475 lx? Where is the limit for acceptance? 5) The normal vision of humans changes during a normal work day. It has been proven in the standard committee that members confirmed that early in the morning they were able to read the screen whereas in the evening they were not, even though nothing had changed with the projector. Is it therefore required that test laboratories hire eye-physicians to verify exactly, before each hour the tester conducts the test, that the normal vision (acuity) is still given? Consequently, testing without having an eye-physician and the 500 lx room available shall be forbidden. 6) Because the colour of the light during test at the ME EQUIPMENT and during verification of the tester's eyes is not defined, should we wait with further testing until Amendment 2 fills the gap? 7) Is it allowed to print out a Jaeger card from the Internet and use this to prove the tester's eyes acuity? If yes, which printer is defined and which paper size is defined, and which Internet Jaeger card shall be downloaded? 8) Are there any suggestions based on equivalent safety to show compliance with this still unclear subclause?

Recommendation 132 *(continued)*

Submitter proposed recommendation	Possible alternatives: – reading the Jaeger card as a single requirement for the tester; – using ISO 8596:2009 (Landolt rings), – advantage: ISO 8596 contains pass-fail-criteria. Provide a definition of fixed letter sizes for markings.
SC 62A recommendation	SC 62A is unable to make a recommendation at this time. This topic should be re-discussed during the preparation of a future revision of IEC 60601-1. See also IEC 62366:2007, H.2.3.4. NOTE The acuity test 20/20 means that the observer is able to read capital letters of 1,5 mm size in a 1 m distance.

4.2.133 End stops to prevent overtravel

Recommendation number	133
Clause(s) number (only)	9.2.3.2
Source/problem	IEC 60050-1:2005/AMD1:2012 included a table with test criteria. One test condition is "Run at maximum speed". Questions: 1) What can be considered as maximum speed? Is it the speed which is configured in this application (NORMAL USE; e.g. fixed configured with motor controller parameters) or the speed which can be reached theoretically? 2) Shall a SINGLE FAULT CONDITION (e.g. the motor controller loses a parameter and allows higher speed) be taken in consideration?
Discussion/comment	It is a general principle, that a) the worst case situation shall be regarded during testing; b) general subclauses such as 4.7 apply to the whole of IEC 60601-1, even if not explicitly repeated at several clauses in IEC 60601-1?
Submitter proposed recommendation	–
SC 62A recommendation	Speed: It is recommended to apply the maximum speed possible to be adjusted in NORMAL USE, including reasonably foreseeable misuse and under NORMAL CONDITION. SINGLE FAULT CONDITION: The ME EQUIPMENT shall be safe for PATIENTS and OPERATORS in NORMAL CONDITION and under any possible SINGLE FAULT CONDITION and under any component faults. It might be necessary to conduct ESSENTIAL PERFORMANCE testing. End stops should be capable of withstanding the maximum impulse energy based on the maximum speed and maximum allowed load during any SINGLE FAULT CONDITION test or under any component faults in order to ensure compliance with 4.7 and 5.1. Tests under SINGLE FAULT CONDITION or component faults should be conducted once.

4.2.134 MOPP barrier with low WORKING VOLTAGE RMS and high WORKING VOLTAGE peak

Recommendation number	134
Clause(s) number (only)	8.8.3, 8.9.1
Source/problem	U_w peak generates high values for MOPP not in line with the end edition
Discussion/comment	We experienced ME EQUIPMENT certified to the 2nd edition that does not pass the DIELECTRIC STRENGTH test when tested to the 3rd edition. For the insulation requirements, the 2nd edition did not consider U_w peak voltages. Only the U_w RMS was used for creepage, clearance and DIELECTRIC STRENGTH. Ed. 2 use: $2 \times (2 \times U_{RMS} + 1\,500)$ Ed. 3 use: $2 \times (1{,}414 \times U_{peak} + 1\,500)$ For sinus, this will lead to same test voltage as in edition 2 but for non-sinus with high peaks, it leads to a significant different test voltage. For MOPP, the required DIELECTRIC STRENGTH test significantly increased from 2nd edition to 3rd edition of IEC 60601-1 especially if U_{RMS} and U_{peak} has high WORKING VOLTAGE measured values. Consequently, those 2nd edition approved switched mode power supplies fail the 3rd edition requirements. Is this intentional or is it a mistake?
Submitter proposed recommendation	–
SC 62A recommendation	This recommendation is related exclusively to MOPP barriers: It is noted and confirmed that some 2nd edition approved switch mode power supplies will fail the 3rd edition 2 MOPP barrier requirements, for example due to a measured high value of a WORKING VOLTAGE peak. That is one of several increased requirements from the 2nd edition to the 3rd edition. 1) DIELECTRIC STRENGTH: For DIELECTRIC STRENGTH test, U_{peak} should be used as WORKING VOLTAGE in Table 6. See as well the note in 8.9.1.15. 2) CREEPAGE DISTANCE: Table 12 WORKING VOLTAGE RMS should be applied. 3) AIR CLEARANCE: IEC 60601-1 requires to use Table 12 for WORKING VOLTAGE RMS However, this is in conflict to IEC 60664 series where AIR CLEARANCE is based on U_{peak}. This conflict should be addressed during the preparation of a future revision of IEC 60601-1. IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 are not sufficiently detailed to explicitly address the very special case of a low WORKING VOLTAGE such as 5 V DC that is present for a long time with an occasional superimposed peak occurring, for example 150 V peak (ultrasound ME EQUIPMENT) or 18 000 V peak (xenon-lamps). This special case should be addressed during the preparation of a future revision of IEC 60601-1.

Recommendation 134 *(continued)*

SC 62A recommendation	For the time being, one solution is to take the U_{peak} as WORKING VOLTAGE. But this will lead to very high AIR CLEARANCE values, because all values in Table 12 have already considered mains transients. Another solution could be short-circuit tests combined with LEAKAGE CURRENT test. When IEC 60601-1 is revised, the following suggestion should be verified: Is it possible for MOPP to use a similar approach as we have it for MOOP, i.e. use the RMS value of Table 12 and add the corresponding peak value of Table 14?

4.2.135 Labeling: spare parts vs. detachable parts vs. ACCESSORIES

Recommendation number	135
Clause(s) number (only)	7.2.2 7.2.4
Source/problem	**7.2.2 * Identification** ME EQUIPMENT and its detachable components shall be marked with the name or trademark of the MANUFACTURER and with a MODEL OR TYPE REFERENCE unless misidentification does not present an unacceptable RISK. ME EQUIPMENT shall be marked with: – the name or trademark and contact information of the MANUFACTURER; – a MODEL OR TYPE REFERENCE; – a serial number or lot or batch identifier; and – the date of manufacture or use by date, if applicable. NOTE See ISO 15223-1 for symbols for MANUFACTURER, serial number, lot or batch, year of manufacture and use by date. The serial number, lot or batch identifier, and the date of manufacture may be provided in a human readable code or through automatic identification technology such as barcodes or RFID. Detachable components of the ME EQUIPMENT shall be marked with: – the name or trademark of the MANUFACTURER; and – a MODEL OR TYPE REFERENCE; unless misidentification does not result in an unacceptable RISK. […] **7.2.4 * Accessories** ACCESSORIES shall be marked with the name or trade-mark of their MANUFACTURER or supplier, and with a MODEL OR TYPE REFERENCE. Where no marking of the ACCESSORIES is practicable, these markings may be affixed to the individual packaging.ACCESSORIES shall be marked with: – the name or trade-mark and contact information of their MANUFACTURER; – a MODEL OR TYPE REFERENCE; – a serial number or lot or batch identifier; and – the date of manufacture or use by date, if applicable. NOTE See ISO 15223-1 for symbols for MANUFACTURER, serial number, lot or batch, year of manufacture and use by date. The serial number, lot or batch identifier, and the date of manufacture may be provided in a human readable code or through automatic identification technology such as barcodes or RFID.

Recommendation 135 *(continued)*

Source/problem (continued)	Where no marking of the ACCESSORIES is practicable, these markings may be affixed to the individual packaging. **3.3** **ACCESSORY** additional part for use with equipment in order to: – achieve the INTENDED USE, – adapt it to some special use, – facilitate its use, – enhance its performance, or – enable its functions to be integrated with those of other equipment ➔ Problem: The above IEC 60601-1 subclauses address requirements for: a) detachable components (not a defined term); b) ACCESSORIES (defined term). When applying these IEC 60601-1 requirements **literally**, then for example, the following parts – which literally fulfil the definition of ACCESSORIES or could be regarded as detachable parts – would FAIL: – IEC 60127 MAINS FUSE; – MAINS cable; – battery cover fixed or not fixed by a screw; – all ENCLOSUREs parts including doors, wheels fixed by a tool; – ECG electrodes (top pads glued on skin); – IBP transducer set; – NIBP cuff; – breathing hose set (incl. y-piece, water trap, inspire. and expir. single hoses). So the real question is: What does IEC 60601-1 practically mean? In summary, this means by applying IEC 60601-1 literally, the ENTIRE medical industry will fail the requirements.
Discussion/comment	At the moment ALL stakeholders (all MANUFACTURERS, test laboratories, Notified Bodies, ministries of health) do not apply IEC 60601-1 so restrictively and literally as reflected by the submitter above.
Submitter proposed recommendation	–
SC 62A recommendation	7.2.2 and 7.2.4 should be read by considering defined terms and notes in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012. **1. Detachable parts:** It is recommended to interpret the undefined term "detachable component" as follows: Is an external component (single item or subassembly) which could be detached from the ME EQUIPMENT or ME SYSTEM without using a tool. NOTE 1 Components inside of the ME EQUIPMENT ENCLOSURE are not considered as detachable parts, because only an authorized expert is allowed to change these parts by using a tool. NOTE 2 Parts which are fixed by a tool to the outside of the ME EQUIPMENT are not considered as detachable parts, because only an authorized expert is allowed to change these parts by using a TOOL. **2. ACCESSORIES:** It is recommended to read 7.2.2 and 7.2.4 in the context of IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 as a whole, as follows:

Recommendation 135 *(continued)*

SC 62A recommendation	When an ACCESSORY is listed in the instructions for use by the MANUFACTURER of the ME EQUIPMENT, then this ACCESSORY belongs to the ME EQUIPMENT as clearly written in 3.63, Note 1: NOTE 1 ME EQUIPMENT includes those ACCESSORIES as defined by the MANUFACTURER that are necessary to enable the NORMAL USE of the ME EQUIPMENT. It is recommended to read the defined term as follows: **3.3** **ACCESSORY** **additional** part for use with equipment in order to: – achieve the INTENDED USE, – adapt it to some special use, – facilitate its use, – enhance its performance, or – enable its functions to be integrated with those of other equipment. There is a clear distinction in IEC 60601-1 between: a) ACCESSORIES defined by the MANUFACTURER: These items are clearly described in the instructions for use and belong to the ME EQUIPMENT according to Note 1 of 3.63 and therefore are already covered by IEC 60601-1 requirements via the type plate of the ME EQUIPMENT plus the instructions for use. These items do not need additional labelling requirements as listed in 7.2.4. Furthermore, all parts fixed by a tool and produced by the real ME EQUIPMENT MANUFACTURER are considered to be integral parts of the ME EQUIPMENT and not ACCESSORIES. b) ACCESSORIES not defined by the MANUFACTURER: Those could be ACCESSORIES produced by a third party. Those items are not listed in the instructions for use and therefore are not covered by the ME EQUIPMENT labelling (type plate plus instructions for use) as mentioned in Note 1 of 3.63. Those ACCESSORIES are defined in 3.3 and indicated by the word "**additional**". Those items shall comply with 7.2.4.

4.2.136 Protective earth impedance of ME SYSTEM > 200 mΩ

Recommendation number	136
Clause(s) number (only)	16.9.2.2, 8.6.4 b), 8.7.2
Source/problem	For ME SYSTEMs which are connected to mains by a mains plug, the protective earth resistance has to be below 200 mΩ instead of the 400 mΩ specified in edition 3.0. If exceeding 200 mΩ, 8.6.4 b) offers an alternative in terms of a current limitation for the affected parts of the system. Diverse ME or non-ME EQUIPMENT, including their mains cables, can have a protective earth resistance between 100 mΩ and 200 mΩ, each. When connecting one of them to another that incorporates a mains outlet (e.g. MSO), the protective earth resistance limit in the ME SYSTEM is exceeded. However, when applying 8.6.4 b) together with 8.7.2, 1st dash, it is not obvious which additional single faults have to be regarded and how an adequate current limitation should work.
Discussion/comment	If, in a ME SYSTEM, the resistance between protective earth connected parts to the common MAINS PLUG exceeds 200 mΩ, the only additional hazardous situation to be regarded is a short-circuit of the live mains wire (L) to such protective earth connected parts. A circuit breaker or fuse has to also cut off safely and quickly in this case, even if the mains installation should be configured only for safe cut-off of devices with 200 mΩ protective earth resistance. The rating of such an additional OVER-CURRENT RELEASE has to be adequately lower than the current rating of the used mains installation circuit.
Submitter proposed recommendation	Compliance with 8.6.4 b) and 8.7.2, 1st dash, is given when additional circuit breakers/fuses with a current rating specifically lower than that of the used hospital mains installation are installed in the mains supply of all devices which exceed 200 mΩ protective earth resistance in a ME SYSTEM. The OVER-CURRENT RELEASEs have to cut off quickly and safely if the live mains wire (L) is shorted to the affected protective earth connected parts. They have to be present in each supply wire which might become live due to reversed polarities by reversible MAINS PLUGS. Example: OVER-CURRENT RELEASES (fuses) installed in both lines (phase and neutral) either installed at the input or at the output of MPSO (or isolation transformer). This measure ensures that if the installation fuse would be assumed to be 10 A to 20 A, and the additional fuses in the MPSO or X-former would be 8 A, a total protective earth impedance of the serial two items of ME EQUIPMENT + MPSO (or X-former) could have up to 400 mΩ in the complete protective earth line.
SC 62A recommendation	The solution described in the submitter's proposal applies exclusively to ME SYSTEMS powered from DETACHABLE POWER SUPPLY CORDS, but not for PERMANENTLY INSTALLED ME EQUIPMENT or PERMANENTLY INSTALLED ME SYSTEMS. The submitter's proposal should be regarded as in compliance with 4.5. Explanation: Where the pathway of a fault current caused by a live (L) to a PROTECTIVE EARTH CONNECTION (PE) fault is protected only by the SUPPLY MAINS circuit over-current release (e.g. circuit breaker or fuse), the protective earth resistance (PER) of that pathway shall not exceed 200 mΩ. Where the pathway of a fault current caused by an L to PE fault is protected by additional intermediate circuit breakers/fuses with current ratings specifically lower than that of the SUPPLY MAINS circuit over-current release, then compliance with 8.6.4 b) and 8.7.2, first dash, is achieved and the PE-resistance to that part of the fault pathway may exceed 200 mΩ but shall be less than 400 mΩ.

4.2.137 Ball pressure test

Recommendation number	137
Clause(s) number (only)	13.2.13.1
Source/problem	It is unclear why the ball pressure test temperature at SINGLE FAULT CONDITION and overload conditions is based only on the results from 13.2.13.2 to 13.2.13.4 since these are dealing only with ME EQUIPMENT with heating elements, ME EQUIPMENT with motors and ME EQUIPMENT for non-continuous operation. (The same problem exists with the 2nd edition, where 52.4.1 is pointing only to 52.5.10 d) to h).) Is the ball pressure test, based on temperatures in SINGLE FAULT CONDITION and overload conditions, not required for all types of ME EQUIPMENT?
Discussion/comment	This could be an overlooked mistake in IEC 60601-1. The ball pressure test should be applied, as applicable, to all types of ME EQUIPMENT. The compliance paragraph should thus refer only to 13.2 as a whole rather than be limited to 13.2.13.2 to 13.2.13.4.
Submitter proposed recommendation	Apply the ball pressure test to all ME EQUIPMENT and base it on the temperature measured at any SINGLE FAULT CONDITION or overload condition under 13.2.
SC 62A recommendation	The maintenance team responsible for the relevant material of IEC 60601-1has confirmed that there is a gap in IEC 60601-1. SINGLE FAULT CONDITION or component faults which do not fall in 13.2.13.2 to 13.2.13.4 can result in elevated temperature of thermoplastic insulation relied upon as a MOP including parts of the ENCLOSURE. The ball pressure test in 13.2.13.1 should be based on the temperatures measured according to 13.2. 13.2.13.1 is supposed to apply beyond ME EQUIPMENT with motors, heaters and ME EQUIPMENT which are classified as non-continuous operation (it deals with testing overload conditions in terms of operating mode). The intent of IEC 60601-1 should be to apply Table 22 to ALL ME EQUIPMENT and not limit Table 22 to motors/heaters and ME EQUIPMENT that is classified as non-CONTINUOUS OPERATION. This makes it clear that exceeding the temperatures in Table 22 is a failure and since the table is not limited to motors/heaters, it applies to all ME EQUIPMENT.

4.2.138 Magnesium alloy ENCLOSURE

Recommendation number	138
Clause(s) number (only)	11.3 b) 3)
Source/problem	11.3 b) 3): "The ENCLOSURE, and any baffle or flame barrier, shall be made of metal (except magnesium) or of non-metallic materials, ..." If pure magnesium shall not be used as the ENCLOSURE, how about the magnesium alloy ENCLOSURE? Some magnesium alloys can contain about 90 % magnesium.
Discussion/comment	It is claimed that if the thickness of the magnesium alloy ENCLOSURE is thin enough, or the duration of ignition is long enough, the sample could be ignited.
Submitter proposed recommendation	The magnesium alloy ENCLOSURE should be treated as non-metallic material, and determine its flammability classification in accordance with IEC 60695-11-10. Minimum requirement: FV2 for TRANSPORTABLE ME EQUIPMENT and FV-1 for FIXED ME EQUIPMENT or STATIONARY ME EQUIPMENT.
SC 62A recommendation	A magnesium alloy ENCLOSURE should be treated as non-metallic material and its flammability classification determined in accordance with IEC 60695-11-10. Minimum requirement: FV2 for TRANSPORTABLE ME EQUIPMENT and FV-1 for FIXED ME EQUIPMENT or STATIONARY ME EQUIPMENT.

4.2.139 Instability with initial movement

Recommendation number	139
Clause(s) number (only)	9.4.1, 9.4.3.1 c), 9.4.3.2 a), 9.4.3.2 b)
Source/problem	In IEC 60601-1-2005/AMD1:2012, 9.4.1 and 9.4.3 have been modified in a way that the acceptance criteria "no unacceptable RISK" by unexpected movement has been deleted in 9.4.1, 9.4.3.1 c), 9.4.3.2 a) and 9.4.3.2 b). On the other hand, the allowed movement of max. 50 mm is specified to be applied "following the initial elastic movement" (9.4.3.1 c), 9.4.3.2 a) and 9.4.3.2 b)). Therefore, it is not clear if, for example, a castor with 2 wheels fitted with brakes (and 2 other wheels not fitted with brakes) is allowed to have an "initial elastic movement" such that it rotates to a position where the brakes become effective before the 50 mm criterion is applied. In IEC 60601-1:2005, this interpretation problem can be solved by an assessment if the resulting RISK is unacceptable or not. With edition 3 as modified by IEC 60601-1-2005/AMD1:2012, more precise instruction is needed. In many cases, the described initial rotation is not causing an unacceptable RISK, but there might be some (few) cases where such an initial rotation is not acceptable. The removal of RISK assessments in IEC 60601-1-2005/AMD1:2012 (and also in 9.4) has been done intentionally in order to avoid too many references to RISK MANAGEMENT activities where they are not necessary, for example when there is no initial movement.
Discussion/comment	–
Submitter proposed recommendation	Clarification that an initial movement, like initial rotation of a castor to a position where a 2-brake system becomes effective, is allowed as long as no electrical connections, gas supplies or breathing gas tubes are disconnected by that movement and the rotation energy is not high enough to injure a person by arms, shelves. etc. This would avoid to re-install a RISK ASSESSMENT reference as clear instruction is given to the test laboratory.
SC 62A recommendation	There exist different kinds of initial movements: a) the rotation around a braked castor axis; b) the rotation of the whole ME EQUIPMENT around one or two locked castor(s); c) first movement of the wheel until the wheel lock activates. NOTE A castor consists of a wheel and fixing holder and perhaps a brake. Cases a) and c) above fall under the wording of IEC 60601-1 of "initial elastic movement, initial creepage, initial pivoting of castors", because it is assumed that those movements are limited to a non-critical value. Case b) above is different. Here, the initial movement can easily be twice the length of the ME EQUIPMENT for one side of the ME EQUIPMENT. Even in this condition of the described longer initial movement, BASIC SAFETY and ESSENTIAL PERFORMANCE shall be maintained. Example: When the whole ME EQUIPMENT is rotating, the HAZARD is that the PATIENT or OPERATOR is crushed between the ME EQUIPMENT and any other object (e.g. a wall). This should be considered.

4.2.140 Ball pressure test

Recommendation number	140
Clause(s) number (only)	13.2.13.1
Source/problem	Temperature to be used for the ball pressure test
Discussion/comment	In 8.8.4.1 it is stated that ball pressure is made at the higher of: – 75 °C or ambient + temperature rise (125 °C or ambient + temperature rise). Similarly, edition 2 states in 59.2: – 75 °C or 40 °C + temperature rise (125 °C or 40 °C + temperature rise). The above text is very clear and can likely not be misunderstood. However, 13.2.13.1 states the ball pressure test is performed at a temperature of 25 °C plus the temperature "measured". Shall "measured" be understood as the temperature rise or the ambient plus the temperature rise? If the latter is correct it means the test is done with an extra safety margin of 25 °C over the total temperature in SINGLE FAULT CONDITION. However, at the NORMAL CONDITION test, there is no safety margin of 25 °C (a rationale for this is missing). The same wording exists in the 2nd edition, 52.4.1. The above text is not clear and not worded as for NORMAL CONDITION and thus it can likely be misunderstood. From experience with 2nd edition test reports, we know several test laboratories have traditionally added only 25 °C to the temperature rise in SINGLE FAULT CONDITION. There can be several reasons for this, for example: a) the vague text in both editions of IEC 60601-1; b) the Table Xb in ed. 2; c) the Table XIX in ed. 2; d) the text in IEC 60335-1:2010, Clause 30, which reads: *"The test is carried out at a temperature of 40 °C ± 2 °C plus the maximum temperature rise determined during the test of Clause 11, but it shall be at least* *75 °C ± 2 °C, for external parts;* *125 ° ± 2 °C, for parts supporting live parts.* ***However**, for parts of thermoplastic material providing supplementary insulation or reinforced insulation, **the test is carried out at a temperature of 25 °C ±2 °C plus the maximum temperature rise** determined during the tests of Clause 19, if this is higher."* Clause 19 of IEC 60335-1:2010 is the clause for abnormal operation. Apparently, there is no extra safety margin in IEC 60335-1. Example: ENCLOSURE temperature in NORMAL CONDITION: delta t 40 at ambient 40 = 80 Ball pressure test is made at: 40 + 40 = 80 °C ENCLOSURE temperature in SINGLE FAULT CONDITION: delta t 60 at ambient 40 = 100 Ball pressure test is made at: 60 + 40 + 25 = 125 °C or 60 + 25 = 85 °C

Recommendation 140 *(continued)*

Discussion/comment	Which temperature shall be added to the temperature rise measured during SINGLE FAULT CONDITION and overload condition? Since IEC 60601-1 1st and 2nd editions, in many respects, are much like the older IEC 60335-1, it is not clear if the ball pressure test is also intended to be handled as in IEC 60335-1. If ambient temperature is 40 °C and temperature rise in SINGLE FAULT CONDITION is 60 °C, that leads to a temperature "measured" of 100. To conduct the ball pressure test at 85 °C seems wrong, while conducting it at plus 25 °C = at 125 °C seems correct. It cannot be conducted at lower temperatures as measured during SINGLE FAULT CONDITION.
Submitter proposed recommendation	–
SC 62A recommendation	IEC 60601-1 opens the door for different interpretations related to the undefined term "measured". It is recommended to read the term "measured" in 13.2.13.1 as meaning: 1) the temperature as measured in 13.2.13.2 to 13.2.13.4 (using the test conditions described in 11.1) that the thermoplastic material relied upon as a MOP will be exposed to; 2) PLUS 25 °C as a safety factor. The test condition as described in 11.1 requires the ME EQUIPMENT to be operated in worst-case NORMAL USE including the maximum ambient operating temperature specified in the technical description. If the laboratory temperature during the test differs from maximum ambient temperature specified in the technical description a correction reflecting this difference in temperature is recommended. The whole approach should be re-evaluated in a future revision of IEC 60601-1, because IEC 60335-1 has a different and even opposite approach to use safety margin for the NORMAL CONDITION test but no safety margin for the SINGLE FAULT CONDITION test. See also IEC 60695-10-2 for general ball pressure horizontal tests.

4.2.141 DIELECTRIC STRENGTH test values

Recommendation number	141
Clause(s) number (only)	8.8.3, Tables 6 and 7
Source/problem	**Problem 1:** There is a conflict between the values given in Table 7 with values that have to be calculated for the range of peak-voltages between 10 001 and 14 140 V (peak). **Problem 2:** Conflict between values for OPERATOR-safety Table 7 and the formula for PATIENT-safety Table 6.
Discussion/comment	**Problem 1, example:** For *U* (peak) = 10 000 V the solid insulation has to be tested with a voltage (RMS) of 10 607 V (according to Table 7). For *U* (peak) = 10 001 V, the formula according to Table 6 has to be used – meaning [1,06 × *U* (peak) / √2]. Therefore, for *U* (peak) = 10 001 V, the calculated test voltage would be 7 496 V (RMS) according to the formula. **Problem 2, example:** For *U* (peak) = 10 000 V, the solid insulation has to be tested with a voltage (RMS) of ca. 10 607 V (according to Table 7). For the PATIENT-safety with a value of 10 000 V (peak), the formula according to Table 6 has to be used – meaning [*U* (peak) / √2 + 2 000] Therefore, for *U* (peak) = 10 000 V, the calculated test voltage would be 9 071 V (RMS) for PATIENT-safety. But normally for MOPP, the value is higher than for MOOP.
Submitter proposed recommendation	**Problem 1:** Change the formula into: 1,061 × *U* (peak) → 1,061 × 10 001 V (peak) = 10 611 V (RMS) The elimination of "/ √2" only causes a new conflict, because with 1,06 × 10 001 V (peak) = 10 601 V (RMS), the test-voltage is still below the value of Table 7 for 10 000 V (peak) = 10 607 V (RMS). **Problem 2:** Change the formula into: *U* (peak) + 2 000 SC 62A acknowledges the issues as valid. NOTE The answer should be based on the base standard, IEC 60664-1.
SC 62A recommendation	SC 62A is unable to make a recommendation at this time. This topic should be re-discussed during the preparation of a future revision of IEC 60601-1.

4.2.142 SECONDARY CIRCUITS

Recommendation number	142
Clause(s) number (only)	8.9.1.12
Source/problem	This subclause is not correct. It states: "Where a SECONDARY CIRCUIT is not earthed and is derived from a SUPPLY MAINS, the circuit shall be subjected to the requirements for primary circuits in Table 13 and Table 14". Can this be clarified, as differing interpretations are arising?
Discussion/comment	–
Submitter proposed recommendation	Following the statement "Where a SECONDARY CIRCUIT is not earthed and is derived from a SUPPLY MAINS but not isolated by two MOP, the circuit shall be subjected to the requirements for primary circuits in Table 13 and Table 14", an additional sentence should be added: "For SECONDARY CIRCUITS isolated by two MOP from mains, Table 15 and 16 apply".
SC 62A recommendation	This recommendation is related solely to MOOP (not to MOPP): MAINS TRANSIENT VOLTAGE is not reduced in non-earthed referenced SECONDARY CIRCUIT. The transient voltage reduction does not depend on having 1 MOOP or 2 MOOP. Consequently, this physical "secondary" circuit should be subjected to the MAINS TRANSIENTS VOLTAGE related to any further subsequent barriers. NOTE 1 Tables 13 and 14 in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 already reflect the impact of transient of non-earth referenced secondary circuits. NOTE 2 For MOPP, the argumentation of the submitter is correct in that 2 MOPP fully protect the secondary part against mains transients, unless the isolation barrier is bridged by big capacitors. NOTE 3 Paragraphs 4 and 5 of 8.9.1.12 already allow, under the listed conditions, the application of Table 15 for further SECONDARY CIRCUITS. If discrete capacitors are used to bridge the isolation barrier between primary and secondary circuit, then Table 15 should not be applied for reduced MAINS TRANSIENT VOLTAGE without measuring the transient level on the secondary side. Measurement of transients should be made in accordance with IEC 60664-1.

4.2.143 LEAKAGE CURRENTS in SINGLE FAULT CONDITION and during component faults

Recommendation number	143
Clause(s) number (only)	13.1.3
Source/problem	This subclause can be interpreted in more than one way, i.e. that LEAKAGE CURRENT measurements should be carried out after every abnormal condition, during each abnormal condition or that LEAKAGE CURRENT measurements can be carried out after several abnormal conditions. What is the right answer?
Discussion/comment	–
Submitter proposed recommendation	–
SC 62A recommendation	IEC 60601-1:2005, 13.1.1, is clear: **"13.1.1 * General** **When** applying the SINGLE FAULT CONDITIONS as described in 4.7 and 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 the ME EQUIPMENT." However, engineering judgement is allowed to avoid unnecessary testing. See 5.1.

4.2.144 Impedance of a PROTECTIVE EARTH CONDUCTOR within a DETACHABLE POWER SUPPLY CORD

Recommendation number	144
Clause(s) number (only)	8.6.4 a), second paragraph
Source/problem	The requirement in subclause 8.6.4 a), sixth paragraph, is unfortunate formulated and hardly feasible.
Discussion/comment	A) Paragraph 5 reads "... cord supplied or specified by the MANUFACTURER, when attached to ...shall not exceed 200 mΩ, ..." The likelihood that another cord-set than the supplied or specified one is used is quite high if the very common standardized appliance coupler C13 is used. B) Paragraph 6 reads "..., testing shall be carried out using a 3 m long cord of appropriate cross sectional area ...". A cord with area 0,75 mm^2 has a maximum allowed R i of 26 mΩ/m at 20 ºC according to IEC 60228. The correlation factor for the commonly used ambient 40 ºC is 0,926 which means the R i will be approximately 28 mΩ/m at 40 ºC. This alone will roughly add 84 mΩ (3 x 28). However, the contact resistance between the wire and the mains plug plus the appliance coupler can be high, in relation to the R i of the copper wire, and differs a lot between different brands and types of cord-sets. The maximum resistance is not specified in the cord-set standard, IEC 60799, but for plugs and connectors there are, for example, thermal requirements instead. It is not reasonable to simply pick any cord-set being 3 m long because this might not represent the worst case scenario described above and hence the test is not meaningful. Another and better way would be to simply add a presumed maximum impedance for the non-existing/non-specified cord-set to the measured value from the appliance inlet (PE) terminal. The figure to add is however unclear since there is no standard stating a maximum contact resistance and R i in the connectors or in the cord-set. The real worst case is probably more than 100 mΩ but perhaps a reasonable value is 100 mΩ (cord 84 mΩ and contacts 16 mΩ). However, in such case, again the theoretical manoeuvre is not meaningful because measurement from the appliance inlet, where the limit is 100 mΩ, would thus be sufficient, as it was before and in the 2nd edition.
Submitter proposed recommendation	Testing should be replaced by the presumption that the cord-set impedance is 100 mΩ.
SC 62A recommendation	This recommendation fills a gap in IEC 60601-1. Testing should be replaced by the presumption that the cord-set impedance is 100 mΩ. This should be regarded as an acceptable alternative to the existing requirement in IEC 60601-1, when there is no DETACHABLE POWER SUPPLY CORD either provided or specified by the MANUFACTURER. The issue should be addressed in a future revision of IEC 60601-1.

4.2.145 Time delay of the 100 VA limit

Recommendation number	145
Clause(s) number (only)	13.1.2
Source/problem	A) The 15 W power limit is measured after 60 s but for the 100 VA limit (introduced by AMD1) there is no time stated. B) The compliance paragraphs are unclear and inconsistent.
Discussion/comment	A) For protection against fire, the energy limits have been relaxed to 100 VA or 6 000 J, if certain design criteria are met. However, the time after which the 100 VA limit applies is not stated. Since the 100 VA or 6 000 J limits are taken from IEC 60950-1, it would be reasonable to also apply the time limits from IEC 60950-1, which is 5 s (electronic/PTC) and 60 s (fuses). B1) The compliance paragraph states that 15 W is drawn for 1 min and, if after 1 min, the supply circuit cannot supply 15 W, it is considered ok. Is this also actually relevant for the energy limit of 900 J (15 W × 60 s = 900 J)? If the power is < 15 W after 60 s but > 30 W after 30 s, this is over 900 J and thus would be a fail (but the current IEC 60601-1 wording does not require to draw 30 W). If this is not the intent of IEC 60601-1, there is no reason to state 900 J because it is the same thing as 15 W at 60 s. On the other hand, test reports showing the measured energy in joule are extremely rare and the IECEE CB TRF No. IEC60601_1K does not ask if the 900 J limit is fulfilled at shorter times than 60 s. B2) The compliance paragraph in AMD1 refers to inspection of design documentation only. This can be difficult when it comes to evaluation of the available power.
Submitter proposed recommendation	A) Apply the time limits from IEC 60950-1. B1) ? B2) The 100 VA limit is checked by the same test method as for the 15 W limit.
SC 62A recommendation	The subclause has a gap, because it does not specify the time when the limits apply. It is recommended to test the 100 VA test and 6 000 J calculation test over a time period of 60 s. NOTE This recommendation was agreed by the maintenance team responsible for the relevant material of IEC 60601-1.

4.2.146 Test voltage multiplied by factor 1,6

Recommendation number	146
Clause(s) number (only)	8.9.3.2 8.8.3
Source/problem	**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 h only, followed by a DIELECTRIC STRENGTH test according to 8.8.3 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.* Two different meanings of the following wording from the above requirement might exist: "..., followed by a DIELECTRIC STRENGTH test according to 8.8.3 except that the test voltage is multiplied by 1,6." A) shall the test voltage be multiplied by 1,6; or B) shall the test follow 8.8.3 only? Clarification and interpretation of word "except" is needed. A better wording of the requirement could be: "..., followed by a DIELECTRIC STRENGTH test according to 8.8.3 (this would mean a 1 min test duration, but no added safety factor of 1,6), or the test voltage is multiplied by 1,6 (and a shorter test duration is acceptable, so no need for the complete 1 min test)." NOTE Regarding IEC 60950-1: 1) IEC 60950-1:2001 is listed in Clause 2 of IEC 60601-1:2005. However, in several other clauses of IEC 60601-1: 2005/AMD1:2012, the referenced edition of IEC 60950-1 is not that of 2001 but rather 2005. 2) 2.10.5.3 of IEC 60950-1:2005 makes reference to 2.10.10 of the same standard and does not require a multiplication factor of 1,6.
Discussion/comment	–
Submitter proposed recommendation	The test voltage need not be applied for 1 min according 8.8.3, if it has been multiplied by 1,6.
SC 62A recommendation	Exception of the factor 1,6 applies to the test voltage only, but **not** to the test duration of 1 min.

4.2.147 Overflow and spillage

Recommendation number	147
Clause(s) number (only)	11.6.2, 11.6.3
Source/problem	Overflow and spillage "*After the procedures, the equipment is to pass the appropriate dielectric strength and leakage tests* [...]".
Discussion/comment	The meaning of "appropriate" refers to the kind of tests, which might be influenced by the ingress of water.
Submitter proposed recommendation	–
SC 62A recommendation	The intent of the word "appropriate" is to ensure that only those LEAKAGE CURRENT and DIELECTRIC STRENGTH tests that could be adversely affected by the PROCEDURES in 11.6 need to be conducted.

4.2.148 DIELECTRIC STRENGTH test of transformers without accessible frame

Recommendation number	148
Clause(s) number (only)	15.5.1
Source/problem	After the short-circuit or overload test, the transformer is to pass the DIELECTRIC STRENGTH test between the primary and secondary windings and the frame. In many cases, the frame is not accessible without destroying the transformer.
Discussion/comment	Has the test only to be performed when the frame is accessible?
Submitter proposed recommendation	–
SC 62A recommendation	Normally, follow the compliance paragraph of 15.5.1.1. However, in cases where the frame is not accessible, the test to the frame should only be required when the insulation to the frame plays a role in the INSULATION CO-ORDINATION. For example, this could be established by inspection of a non-moulded (non-potted) sample.

4.2.149 Expected voltage on SIP/SOPs

Recommendation number	149
Clause(s) number (only)	8.1 a), 8.7.4.6 and Figure 14
Source/problem	8.1 a), first dash: "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" 1) What does "any voltage" mean in 8.1 a), first dash? The NORMAL CONDITION maximum voltage from the external device. 2) Is this voltage to be earth referenced? Can be earthed or floating, both are possible. Are all SIP/SOP connections to be shorted together? Not required for determination of the SIP/SOP voltage.
Discussion/comment	The change in the 3rd edition making this test a NORMAL CONDITION is a significant change. Unless the SIP/SOP circuit is floating, there is a likelihood that an earthed ENCLOSURE becomes connected to the SIP/SOP voltage, so that in the SINGLE FAULT CONDITION of open earth there will be excessive TOUCH CURRENT. It is covered by 16.6.1. Is the intent to mimic NORMAL USE, i.e. apply signal voltages that would occur in NORMAL USE, or is it to cover the SINGLE FAULT CONDITION of the connected equipment, which might mean the highest voltage possible to all pins (60 V DC etc. for IEC 60601-1 and IEC 609501-1 compliance equipment)? Between ±5 V and ±60 V DC, there is not much difference related to safety. Differences would arise if connections to telephone networks with 120 V peak in NORMAL CONDITION would be conducted.
Submitter proposed recommendation	–
SC 62A recommendation	Case A: When testing a single ME EQUIPMENT, it is recommended to use the voltage within the SIP/SOP circuit of the ME EQUIPMENT in NORMAL CONDITION for LEAKAGE CURRENT tests. Case B: When testing a ME SYSTEM, it is recommended to use the voltage within the SIP/SOP circuits of the ME SYSTEM in NORMAL CONDITION when conducting leakage current tests.

4.2.150 Flammability rating for transformer bobbin

Recommendation number	150
Clause(s) number (only)	11.3 a)
Source/problem	There is no requirement for flammability rating of transformer bobbins
Discussion/comment	Is this an omission?
Submitter proposed recommendation	Interpret: windings are considered to be components
SC 62A recommendation	IEC 60601-1 does not include bobbin material in the list of 11.3 a). Therefore, the requirements for temperatures in Table 31 are considered to be comprehensive enough. The topic should be reconsidered when preparing a future revision of IEC 60601-1.

4.2.151 COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS

Recommendation number	151
Clause(s) number (only)	4.9
Source/problem	1) What is a COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS? One perfect example is a Y capacitor bridging 2 MOP, because if it fails, the mains might be accessible either for the PATIENT or for the OPERATOR. However, what other example exists as COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS? 2) 4.9 says: "A COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS shall be used when a fault in a particular component can generate an unacceptable RISK." Question: Is an IEC 60127 fuse a COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS in the light of the above IEC 60601-1 wording? I would say NO, because if the fuse would fail (SC), there is no **immediately** unacceptable RISK. Only if the fuse fails AND in addition an OL or SC occurs, an unacceptable RISK can arise, but this double problem does not match with the wording of IEC 60601-1:2005, 4.9, which requires that "WHEN" after the COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS fails an unacceptable RISK occurs. 3) What are the differences between COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS and critical components as they are identified and documented during testing? Does the difference consist of the fact that COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS shall be under a factory inspection whereas critical components are not required to be under a factory inspection? Example: Is an opto-coupler a COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS or a critical component?
Discussion/comment	The term "critical component" is not defined in IEC 60601-1. The term is used within approval schemes. Examples for a COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS are those mentioned in 4.7 a): reinforced insulation, tensile safety factor of 8x, etc. A Y capacitor when used as 1 MOP is a critical component but not a COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS. However, if a Y1 capacitor is used as 2 MOP, it is a COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS. An IEC 60127 fuse is not a 100 % match with the requirements in 4.9 and therefore it is not regarded as a COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS, but it is often a critical component.
Submitter proposed recommendation	A COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS is a critical component that creates an unacceptable RISK **immediately** when it fails. Examples are Y-capacitors, a dead-man-switch with a spring. In this meaning, an IEC 60127 fuse is not a COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS, but is a critical component.

Recommendation 151 *(continued)*

SC 62A recommendation	The term "critical component" is not used in IEC 60601-1. The term is used within approval schemes. Examples for a COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS are those mentioned in 4.7 a): REINFORCED INSULATION, TENSILE SAFETY FACTOR of 8x, etc. If a Y capacitor is used as 2 MOP, it is required to be a COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS. A correctly rated Y1 capacitor is one example. The same is valid for an opto-coupler as well other components with REINFORCED INSULATION in respect to electrical safety. An IEC 60127-1 fuse is not a 100 % match with the requirements in 4.9 and, therefore, it is not regarded as a COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS, but it is often a critical component.

4.2.152 Peak and RMS WORKING VOLTAGES

Recommendation number	152
Clause(s) number (only)	Table 12
Source/problem	The table is unclear and does not cover all kinds of voltage shapes.
Discussion/comment	1) The designations of the columns V DC and V RMS are contradictory, because for a DC voltage without ripple, the RMS value has, per definition, the same numerical value (e.g. 17 V DC = 17 V RMS). ➔ Due to the fact that most AC voltages will be rectified by diodes, the higher DC value in Table 12 is regarded as correct. See also IEC 60664-1:2007, 6.1.1, where AC values are equivalent to DC values when the AC values are multiplied by a factor of 1,414. 2) If, for example, a constant voltage of 16 V DC (first line of Table 12) turns into a rectangular pulsing voltage (0 V to 16 V) with 15 V RMS: ➔ For this low voltage, the issue is not related to MAINS transients: Take the 15 V RMS for CREEPAGE DISTANCE and interpolate if possible. Take the 16 V DC for CL. – Does this mean that in Table 12 the second line has to be used (because a voltage having > 10 % ripple is not to be considered as DC), even though the RMS value has decreased? – What if the rectangular voltage range is –0,5 V to +16 V? – What about an AC voltage with a very low frequency, for example changing polarity 1 time per minute or per hour? Is there a frequency limit, where an AC voltage has to be considered DC due to the low frequency (e.g. as 0,1 Hz for LEAKAGE CURRENT measurement in 8.7.3 b)? 3) Peak voltages are not covered by the table.
Submitter proposed recommendation	Table 12 should be adapted to solve the above described problems. As in IEC 60950-1, the table should handle peak voltages for clearance and RMS values for creepage. Interim solution: Application of the RMS column for sinusoidal voltages only; usage of the DC column for the peak value of all non-sinusoidal voltage shapes (e.g. WORKING VOLTAGE across the transformer of a switch mode power supply unit).
SC 62A recommendation	For this low voltage, the issue is not related to MAINS TRANSIENT VOLTAGE. It is recommended to use 15 V RMS for CREEPAGE DISTANCE and interpolate if possible. It is recommended to use 16 V DC for AIR CLEARANCE. This subject should be reconsidered when preparing a future revision of IEC 60601-1. See also recommendation 4.2.134.

4.2.153 Critical components

Recommendation number	153
Clause(s) number (only)	–
Source/problem	What does critical components mean and what does critical refer to? We could not find anything in IEC 60601-1 that reflects this. Why does a test laboratory ask for a list of critical components?
Discussion/comment	–
Submitter proposed recommendation	–
SC 62A recommendation	The term "critical component" is not used and therefore is not defined within IEC 60601-1. However, the IECEE CB test certification scheme deals with this topic. SC 62A is unable to make a recommendation at this time. NOTE 1 IECEE OD 2020 includes examples, such as AC inlet, fuse, fuse holder, ENCLOSURE, X-capacitor, line filter, triple insulation wire, transformer, bobbin of transformer, switch. See also IECEE OD 2039.

4.2.154 LEAKAGE CURRENT test for ME EQUIPMENT with multiple APPLIED PARTS

Recommendation number	154
Clause(s) number (only)	8.7.4.9; Annex A, Subclause 8.7.4.9; 3.8; 3.78; 8.5.2.1; Annex A, Subclause 8.5.2.1
Source/problem	The description of the test on multiple APPLIED PARTS is in contrast with the related rationale in Annex A and other definitions.
Discussion/comment	Out of the above mentioned subclauses, it could be concluded that PATIENT CONNECTIONS of the same APPLIED PART do not need to be grounded. Furthermore, it is to be decided by the MANUFACTURER if a separation barrier between different functions is required. In Annex A, the grounding is related to other functions not in use.
Submitter proposed recommendation	Modify 8.7.4.9.* *ME EQUIPMENT with multiple APPLIED PARTS is investigated to ensure that the PATIENT LEAKAGE CURRENT and the PATIENT AUXILIARY CURRENT do not exceed the allowable values while all other PATIENT CONNECTIONS of the remaining APPLIED PARTS are:* *1) connected together, but not to earth, and* *2) connected to earth.*
SC 62A recommendation	8.7.4.9 is not limited to ME EQUIPMENT with "multiple APPLIED PARTS", but it includes ME EQUIPMENT with one APPLIED PART but with multiple PATIENT CONNECTIONS, such as an ECG. In addition, 8.7.4.9 covers the case of one APPLIED PART with multiple functions. If engineering judgment indicates that the PATIENT AUXILIARY CURRENT measurement according to 8.7.4.8 has already covered the measurements in 8.7.4.9, the LEAKAGE CURRENTS measurements in 8.7.4.9 need not be conducted.

4.2.155 DIELECTRIC STRENGTH test value for extruded and spirally wrapped multi-layer wires

Recommendation number	155
Clause(s) number (only)	8.8.2 d) and e), Annex L
Source/problem	Triple insulated wire (TIW). Subclauses 8.8.2 d) and e) require TIW to pass the tests of Annex L. They also require the test voltage to be 1,6 times the value from 8.8.3. Therefore, for 2 MOPP and a WORKING VOLTAGE of 570 V peak as above, we have 4 612 V AC× 1,6 = 7 380 V AC. This seems quite excessive.
Discussion/comment	–
Submitter proposed recommendation	Remove the 1,6 times factor from Annex L.
SC 62A recommendation	A) For extruded TIW: 8.8.2 e) applies to triple extruded wires. Annex L requires to test a twisted pair with a test voltage of at least twice the appropriate voltage in Table 6. However, the twisted pair does not reflect the real condition in the ME EQUIPMENT, where only one side has the TIW. Consequently, we do not have an increased HV test value for extruded TIW for 2 MOPP. The final component DIELECTRIC STRENGTH test uses not more than the values of Table 6. B) For spirally wrapped TIW: 8.8.2 e) applies to spirally wrapped TIW. Annex L requires testing a twisted pair with a test voltage of at least twice the appropriate voltage in Table 6. However, the twisted pair does not reflect the real condition in the ME EQUIPMENT, where only one side has the TIW. Consequently, we do not have an increased HV test value for spirally wrapped TIW in Annex L for 2 MOPP. However, in addition, this spirally wrapped TIW shall have an overlap of each layer, which cannot be checked at a finished sample. Therefore, the DIELECTRIC STRENGTH test is applied with a factor of 1,6. Attention is drawn to the compliance paragraph which states that a material data sheet is accepted as evidence of compliance with Annex L requirements.

4.2.156 DIELECTRIC STRENGTH test after thermal cycling test

Recommendation number	156
Clause(s) number (only)	8.9.3.4
Source/problem	8.9.3.4 was taken from IEC 60950-1 but it omits the voltage stress of 500 V AC being imposed on the item being tested.
Discussion/comment	–
Submitter proposed recommendation	The subclause should have the following added as the first paragraph: "A sample of a component or subassembly is subjected to the following sequence of tests. For transformers, magnetic couplers and similar devices, if insulation is relied upon for safety, a voltage of 500 V RMS at a frequency of 50 Hz or 60 Hz is applied between windings, and also between windings and other conductive parts during the following thermal cycling."
SC 62A recommendation	While it is noted that the requirements in IEC 60601-1 and IEC 60950-1 differ, SC 62A has to assume that the writers of the 3rd edition of IEC 60601-1 have intentionally modified the requirements as reflected in IEC 60601-1:2005, 8.9.3.4.

4.2.157 Required MOOP values higher than MOPP values

Recommendation number	157
Clause(s) number (only)	8.9
Source/problem	MOOP can be worse than MOPP
Discussion/comment	Example: Up to 3 000 m (multiplication factor only for MOOP) WORKING VOLTAGE: 242 V AC RMS/ 570 V AC V peak 2 MOOP: (4,0 mm + 0,6 mm) × 1,14 = 5,3 mm (clearance) 2 MOPP: 5,0 mm (clearance) MOPP is based on the RMS WORKING VOLTAGE, MOOP based on the peak voltage. As you can see, this example shows that the MOOP is worse than the MOPP, which does not make sense. This needs to be addressed at some stage.
Submitter proposed recommendation	–
SC 62A recommendation	Figure A.12 should be regarded as normative.

4.2.158 Optocouplers

Recommendation number	158
Clause(s) number (only)	8.9.3
Source/problem	8.9.3 applies to optocouplers amongst other things. Subsequent clauses then require the optocoupler to undergo a DIELECTRIC STRENGTH test of 1,6 times the voltage from 8.8.3. In switched mode power supplies, the optocoupler typically has a WORKING VOLTAGE of 240 V AC giving 340 V peak. The DIELECTRIC STRENGTH voltage is then 4 000 V AC for 2 MOPPs times 1,6, giving 6 400 V AC. This is excessively high for typical optocouplers.
Discussion/comment	An optocoupler has an optical medium between the input and output and in order to rely on the medium for a distance through we shall be sure that it forms a cemented joint. That is what 8.9.3 deals with.
Submitter proposed recommendation	Remove the 1,6 times factor from the subclauses in 8.9.3.
SC 62A recommendation	SC 62A recommendation number 4.2.131 deals with this topic.

4.2.159 Impact test

Recommendation number	159
Clause(s) number (only)	15.3.3
Source/problem	Impact test on BODY WORN ME EQUIPMENT was introduced by IEC 60050-1:2005/AMD1:2012. An impact test is sometimes also justified for HAND-HELD ME EQUIPMENT, which could impact hard objects due to foreseeable misuse or rough handling. However, an impact test is not required by IEC 60601-1 for HAND-HELD ME EQUIPMENT. The impact test on BODY WORN ME EQUIPMENT is required by IEC 60601-1 but sometimes this is not justified.
Discussion/comment	A sleep disorder diagnostic ME EQUIPMENT with the size of 60 mm × 50 mm × 15 mm is attached to the PATIENT, together with an elastic sensor band around the chest. The ME EQUIPMENT is held in place by its connection to the sensor band (like a belt buckle). The whole ME EQUIPMENT is regarded as an APPLIED PART. This is for diagnosis of sleep disorders and thus it has no EP. The ME EQUIPMENT has an internal 3 V battery and the weight of it is < 100 g. The impact test is supposed to simulate that the ME EQUIPMENT is hit by a foreign object causing unacceptable damages to the ENCLOSURE. The reference to inspection of RISK MANAGEMENT FILE is deleted by IEC 60050-1:2005/AMD1:2012. But the reference to "unacceptable RISK" is still in the compliance paragraph and therefore IEC 60601-1 justifies to use RISK MANAGEMENT instead of equivalent safety. An object hitting the ME EQUIPMENT strapped to the chest of the PATIENT during sleep is very unlikely. Should this happen and the ENCLOSURE break, it will only give access to 3 V DC on condition that both poles become accessible. The RISK of long term contact of 3 V is very minor. Strictly, this is a failure of BASIC SAFETY because 3 mA DC can be accessed by the PATIENT. However, the likelihood that this would happen is very low. The rationale gives an opening by reference to 4.5 (equivalent safety). However, this seems not applicable in the case described.
Submitter proposed recommendation	The impact test can be waived on BODY WORN ME EQUIPMENT, if the RISK of impact in NORMAL USE is deemed negligible or the RISK of access to hazardous parts is deemed negligible, considering the INTENDED USE. It shall be inspected that this issue has been handled in the RISK MANAGEMENT FILE.
SC 62A recommendation	The impact test according to 15.3.3 should be applied. The compliance paragraph uses the term "unacceptable RISK" for assessment of the results. Therefore, IEC 60601-1 justifies the use of RISK MANAGEMENT instead of alternative RISK CONTROL according to 4.5.

4.2.160 Spillage test in NORMAL CONDITION and in SINGLE FAULT CONDITION

Recommendation number	160
Clause(s) number (only)	11.6.3
Source/problem	A spillage test is required on ME EQUIPMENT requiring handling of liquids or where spillage is likely to occur (reasonable foreseeable misuse). The spillage test would thus not be required for ME EQUIPMENT not requiring liquids in NORMAL USE and which is used only in a dry environment. Unfortunately, the rationale causes some confusion since the first and second sentence of the first paragraph is contradictive to the last paragraph.
Discussion/comment	According to first paragraph of the rationale, spillage is regarded as NORMAL CONDITION on ME EQUIPMENT that requires liquids in NORMAL USE or where spillage is likely to occur. The last paragraph states that spillage on ME EQUIPMENT not requiring liquids is considered as SINGLE FAULT CONDITION. Thus it is unclear if ME EQUIPMENT not requiring liquids but used where spillage is likely to occur is regarded as NORMAL CONDITION according to first paragraph or SINGLE FAULT CONDITION according to last paragraph? Where the spillage test is considered as SINGLE FAULT CONDITION, is another SINGLE FAULT CONDITION also applied according to the last paragraph in the requirement text? Should spillage from a bottle of cleaning agent used on a soft cloth be regarded as reasonable foreseeable misuse causing the need for spillage test as a SINGLE FAULT CONDITION? A spillage test on, for example, an ECG-printer or a mammographic X-ray equipment seems too stringent even as a SINGLE FAULT CONDITION.
Submitter proposed recommendation	–
SC 62A recommendation	Spillage is considered NORMAL USE for ME EQUIPMENT that requires the handling of liquids for its INTENDED USE. Spillage is considered a SINGLE FAULT CONDITION for ME EQUIPMENT that does not require handling of liquids for its NORMAL USE but is used or likely will be used in an environment where spillage can occur. Small amounts of cleaning agents on a cloth are not regarded as included in this concept. Spillage test is considered not applicable to ME EQUIPMENT not requiring liquids and which are intended for use only in a dry environment such as ECG-printers and mammographic X-ray equipment.

4.2.161 TYPE B APPLIED PART connected to ACCESSIBLE PARTS

Recommendation number	161
Clause(s) number (only)	8.5.2.2
Source/problem	A TYPE B APPLIED PART shall either be PROTECTIVELY EARTHED or be isolated with 1 MOPP. IEC 60601-1 is unclear in two respects: 1) Current for the PE-impedance test? It is not explained why it shall be PROTECTIVELY EARTHED and which current capacity is required. Is it for protection against internal sources or from external mains voltage sources, even though it is classified as Type B? 2) Requirements for 1 MOPP? It is not explained on which voltage the 1 MOPP shall be based. Is it the actual WORKING VOLTAGE or the mains voltage? If the latter applies, it means there is no difference between type BF and non- PROTECTIVELY EARTHED type B which is significantly more stringent than the 2nd edition.
Discussion/comment	TYPE B APPLIED PARTS are not designed to maintain protection for the PATIENT with mains voltage on the PATIENT. Thus the insulation requirement of 1 MOPP shall be based on the actual WORKING VOLTAGE. TYPE B APPLIED PARTS that are PROTECTIVELY EARTHED shall have a current capability related to available current in the PATIENT circuit.
Submitter proposed recommendation	TYPE B APPLIED PARTS that are not PROTECTIVELY EARTHED shall have insulation of 1 MOPP based on the actual WORKING VOLTAGE. TYPE B APPLIED PARTS that are PROTECTIVELY EARTHED shall have a current capability related to available current in the PATIENT circuit.
SC 62A recommendation	The two normative requirements in 8.5.2.2 and 8.7.4.7 d) are in contradiction because 8.5.2.2 allows an ACCESSIBLE PART to be connected to the APPLIED PART under certain conditions whereas 8.7.4.7 d) ban this solution completely. The link to RISK MANAGEMENT in 8.5.2.2 should be regarded as priority and should be used as well for 8.7.4.7 d).

4.2.162 Current/power labeling

Recommendation number	162
Clause(s) number (only)	7.2.7
Source/problem	Non-safety related requirement for rated input and thus unjustified in IEC 60601-1.
Discussion/comment	Current/power shall be stated for both the upper and the lower voltage rating if the difference is > 10 %. To mark an ME EQUIPMENT with a lower rating than the maximum is perhaps of interest for a hospital when evaluating the capability needs for their installation. However, it seems to have nothing to do with safety. This requirement is identical with the 2nd edition and yet there are numerous certified power supply units on the market with only one current rating. Example: IEC 60601-1 requires: 100 V to 240 V, 4 A to 2 A Equally safe is: 100 V to 240 V, 4 A IEC 60601-1 requirement should be enforced only for high power consuming ME EQUIPMENT, for example > 3 kW or > 15 A.
Submitter proposed recommendation	For equipment rated < 3 kW or 15 A, it is sufficient to state the maximum current/power rating only.
SC 62A recommendation	It is recommended that the rating "100 V to 240 V, XA", where X could go up maximum to 10 A, is sufficient to fulfil the requirement of 7.2.7, because value XA is understood to be valid for both upper and lower voltage limit.

4.2.163 Separate power supply part of ME EQUIPMENT or ME SYSTEM

Recommendation number	163
Clause(s) number (only)	7.9.2.3
Source/problem	Unjustified requirement regarding ME EQUIPMENT versus ME SYSTEM
Discussion/comment	It is required to specify in the instructions for use whether the separate power supply unit is part of the ME EQUIPMENT or if the combination is a ME SYSTEM. Whether it is a ME EQUIPMENT or a ME SYSTEM is simply a matter of semantics. It is difficult to see the rationale behind this requirement, i.e. what is the benefit for the OPERATOR to have this information in the instructions for use? The vast majority of OPERATORS will anyway not understand the difference. This is particularly true when the OPERATOR is a layman, i.e. a PATIENT or relative? Perhaps the information could have some value for a technician and thus it should be acceptable to have this information in the technical description only. However, it is still unclear what the benefit is.
Submitter proposed recommendation	It is sufficient to declare in the technical description whether equipment with a separate power supply unit is to be regarded as a ME EQUIPMENT or a ME SYSTEM. The information could have some value for a technician.
SC 62A recommendation	It is recommended to regard it as sufficient if the technical description declares whether equipment with a separate power supply unit is to be regarded as ME EQUIPMENT or an ME SYSTEM. The topic should be reconsidered when preparing a future revision of IEC 60601-1.

4.2.164 Specification of the allowed power supply

Recommendation number	164
Clause(s) number (only)	7.2.5
Source/problem	A MANUFACTURER claims 7.2.5 does not apply to their ME EQUIPMENT which uses a separate power supply unit.
Discussion/comment	The change of the text by IEC 60050-1:2005/AMD1:2012 is unfortunate and confusing. Old text: "If ME EQUIPMENT is intended to receive its power from other equipment including ME EQUIPMENT in an ME SYSTEM ...." New text: "If ME EQUIPMENT is intended to receive its power from other electrical equipment in an ME SYSTEM ..." Strictly, this new text can be interpreted to mean that a stand-alone power supply unit is always regarded as part of a ME SYSTEM. However, this is contradicted by 7.9.2.3 and 8.2.1 in which it is stated that: "... either the power supply shall be specified as part of the ME EQUIPMENT or the combination shall be specified as an ME SYSTEM." The MANUFACTURER specified their equipment as a ME EQUIPMENT (not a ME SYSTEM) and therefore claims they need not meet any of the alternative requirements in 7.2.5.
Submitter proposed recommendation	Common sense will show that 7.2.5 shall be met whether or not the product is regarded as a ME EQUIPMENT or a ME SYSTEM.
SC 62A recommendation	It is recommended to apply 7.2.5 as well for external power supply which is part of ME EQUIPMENT.

4.2.165 Mains transients for opposite polarity on the secondary side or battery pole to pole barrier

Recommendation number	165
Clause(s) number (only)	8.9.1.12, 15.4.3.5 and 15.5.1.1
Source/problem	It is unclear if and when mains transients shall be considered when evaluating insulation between OP (opposite polarity) in secondary circuits, including battery circuits in mains supplied ME EQUIPMENT. The heading of Table 15 is unclear.
Discussion/comment	The heading of Table 15 leads to misinterpretations because it does not indicate that the table is not valid for all types of secondary circuits. From 8.9.1.12, it is clear that isolation distances for protection against hazardous voltages are derived from: – for earthed secondary: Table 15; – for non-earthed secondary: Tables 13 and 14; – for non-earthed secondary circuits, preceded by an earthed screen: Table 15. Mains transients are earth-related and therefore do not stress insulation of opposite polarity in non-earthed secondary circuits. However, mains transients will likely stress the insulation of opposite polarity in earthed secondary circuits, i.e. where one side of the opposite polarity is earth connected. Table 15, column 5, "Circuit not subject to transient overvoltages", thus applies for opposite polarity in non-earthed secondary circuits, including opposite polarity in non-earthed battery circuits in mains supplied ME EQUIPMENT. For opposite polarity in earth related secondary circuits, including opposite polarity in earth-related battery circuits in mains supplied ME EQUIPMENT, Table 15, columns 2 to 4 apply.
Submitter proposed recommendation	–
SC 62A recommendation	The aspect of MAINS TRANSIENT VOLTAGE stressing opposite polarity within the areas of – secondary side of a MAINS SUPPLY TRANSFORMER in front of the first protection device, and – between plus and minus pole of a battery in front of the first protection device is not addressed within IEC 60601-1. SC 62A recommends not to take into consideration MAINS TRANSIENT VOLTAGE at the areas described above because these MAINS TRANSIENT VOLTAGES will never stress these opposite polarity barriers. Rationale: MAINS TRANSIENT VOLTAGES are earthed-related. If such mains transients with full level or reduced level occur at these areas, there will always be many bypasses which avoid a breakdown of the opposite polarity barriers such as a) the secondary winding itself or the battery itself, and b) the electronic loads after the protection device (e.g. after the fuse).

4.2.166 Keep dry and umbrella symbol

Recommendation number	166
Clause(s) number (only)	IEC 60601-1-11:2010, subclauses 7.2 and 8.3.1
Source/problem	The first reference is in 7.2, "Additional requirements for marking of IP classification". From this subclause, it seems that if the device does not pass the test to IP21/22, then it is possible to mark the device "Keep dry" and have an IPX0 rating. However, later in IEC 60601-1-11, the referenced subclause 8.3.1 appears to contradict 7.2 and states the requirement for all devices to be tested to IP21/22.
Discussion/comment	–
Submitter proposed recommendation	The position as expressed in IEC 60601-1-11 is clear and not at all at the way the request was presented. 8.3.1 is mandatory for all kind of home use ME EQUIPMENT, i.e. only HAND-HELD, BODY-WORN or TRANSIT OPERABLE ME EQUIPMENT need comply with IP 22. All other home healthcare environment equipment needs to comply with IP 21 according to IEC 60601-1-11. When equipment is only intended to be operated while inside a carrying case (i.e. operated with the raincoat), the carrying case can provide part of the required protection, otherwise the equipment ENCLOSURE needs to comply with the requirement.
SC 62A recommendation	8.3.1 is mandatory for all kinds of home use ME EQUIPMENT, i.e. only HAND-HELD, BODY-WORN or TRANSIT OPERABLE ME EQUIPMENT need to comply with IP 22. All other home healthcare environment equipment needs to comply with IP 21 according to IEC 60601-1-11:2010 and IEC 60601-1-11:2015. When ME EQUIPMENT is only intended to be operated while inside a carrying case (i.e. operated with the raincoat), the carrying case can provide part of the required protection, otherwise the equipment ENCLOSURE needs to comply with the requirement. For example, the ENCLOSURE of a PORTABLE ME EQUIPMENT that meets IP22 only with its carrying case should be marked with "Keep dry" text or symbol, even if the ENCLOSURE without the carrying case meets IP21.

4.2.167 MOBILE and STATIONARY ME EQUIPMENT with wheels

Recommendation number	167
Clause(s) number (only)	3.44 and 3.71; 3.65 and 3.118
Source/problem	**"3.65 MOBILE** term referring to TRANSPORTABLE equipment that, once installed and placed into service, is intended to be moved from one location to another while supported by its own wheels or equivalent means" **"3.118 STATIONARY** term referring to equipment that, once installed and placed into service, is not intended to be moved from one place to another" Is there an intended difference between "location" and "place"? **"3.71 NORMAL USE** "NOTE NORMAL USE should not be confused with INTENDED USE. While both include the concept of use as intended by the MANUFACTURER, INTENDED USE focuses on the medical purpose while NORMAL USE incorporates not only the medical purpose, but maintenance, transport, etc. as well."
Discussion/comment	The mobility requirements are unclear with regard to the INTENDED USE and the definitions of NORMAL USE, MOBILE, STATIONARY and TRANSPORTABLE. A table has small wheels for transportation to the place of use. During INTENDED USE, the wheels are retracted so that the ME EQUIPMENT is STATIONARY resting on the fixed base. However, the wheels will be extracted frequently by an easy accessible foot control so that the table can be moved aside when cleaning the floor. Even though not specified, the wheels are likely used during transport from the operating room to another location for service/maintenance. The wording "not intended to be moved from one place/location to another" is a little vague and the MANUFACTURER interprets that this is meant to be from one room to another room rather than moved aside for cleaning of the floor. The MANUFACTURER claims it is not MOBILE. However, per definition it is not STATIONARY either. Shall the table pass the threshold test, rough handling and instability tests?
Submitter proposed recommendation	The ME EQUIPMENT shall maintain BS and EP during INTENDED USE as well as during NORMAL USE. NORMAL USE includes maintenance and service. Cleaning of the floor, where the table has been placed, is part of the daily routine, i.e. maintenance.
SC 62A recommendation	This issue and the example of a solution below should be considered when preparing a future revision of IEC 60601-1. If a ME EQUIPMENT contains wheels only for the purpose of allowing, for example, cleaning, servicing or positioning, and the ME EQUIPMENT cannot be moved to another location without the use of a tool, the ME EQUIPMENT is not assumed to be MOBILE and requirements for MOBILE ME EQUIPMENT are not applicable. In this case, the conditions of safe use of the wheels have to be described in the ACCOMPANYING DOCUMENTS.

4.2.168 Varistors installed in the MAINS PART

Recommendation number	168
Clause(s) number (only)	4.8
Source/problem	A few MANUFACTURERS install a varistor (VDR) after the mains fuses. Barrier 1 MOOP between mains and protective earth typically 1 500 V RMS failed at 700 V RMS. The design probably leads to mains fuses opening if the voltage at the varistor gets too high. Is there any guidance on how to deal with varistors?
Discussion/comment	– As this is a new design, no experience exists. – The safety philosophy is 1 MOOP plus PE. The fault of a semiconductor is more likely than breakdown of other components such as wire insulation. We do not have values about the reliability of VDRs, like we have them for capacitors according to IEC 60384-14 Y1 or Y2 type. The BASIC INSULATION (1 MOOP) is therefore in doubt. – If the protective earth in the POWER SUPPLY CORD is interrupted (1 SINGLE FAULT CONDITION) plus the VDR fails (NORMAL CONDITION), we would have mains on the ENCLOSURE. – Varistors in MAINS PARTS including metal oxide types (MOV's) produce leakage currents. Due to ageing this LEAKAGE CURRENT increases. Increased LEAKAGE CURRENT leads to higher temperatures in varistors. Finally temperatures could be high enough to cause the equipment to burn. Therefore varistors cannot be accepted without a protective device, neither up to 1 500 V nor above 1 500 V.
Submitter proposed recommendation	
SC 62A recommendation	It is strongly recommended not to use VDR's (MOV's, varistors) between line to neutral. To reduce transients between line and neutral, X-capacitors can be used. Between line/neutral to PROTECTIVE EARTH, a VDR should a) be used only after the MAINS fuse, and b) be used only when it is used in series with a GDT (gas discharge tube) which fulfils the requirements for 1 MOP in accordance with 4.8 of IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, and c) meet the requirements of Clause G.8 of IEC 62368-1:2014.

4.2.169 Using Y2 capacitors for MOPP

Recommendation number	169
Clause(s) number (only)	8.5.1.2
Source/problem	The normative part states "A Y capacitor (Y1 or Y2 only) complying with IEC 60384-14 is considered equivalent to one MOPP" but the informative rationale requires only Y1 for WORKING VOLTAGE of 212 V to 354 V peak.
Discussion/comment	–
Submitter proposed recommendation	–
SC 62A recommendation	It is recommended to read 8.5.1.2 together with its rationale in Annex A. In this specific case, two serial Y2 capacitors do not comply with a 4 000 V RMS dielectric requirement, because in accordance with IEC 60384-14, a single Y2 capacitor complies with continuous 1 500 V RMS only. When preparing a future revision of IEC 60601-1, it is recommended to discuss if the normative part of IEC 60601-1 should reflect this special case instead of having the information only in the informative Annex A.

4.2.170 Overtravel end stops – Specification of the speed

Recommendation number	170
Clause(s) number (only)	9.2.3.2
Source/problem	In IEC 60050-1:2005/AMD1:2012, Table 33 has been added to 9.2.3.2. In line 4 "Manually driven or manually driven, power assisted", movements against an end stop, 50 cycles shall "run at any speed, including reasonably foreseeable misuse". It is not obvious which (reproducible) test conditions are addressed by that line.
Discussion/comment	Some shelves and support arms for equipment, but also some supply units, are made in such a way that they are movable manually. In those cases, the applied forces can be derived rather than any (final) speed from INTENDED USE and foreseeable misuse. For example, leaning against a supply unit or with a force as defined in 9.4.2.3.a) or 9.4.3.2.b) with max. 150 N can be derived as test condition from existing other subclauses, while the achievable end speed depends on the device under test. Is it acceptable to take that force (or other forces applicable as worst case condition for INTENDED USE including foreseeable misuse) and to combine it with the worst case momentum (e.g. longest support arm) of the device under test instead of a sometimes undefinable speed?
Submitter proposed recommendation	Interpret the test condition "Run at any speed, including reasonably foreseeable misuse" as follows: In cases where worst case test conditions can better be derived from worst case forces (e.g. as defined in 9.4.2.3 a) or 9.4.3.2 b)) and worst case momentum of the device under test than from achievable end speed, it is acceptable to take that worst case force and momentum.
SC 62A recommendation	Interpret the test condition "Run at any speed, including reasonably foreseeable misuse" as follows: In cases where worst case test conditions can better be derived from worst case forces (e.g. as defined in 9.4.2.3 a) or 9.4.3.2 b)) and worst case energy of impact at the end stop (= force times distance) of the device under test than from achievable end speed, it is acceptable to take that worst case force or energy of impact.

4.2.171 CREEPAGE DISTANCE and AIR CLEARANCE between input and output of fuse contacts

Recommendation number	171
Clause(s) number (only)	8.9.1
Source/problem	Unclear requirements for CREEPAGE DISTANCES and AIR CLEARANCE between fuse contacts.
Discussion/comment	The product has a certified mains fuse mounted on a PCB. The CREEPAGE DISTANCE between the printed tracks on the PCB on each side of the fuse is much less than the distance required for 1 MOOP. A minimum distance is required in order to guarantee that the fuses will not be bridged. Unfortunately it seems IEC 60601-1 has no specific text on this topic but it is common praxis that parts on either side of an open fuse are regarded as parts of opposite polarity. Therefore, 1 MOOP should be applied to be in line with 8.9.1.1, first dash. In IEC 60065, the distance across a fuse shall meet BI. In IEC 60950-1 the distance across a fuse is limited to functional insulation. Since functional insulation is not recognized by IEC 60601-1, a distance of 1 MOOP should be required. One member of the maintenance team responsible for the relevant material of IEC 60601-1 has remembered: This topic was discussed with the maintenance team responsible for the relevant material of IEC 60601-1during the writing of IEC 60050-1:2005/AMD1:2012. The result was that there are 2 extremes: a) not requiring 1 MOOP would mean that we have a gap in IEC 60601-1; b) requiring 1 MOOP would mean that too many IEC 60601-1 and IEC 60950 approved power supplies/linear transformers/PCB's would fail. The maintenance team responsible for the relevant material of IEC 60601-1was not aware of any incident or near incident based on the fact that no requirements have been set for CREEPAGE DISTANCES and AIR CLEARANCE between input and output fuse contacts. To ensure PATIENT care, it was intentionally decided that this aspect was not addressed in IEC 60601-1 with a requirement. It is simply unrealistic that the IEC 60950 field will change its power supplies due to an IEC 60601-1 requirement.
Submitter proposed recommendation	8.9.1.1, first dash, should be applied between fuse contacts.
SC 62A recommendation	SC 62A is not aware of any incidents on the market due to spacing of fuse contacts. Other standards do not define spacing for fuse contacts. There seems to be no need that IEC 60601-1 be the first standard to define requirements for that aspect.

4.2.172 Examples of SINGLE FAULT CONDITION

Recommendation number	172
Clause(s) number (only)	4.7 a)
Source/problem	The example "suspended masses without MECHANICAL PROTECTIVE DEVICES employing a TENSILE SAFETY FACTOR of 8X" is wrong in this context under 4.7 a)
Discussion/comment	4.7 a) talks about when equipment can be considered as SINGLE FAULT SAFE. The example (see above) is wrong and could be misinterpreted in such a way that safety factors below 8 would not be considered as safe and additional measures would be required in this case.
Submitter proposed recommendation	–
SC 62A recommendation	It is recommended to replace the example in 4.7.a) by: "suspended masses without MECHANICAL PROTECTIVE DEVICES complying with Table 21, rows 1 to 4."

4.2.173 Examples of ME SYSTEMS

Recommendation number	173
Clause(s) number (only)	Table I.1, examples 1a, 2a and 2c
Source/problem	At an IEC 62353 project team meeting, the question was raised: Is the following English language text in Table I.1, example 2c clear and unambiguous? – Do not use metal connector housing or, – SEPARATION DEVICE In a SC 62A meeting, the following question was raised: Is the proposed solution, for example in 1a and 2a, always correct?
Discussion/comment	Example 2c: Note 5 of Table I.1 clarifies the meaning of the concerned example: NOTE 5 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", then additional safety measures could be necessary, for example: additional protective earth for "B" or separating transformer or SEPARATION DEVICE. Examples 1a and 2a: There exists a RISK of increased LEAKAGE CURRENTS and the proposed solutions could be insufficient.
Submitter proposed recommendation	–
SC 62A recommendation	The following proposed improvements are recommended: Example 2c: Improve wording of the example in a future revision of IEC 60601-1. For example write "Use SEPARATION DEVICE". Examples 1a and 2a: Improve the proposed solutions in future revision of IEC 60601-1. "NOTE The examples in Table I.1 do not claim to cover all possible ME SYSTEMS. In addition, proposed solutions in Table I.1 are not intended to be the only possible solutions acceptable." Note that just because both products are ME EQUIPMENT does not automatically mean there are no possible LEAKAGE CURRENT issues in example 2a.

4.2.174 Cross sectional area of POWER SUPPLY CORD for rated input current > 63 A

Recommendation number	174
Clause(s) number (only)	8.11.3.3, Table 17
Source/problem	The maximum current range in Table 17 is $40 < I \leq 63$. There exists ME EQUIPMENT with a POWER SUPPLY CORD connection that operates with higher currents.
Discussion/comment	National electrical codes provide requirements for cross-sectional area of electrical supply conductors. Table 17 does not provide advice for ME EQUIPMENT operating at currents higher than 63 A.
Submitter proposed recommendation	–
SC 62A recommendation	It is recommended for ME EQUIPMENT utilizing POWER SUPPLY CORDS and operating at currents above 63 A to refer to national electrical code requirements in the country where the device is intended to be installed to determine the cross-sectional area requirements.

4.2.175 Biocompatibility for quasi APPLIED PARTS

Recommendation number	175
Clause(s) number (only)	4.6 11.7
Source/problem	Are the requirements of subclause 11.7 (Biocompatibility) applicable for parts which fall under the definition of subclause 4.6 (quasi-APPLIED PARTS)?
Discussion/comment	4.6 asks for an assessment to identify parts which are not APPLIED PARTS according 3.8 but might come in contact with the PATIENT. If a part falls under the definition of 4.6, all relevant requirements for TYPE B APPLIED PARTS shall be applied (except marking). 11.7 has to be applied for parts which are intended to come into direct/indirect contact with the PATIENT. Shall 11.7 be applied for parts which fall under the definition of 4.6?
Submitter proposed recommendation	–
SC 62A recommendation	SC 62A concurs that 4.6 could be read and understood differently. Therefore our recommendation is to apply RISK MANAGEMENT to find out if 11.7 applies to a part that can come in contact with the PATIENT. The expected contact time is one factor which could have significant impact for the decision about whether 11.7 should apply or not.

4.2.176 Floating reference earth

Recommendation number	176
Clause(s) number (only)	8.7
Source/problem	The use of the FE-symbol in Figures 9 to 11 and Figures 13 to 20 is unfortunate because it is often misunderstood, so that the test circuit, which primarily is supposed to be floating, instead is connected to earth of the installation.
Discussion/comment	The FE-symbol is intended to indicate the floating measurement reference point, i.e. the artificial earth/neutral point. Quote from the rationale (Annex A) of 8.7.4.2: "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 can provide additional protection for the person carrying out the measurements." However, it is allowed to do measurements with an earthed circuit in special cases when needed, for example due to high power consumption. Quote from the rationale (Annex A) of 8.7.4.3: "The isolation transformer in the measuring supply circuit provides additional protection for the person making the measurements and increases the accuracy of the LEAKAGE CURRENT measurements."
Submitter proposed recommendation	It is clear from Table 5 and the rationale that the existing FE-symbol in Figures 9 to 11 and Figures 13 to 20 shall be understood as a floating reference point that is not supposed to be connected to earth if not absolutely necessary. In a future revision of IEC 60601-1, it is recommended to replace the FE-symbol by another more neutral symbol that is not likely to be misunderstood, and in Table 5 to change the meaning of the symbol to: "Floating reference earth (for LEAKAGE ...."
SC 62A recommendation	It is recommended that in a future revision of IEC 60601-1 the functional earth symbol should be replaced by another reference ground symbol.

4.2.177 SINGLE FAULT CONDITION in OXYGEN RICH ENVIRONMENT

Recommendation number	177
Clause(s) number (only)	11.2.3
Source/problem	SINGLE FAULT CONDITIONS related to OXYGEN RICH ENVIRONMENTS: "Failure of insulation (whether solid material or spacing) providing the equivalent of at least 1 MOPP but less than 2 MOPP (as described in 8.8 and 8.9) that could create a source of ignition (as defined in 11.2.2.1 a))." The requirement for MOPP spacing in 11.2.3 deviates from the requirements given in IEC 60079-11 relating to intrinsic safety in explosive atmospheres, whereas the requirements are much closer when the spacing for MOOP is considered. Considering the 1 MOPP, 17 V value of 1,7 mm, any spacing violation less than that could be short-circuited in NORMAL CONDITION ("free-fault"). With the current state-of-the-art electrical component package sizes, there are very few components that would meet this value from pin to pin, making it impossible to lay a board out to meet 11.2.3 as it stands and there is no provision for reduced spacing in a PD1 environment.
Discussion/comment	Is the MOPP requirement appropriate as specified in IEC 60601-1? It would seem that the requirement for MOOP would be more appropriate for the following reasons: From IEC 60079-11, relating to intrinsic safety in explosive atmospheres, the infallible spacing values are given in Table 5, and a 30 V creepage of 2,0 mm is given. This is equivalent to DOUBLE INSULATION (NORMAL CONDITION or "free-fault" failures are considered at less than 1/3 of that value). Using the MOPP Table 12 from IEC 60601-1, a DOUBLE INSULATION creepage at 17 V is 3,4 mm. Using the MOOP Table 16 would lead to 2,4 mm for up to 50 V. IEC 60079-11 also specifies reduced spacing under a coating, (presumably associating to a pollution degree 1 environment) of 0,7 mm. The equivalent MOOP from IEC 60601-1 would be 0,8 mm from Table 15 via Table 16. MOPP requirements do not have any provision for reduced spacing in reduced pollution environments. The spacing requirements from IEC 60079-11 line up much better to the MOOP requirements of IEC 60601-1. IEC 60079-11 requirements are well established and provide safety from ignition in explosive atmospheres, which would lead to a severity of failure (in my opinion) at least equivalent to the severity of an ignition leading to an oxygen fire in the presence of a PATIENT, if not more severe. One would think that the requirements in an oxygen atmosphere would not be more onerous than the requirements in an explosive atmosphere.

Recommendation 177 *(continued)*

Discussion/comment (continued)	The requirements and philosophies from the two standards seem to be in alignment with the exception of this MOOP/MOPP discrepancy, and leads me to think that this could have been done in error. SC 62A discussion: Complex ME EQUIPMENT often contains many 2 MOOP barriers. Consequently, these 2 MOOP are less than 2 MOPP and, therefore, short-circuit of such 2 MOOP is considered a SINGLE FAULT CONDITION in 11.2.3. SC 62A would like to know the rationale for combining 11.2.3 with MOPP in the light of the above submitter rationale. Therefore, the issue is transferred to maintenance team responsible for the relevant material of IEC 60601-1.
Submitter proposed recommendation	Re-word the failure condition specified in 11.2.3 to consider the spacing based on MOOP spacing as follows. Also for clarification, a note is recommended. "Failure of insulation (whether solid material or spacing) providing the equivalent of at least 1 MOOP but less than 2 MOOP (as described in 8.8 and 8.9) that could create a source of ignition (as defined in 11.2.2.1 a)). NOTE Insulation less than 1 MOP can be short-circuited; however, this is considered NORMAL CONDITION."
SC 62A recommendation	The issue was referred to maintenance team responsible for the relevant material of IEC 60601-1, with the following result: The maintenance team responsible for the relevant material of IEC 60601-1 acknowledged that the issue needs to be clarified. However, due to the fact that the wording in 11.2.3 is clear, we cannot change the standard requirement at the moment. Therefore, the issue is put on the agenda for a future revision of IEC 60601-1. Discussions about a solution of alternative RISK CONTROL measure related to the transient energy level within an OXYGEN RICH ENVIRONMENT has been started but not completed. SC 62A is unable to make a recommendation at this time. The issue is put on the agenda for a future revision of IEC 60601-1.

4.2.178 Laser requirements

Recommendation number	178
Clause(s) number (only)	10.4
Source/problem	Laser hazards not addressed
Discussion/comment	IEC 60601-1 addresses lasers in 10.4, but there is no requirement for RISK MANAGEMENT of lasers with intended AEL (accessible emission limit) values of class 2, 2M and 3R (class 1 lasers are inherently safe and classes 3B and 4 are covered by IEC 60601-2-22). 10.4 requires compliance with IEC 60825-1, which clearly states that Class 2 and 3R lasers can be hazardous, but there are no safety requirements if the AEL are designed to be greater than class 1 for the intended function of the equipment. While standards such as IEC 60601-2-22 and IEC 60601-2-57 focuses on both PATIENT and OPERATOR safety, IEC 60825-1:2007 comes from the occupational safety at work for OPERATORS and any other person standing nearby. IEC 60825-1:2007 contains technical requirements for 2, 2M and 3R laser products, for example in 4.2, 4.2.2, 4.3, 4.7, and 4.9. In addition, descriptive safety requirements are defined in Clause 5. IEC 60825-1:2007 requirements for class 2, 2M and 3R laser are regarded as sufficient. It is not regarded as appropriate for IEC 60601-1 to go above the requirements of IEC 60825-1:2007 and define further requirements for lasers. A link to RISK MANAGEMENT seems to be contra-productive, because we want to reduce the links to RISK MANAGEMENT within IEC 60601-1 wherever possible. In addition, for clear gaps, 4.2 is applicable anyway (see 4.2.3.2 of IEC 60601-1:2005/AMD1:2012).
Submitter proposed recommendation	–
SC 62A recommendation	Gaps are to be handled according to 4.2. IEC 60601-1 covers the issues of handling gaps.

4.2.179 Flammability rating of insulated wires

Recommendation number	179
Clause(s) number (only)	11.3 a)
Source/problem	Flammability rating for insulated wires.
Discussion/comment	Some internal insulated wires are not approved and marked with FV-1. Can an insulated wire complying with IEC 60332-1-2 (> 0,5 mm^2) or IEC 60332-2-2 (≤ 0,5 mm^2) also be used?
Submitter proposed recommendation	Internal wires complying with IEC 60332-1-2 (> 0,5 mm^2) or IEC 60332-2-2 (≤ 0,5 mm^2) can be used to show compliance with 11.3 a) for insulating wires.
SC 62A recommendation	It is recommended that the wording in Annex A about alternative wires complying with – IEC 60332-1-2 (> 0,5 mm^2), – IEC 60332-2-2 (≤ 0,5 mm^2), and – UL 2556 (rating of VW-1) should be normative. Another topic to be included in work for a future revision of IEC 60601-1: The rationale in Annex A, subclause 11.3, regarding IEC 60950-1 is in contradiction with the normative requirement in 11.3 and 13.1.2.

4.2.180 Infrared lamps

Recommendation number	180	
Clause(s) number (only)	IEC 60601-1:2005, 11.1.2.1, 8.4.2 c), 5.9.2.1. IEC 60601-1-11:2010, 8.3.1 and IEC,60601-1-11:2015, 8.3.1.	
Source/problem	Many infrared lamps have a very simple design: mains power cord, E27 socket, ENCLOSURE and the lamp. These devices PASS the 2nd Ed. but FAIL the 3rd Ed. of IEC 60601-1.	
Discussion/comment	**2nd ed. IEC 60601-1:1988, IEC 60601-1:1988/AMD1:1991 and IEC 60601-1:1988/AMD2:1995**	**3rd ed. IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012**
	AP-temperature and ENCLOSURE temp: **Excluded** by Clause 42, Table 10a.	**AP-temperature:** If the glass = output of the light is regarded as "quasi AP" based on 4.6 plus 11.1.2.1 "APPLIED PART intended to supply heat to the PATIENT", then there exists no standard temperature limit for the glass. **ENCLOSURE-temperature:** In the best case, the limit of 86°C applies out of Table 23. ➔ **FAIL**, measured in NORMAL CONDITION 122 °C when corrected to 40 °C environment.
	Accessible voltage: **Excluded** by 16 e) 2) and recommendation 12 for the 2nd edition: 16 e) plus the recommendation 12 allow access to LIVE parts during removal of lamps without any limitation to the voltage value, i.e. 240 V RMS is included, and you find such 2nd edition approved devices on the market.	**Accessible voltage:** The changing of the lamp is possible without the aid of a tool (= the same as for a normal household lamp). During changing the lamp, 230 V contacts are accessible. ➔ **FAIL,** 8.4.2 c) and 5.9.2.1 of the 3rd edition: 8.4.2 c) allows access to parts which could produce touch currents of about 100 µA, for example at lamp holder contacts, but ONLY if the voltage remains ≤42,4 V peak, i.e. 240 V RMS. is EXCLUDED. And, therefore, the infrared lamps FAIL the 3rd edition.
	IP-protection: No requirement in the 2nd Edition.	**IP-protection:** IEC 60601-1-11 requires IP21. ➔ **FAIL**, lamp could be adjusted in different positions, for example upwards.

Recommendation 180 *(continued)*

Discussion/comment (continued)	The FAILS related to IEC 60601-1-11 and related to the ENCLOSURE temperature are clear. However, the FAIL related to accessible MAINS voltage during changing the lamp is not clear: For lamp holders with an Edison socket such as E27, there exists horizontal safety standards. It is normally expected that product safety standards implement horizontal safety standard requirements as far as possible, or if the product safety standard deviates from a horizontal safety standard, there should be a justification provided. However, there is no such justification given within IEC 60601-1:2005 for the banning of E27 sockets for lamps.
Submitter proposed recommendation	–
SC 62A recommendation	The next revision of IEC 60601-1 should provide justification for banning lamp sockets with accessible voltages above of 60 V DC and 42,4 V peak (e.g. E27 socket) within IEC 60601-1:2005, Annex A. Alternatively, under certain conditions, the banning of such sockets should be withdrawn by the next revision of IEC 60601-1.

4.2.181 Identification of internal fuses

Recommendation number	181
Clause(s) number (only)	7.3.4
Source/problem	The labelling requirement in 7.3.4 for "fuses and replaceable THERMAL CUT-OUTS and OVER-CURRENT RELEASES that are accessible only by the use of a TOOL" can be read in such a way that even non-replaceable fuses and non-replaceable OVER-CURRENT RELEASES inside of the ME EQUIPMENT have to be labelled with the full rating information either adjacent to the component (e.g. on the printed circuit board) or in the ACCOMPANYING DOCUMENTS. However, for repair purposes (non-replaceable fuses, THERMAL CUT-OUTS or OVER-CURRENT RELEASES result in a repair), IEC 60601-1 gives a deviating instruction in 7.9.3.3. This seems to be an internal contradiction in IEC 60601-1. There is also no explanation for the conflicting requirements, for example why 7.3.4 should be applied only on replaceable THERMAL CUT-OUTS, but on replaceable and non-replaceable fuses and OVER-CURRENT RELEASES? Writing full rating information beside a fuse on the PCB, however, is mostly not possible due to limited space, and identifiers are commonly used and resolved in the circuit diagrams and parts lists for components not intended to be replaced or repaired by the RESPONSIBLE ORGANIZATION.
Discussion/comment	For non-replaceable internal fuses, THERMAL CUT-OUTS and OVER-CURRENT RELEASES (i.e. those accessible only with a tool and after access also not exchangeable or only exchangeable with a special tool or with soldering), should the requirements of 7.9.3.3 be applied?
Submitter proposed recommendation	–
SC 62A recommendation	It is recommended that no distinction be made in 7.3.4 between fuses, THERMAL CUT-OUTS and OVER-CURRENT RELEASES; read the word "replaceable" for all three component types to be in line with the requirements of 7.9.3.3.

4.2.182 Chargers for ME EQUIPMENT used at home

Recommendation number	182
Clause(s) number (only)	IEC 60601-1-11
Source/problem	There is no guidance on when a PATIENT ceases to be such and becomes an OPERATOR when the OPERATOR does not require the MOPP but MOOP is sufficient. ➔ SC 62A: This is clarified in 7.9.2.1 of IEC 60601-1:2005/AMD1:2012. There is no clause for protection against electrical hazards ➔ SC 62A: This is clarified by the whole IEC 60601 series.
Discussion/comment	A BODY-WORN home healthcare device clearly requires MOPP. However, if the medical device is disconnected from the PATIENT and then connected to a mains powered charger – this latter operation is not medically related and is no different from the OPERATOR handling an iPhone and connecting it to a charger. So, clearly, the mains charger can be an IEC 60950-1 compliant one as long as simultaneous connection to the charger and to the PATIENT is not possible. If simultaneous connection of the device to the PATIENT and the device to a mains connected charger is possible, then clearly the charger has to comply with IEC 60601-1. ➔ SC 62A: According to 7.9.2.3, the charger can remain IEC 60950-1 compliant. HOWEVER – at the instant that the PATIENT disconnects the device from the charger there could be the possibility of a LEAKAGE CURRENT path from the PATIENT to earth through the charger via the DC connector, and this could be > 0,1 mA. ➔ SC 62A: Correct. The DC connector is covered by 8.4.2 c) for voltage and energy limitation. See recommendation 191. HOWEVER – this is no different from the situation where the PATIENT is using the medical device and touching a domestic appliance or iPhone charger. Clarification of when MOPP is required is needed. ➔ SC 62A: Is already clarified in IEC 60601-1.
Submitter proposed recommendation	Make a decision that parts of a MEDICAL ELECTRICAL SYSTEM used in the home healthcare environment (e.g. a mains powered battery charger) might not require MOPP if normal operation does not subject the PATIENT to a higher RISK than that which normally exists in the home. The next revision of IEC 60601-1-11:2015 should consider creating a new clause addressing the following specific aspect: "The PATIENT in the home healthcare environment shall be protected against electrical HAZARDS by verifying that the device complies with Clause 8 of IEC 60601-1:2005. However, parts of a MEDICAL ELECTRICAL SYSTEM (e.g. a mains powered battery charger) might not require MOPP if normal operation does not subject the PATIENT to a higher RISK than that which normally exists in the home."
SC 62A recommendation	The issue is covered by IEC 60601-1 series.

4.2.183 CLASS II ME EQUIPMENT with FUNCTIONAL EARTH CONDUCTOR

Recommendation number	183
Clause(s) number (only)	8.6.9
Source/problem	Some CLASS II ME EQUIPMENT with an earth conductor has appeared on the market even though they do not have any earthed internal screen.
Discussion/comment	It is unclear why it is allowed, and what is the benefit of classifying ME EQUIPMENT with an earth lead as a CLASS II product. This is against the common safety understanding among the population and is much disliked by some national electrical safety authorities. It is also unclear why this relaxation is limited to internal screens only. In some CLASS II ME EQUIPMENT, the earth lead is used for other purposes than internal screens and sometimes it is not used at all, i.e. it is simply connected to an empty terminal. An example is that in order to achieve more rigidity a three pin APPLIANCE INLET is used on CLASS II ME EQUIPMENT, which allows the use of a CLASS I cord-set, but there is nothing else connected to the earth terminal. Is ME EQUIPMENT with an unused earth terminal or an earth terminal used for other functional purposes than an internal screen allowed to be marked with the CLASS II symbol?
Submitter proposed recommendation	ME EQUIPMENT with an unused earth terminal or an earth terminal used for other functional purposes than an internal screen is not allowed to be marked with a CLASS II symbol. Even when connected to an internal screen, the use of a CLASS II symbol should be avoided or, if used, it should be justified.
SC 62A recommendation	SC 62A has the feeling the submitter's proposal seems too stringent. IEC 60601-1 does not define the term "isolated internal screens". That allows MANUFACTURERS and test laboratories to have a certain margin of interpretation of the words. In 8.6.9, IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 defines the required safety requirements that shall be fulfilled. As long as the safety requirements are fulfilled, there is no safety reason to reject the following designs: A) ME EQUIPMENT with an unused earth terminal; B) ME EQUIPMENT with an earth terminal used for other functional purposes than an internal screen. SC 62A does not see any safety reason to be more stringent than IEC 60601-1 and to ban such CLASS II devices. During the next revision of IEC 60601-1, it should be considered if the term "internal screen" is the only example or if others might exist as well.

4.2.184 Symbol ISO 7010-W001 (2011-05) on a MULTIPLE SOCKET-OUTLET (MSO)

Recommendation number	184
Clause(s) number (only)	16.9.2.1 b), first dash
Source/problem	The requirement to mark a multiple socket-outlet (MSO) with the general warning sign (no. 2 in Table D.2) is in contradiction with how signs/symbols should be used.
Discussion/comment	The purpose of marking an MSO with the general warning sign is unclear. The general warning sign should not be used alone because it does not inform the user of the meaning. In 7.5, it is made clear that a safety signs shall be clear about its meaning. If a suitable sign is not available one can construct a sign for the particular meaning or use the general warning sign together with an explanatory text. The general warning sign should be replaced by the "refer to instruction" manual sign.
Submitter proposed recommendation	As an alternative, the mandatory action sign no. 10 in Table D.2 can be used.
SC 62A recommendation	SC 62A has the consensus that 16.9.2.1 b) is clear.

4.2.185 PATIENT leads connectors

Recommendation number	185
Clause(s) number (only)	8.5.2.3
Source/problem	8.5.2.3 is too rigid (both too stringent and too non-stringent) and does not consider the various protection degrees, fixed or temporarily APPLIED PARTS and various length of PATIENT leads/cables. IEC 60601-1 makes no difference between A) APPLIED PARTS fixed to the PATIENT, and B) APPLIED PARTS temporarily held against the PATIENT by the OPERATOR. The requirement in 8.5.2.3 seems a bit too stringent in some cases of B), for example a dental ultrasonic scaler probe or a light therapy probe in metal. Disputes between test laboratories and MANUFACTURERS are common, and experience shows that test laboratories are not aligned because some claim that a lead/cable on a probe belonging to B) above is not regarded as a PATIENT lead/cable. Unfortunately, no such example is displayed among Figures A.1 to A.7. Shall 8.5.2.3 be strictly applied to all types of ME EQUIPMENT?
Discussion/comment	The intention of IEC 60601-1 is to assure that the PATIENT will not be accidently earthed or exposed to voltage potentials. This could happen if the remote end connector is detached, accidently or deliberately, by an OPERATOR or any other person. In case A) (fixed to PATIENT), this makes perfect sense. However, there is significantly less likelihood that this will happen in case B) (temporarily held against the PATIENT by the OPERATOR). For ME EQUIPMENT with TYPE CF APPLIED PARTS, 8.5.2.3 should be applied without any exceptions. Even though the third, fourth and fifth dashes in 8.5.2.3 do not refer to RISK MANAGEMENT, the RISK MANAGEMENT approach would be reasonable, at least for the third and fourth dashes, for remote connectors of TYPE B APPLIED PARTS (perhaps also for TYPE BF APPLIED PARTS) that are only temporarily held against the PATIENT by the OPERATOR. The likelihood that such a tool/probe is in contact with the PATIENT while it is not working due to detached connector is very low. The same problem exists for PATIENT leads that are very short, for example ≤ 12 cm. In this case, the third and fourth dashes of 8.5.2.3 seem too stringent for some APPLIED PARTS.
Submitter proposed recommendation	RISK MANAGEMENT can be accepted for the first two dashes of 8.5.2.3 for an APPLIED PART of TYPE B or BF that is only temporarily held against the PATIENT by the OPERATOR or for an APPLIED PART of TYPE B or BF where the PATIENT lead or cable is maximum 12 cm.
SC 62A recommendation	The term "remote" needs to be clarified. The following is recommended as clarification: a) Short leads or cables, which are short enough not to come in contact with earth (e.g. 12 cm length) should not to be considered as remote with respect to contact to ground. Therefore, the third and fourth dashes of 8.5.2.3 should be regarded as not applicable. NOTE 1 This interpretation is based on the fact that if a short cable would come in contact with earth, the PATIENT'S body is assumed to be already in contact with earth. NOTE 2 The fifth and sixth dashes still apply. b) The aspect related to OPERATOR HAND-HELD APPLIED PARTS should be considered during the next revision of IEC 60601-1. SC 62A is unable to make a recommendation at this time.

4.2.186 Rationale for IP2X

Recommendation number	186
Clause(s) number (only)	Annex A, Subclause 6.3
Source/problem	Incorrect rationale leading to misleading marking. The rationale in Annex A, Subclause 6.3, claims that ME EQUIPMENT meeting the requirements of 5.9 automatically allows MANUFACTURERS to rate the ME EQUIPMENT as IP2X because the requirements for IP2X in IEC 60529 are the same as in 5.9. This is simply not true.
Discussion/comment	The requirement for IP2X in IEC 60529 is twofold. 1) Protection for persons: The standard test finger (12 mm) shall not be able to enter the encapsulation in such a way that hazardous parts become accessible (there shall be adequate clearance from hazardous parts). See Table 1 in IEC 60529:1989 and IEC 60529:1989/AMD1:1999. 2) Protection for the equipment: The sphere (12,5 mm) shall not be able to fully enter the encapsulation. Following the rationale in IEC 60601-1 means that an IP2X rated ME EQUIPMENT could have an opening of > 12,5 mm (allowing the sphere to enter) even though the entered standard test finger does not reach any hazardous parts. This is not in compliance with the equipment protection requirement in IEC 60529.
Submitter proposed recommendation	–
SC 62A recommendation	The identification of the gap between IEC 60601-1 and IEC 60529:1989 and IEC 60529:1989/AMD1:1999, Tables 1 and 2, related to IP2X is that protection of persons (Table 1) is equivalent while protection of equipment against solids (Table 2) is not fully equivalent. It is recommended to label ME EQUIPMENT with IP2X only if compliance with Table 2 of IEC 60529:1989 and IEC 60529:1989/AMD1:1999 is given as well. It is recommended that, during the next revision of IEC 60601-1, Annex A, Subclause 6.3, be deleted, because it is proved to be not correct.

4.2.187 Battery – Limited power

Recommendation number	187
Clause(s) number (only)	11.3 and 13.1.2
Source/problem	Energy content in batteries above the limited energy limits. Where does the border line go regarding the "supply circuit", as mentioned in 13.1.2? After an external fuse directly on the output of the battery or before the external fuse, or even before the protection circuit built into the certified battery?
Discussion/comment	Presume an ME EQUIPMENT powered by an internal battery, which is certified to a standard such as IEC 62133, and with an output over-current protection ensuring the available energy from the battery is below the limits for limited energy. This would mean that a fire ENCLOSURE is not required around the remaining circuitry. However, the stored energy inside the battery itself is above the limits for limited energy should a failure occur in the certified battery. In such a case, is a fire ENCLOSURE required?
Submitter proposed recommendation	A fire ENCLOSURE is not required when a certified battery is used (IEC 60086-4 or IEC 62133) and the output from the battery has an over-current protection device ensuring the available energy is below the levels for limited energy in 13.1.2.
SC 62A recommendation	SC 62A is unable to make a recommendation at this time. This issue should be address during the next revision of IEC 60601-1. SC 62A would recommend that the next revision of IEC 60601-1 include comprehensive guidance on how to deal with certified batteries and battery packs.

4.2.188 TYPE B APPLIED PART separated from ACCESSIBLE PARTS

Recommendation number	188
Clause(s) number (only)	8.5.2.2
Source/problem	PATIENT CONNECTIONS of a TYPE B APPLIED PART that is not PROTECTIVELY EARTHED shall be separated by one MOPP.
Discussion/comment	It is unclear if this MOPP shall be based on the rated voltage (would mean same distances as for BF and CF) or on the actual WORKING VOLTAGE in the APPLIED PART.
Submitter proposed recommendation	Apply 1 MOPP based on the actual WORKING VOLTAGE in the APPLIED PART.
SC 62A recommendation	IEC 60601-1 provides 3 options: a) the APPLIED PART is protective earth connected; b) the APPLIED PART is classified TYPE B but has a barrier between the APPLIED PART and the non-protective earth accessible part of 1 MOPP based on MAINS VOLTAGE – see Table 4 and Figure 18; c) the ACCESSIBLE PART is deemed contiguous with the APPLIED PART, and RISK MANAGEMENT shows that the ACCESSIBLE PART is not likely to be subjected to external voltages. The link to RISK MANAGEMENT in 8.5.2.2 should be used as well for cases where the ACCESSIBLE PART is not fully contiguous with the APPLIED PART.

4.2.189 Protective earth test > 25A

Recommendation number	189
Clause(s) number (only)	8.6.4 a)
Source/problem	In the compliance statement, the text "*A current of 25 A or 1,5 times the highest rated current of the relevant circuit(s)*" is not clear.
Discussion/comment	What is *"the relevant circuit"*? In the 2nd edition of IEC 60601-1, it was the *"RATED current of the EQUIPMENT"* and it can therefore be interpreted that the meaning in the 3rd edition is the same thing as in the 2nd edition. Also, the 3rd edition of IEC 61010-1 states 25 A or *"a current equal to twice the rated current of the equipment."* However, the equipment rating seems completely irrelevant and there can be a significant difference between the rated current of the equipment and the rated current of the equipment mains fuse. Therefore, the test should be based on the equipment fuse rating rather than the equipment rating. If instead the meaning is the rated current of the over-current protection in the fixed building installation, there is a problem how to find out the rated current. It would require that the maximum rating of the over-current protection in the building is always specified in the instructions for use and technical description, even for plug connected ME EQUIPMENT, which seems not reasonable. Perhaps one can presume a 16 A fuse in Europe and a 20 A fuse in Canada. It seems too stringent to test based on the building installation rather than on the equipment fuse value, for example in the case of an appliance inlet assembly with built-in fuse holder.
Submitter proposed recommendation	–
SC 62A recommendation	It is recommended that the text "the highest RATED current of the relevant circuit(s)" should be understood as the RATED current of the mains over-current protection in the ME EQUIPMENT, when present, for all circuits located behind the mains over-current protection. For the area in front of the mains over-current protection in the ME EQUIPMENT, the "highest RATED current of the relevant circuit(s)" should be understood as the rating of the over-current protection in the building installation.

4.2.190 Reference to IEC 62304:2006

Recommendation number	190
Clause(s) number (only)	Clauses 2 and 14 IEC 62304:2006
Source/problem	The reference to IEC 62304 is dated 2006, which shall therefore be used whereas the forthcoming IEC 60050-1:2005/AMD1:2012 will address legacy software which is a very important addition allowing MANUFACTURERS to demonstrate compliance of their software. Redesigning software completely is usually not an option (IEC rules disallow undated reference for normative standards if only part of the standard is referenced as here in Clause 14).
Discussion/comment	–
Submitter proposed recommendation	Allow use of the most up to date version of IEC 62304
SC 62A recommendation	Because IEC 60601-1 has a gap about how to deal with legacy software, the MANUFACTURER is forced to use RISK MANAGEMENT to fill the gap. Because RISK MANAGEMENT according to ISO 14971 requires the MANUFACTURER to use International Standards, application of 4.4 of IEC 62304:2006/AMD1:2015 should be regarded as one acceptable solution. In addition, ISO 14971 requires that RISK MANAGEMENT shall be based on the state of the art, which means that newer International Standards should be taken into account. See as well NOTE 3 in 14.1 of IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012.

4.2.191 The SIP/SOP pin to earth TOUCH CURRENT

Recommendation number	191
Clause(s) number (only)	8.4.2 c)
Source/problem	LEAKAGE CURRENT measurements from connector pins to earth. The subclause is being interpreted differently among test laboratories.
Discussion/comment	Some test laboratories have not documented the LEAKAGE CURRENT from SIP/SOP connector pins or SMPS output pins to earth, which can easily be verified by reviewing existing TRFs on the market related to both 2nd and 3rd editions of IEC 60601-1. The rationale for not measuring this described LEAKAGE CURRENT is that 8.4.2 c) explicitly mentions that the limits for TOUCH CURRENT do not apply for accessible contacts of connectors. This exemption is combined with the requirement that these connectors shall have a maximum allowed voltage of 42,4 V peak or 60 V DC, plus energy power limitation in NORMAL CONDITION and SINGLE FAULT CONDITION. Does the conditional exclusion of measuring TOUCH CURRENT on SIP/SOP connectors and power output connectors, in circuits separated with 2 MOP from the mains supply, includes the LEAKAGE CURRENT generated from the MAINS VOLTAGE source, even though the voltage potential is typically much above 42,4 V peak (at 240 V AC mains supply), or is the conditional exclusion related only to currents typically generated by the secondary voltage source of maximum 42,4 V peak or 60 V DC, i.e. the "secondary WORKING VOLTAGE"?

Recommendation 191 *(continued)*

	It seems the exclusion was introduced in order to not enforce all connectors to be touch proof but, on certain conditions, to allow OPERATOR access to, for example, secondary 5 V DC (even though it could generate a current of 5 mA DC). Following IEC 60601-1 to the letter, as also evident by the note in 8.4.2, means that SIP/SOP connectors, power supply output connectors, etc. shall normally be regarded as ACCESSIBLE PARTS of the ENCLOSURE and thus meet the TOUCH CURRENT requirements for currents generated from the mains source, when measuring it with a high impedance test equipment, which for the vast majority of ME EQUIPMENT is a voltage in the range of 100 V to 240 V AC. NOTE It is usually assumed that, in NORMAL CONDITION, the TOUCH CURRENT limit 100 µA applies and, in SINGLE FAULT CONDITION (e.g. protective earth open or neutral conductor open), the limit 500 µA applies for MOOP ACCESSIBLE PARTS.
Submitter proposed recommendation	As stated in IEC 60601-1, the conditional exclusion is related only to currents generated by a voltage of maximum 42,4 V peak or 60 V DC
SC 62A recommendation	The wording in 8.4.2 c) should be improved to avoid misunderstanding. According IEC 60601-1, it is strictly required to measure the concerned SIP/SOP-pin to earth voltage first: Connect a resistor of 10 kΩ ± 5 % (8 W for measurements up to 280 V RMS) between the SIP/SOP-pin (or other output connector) to earth. Connect in parallel to the 10 kΩ resistor a voltmeter or an oscilloscope to measure the voltage. If the voltage measured above is less than 60 V DC or 42,4 V peak AC, a subsequent LEAKAGE CURRENT test is not necessary. NOTE A similar approach exists in IEC 60950-1:2005, subclause 1.4.9. 10 kΩ has been selected, because it shall be a value higher than the body impedance of the OPERATOR (= 1 kΩ) and lower than the expected impedance of the insulation barrier (approximately MΩ). Furthermore, IEC 60950-1 used a 5 kΩ resistor, and therefore using a 10 kΩ resistor is on the safe side. If the voltage measurement above leads to exceeded levels, then the following guide is recommended to measure the TOUCH CURRENT: It is recommended to measure the TOUCH CURRENT from SIP/SOP connectors to earth and as well from separate power supply output connectors to earth for the following items: – CLASS II power supply units; – CLASS II ME EQUIPMENT; – CLASS I ME EQUIPMENT with floating (non-earth referenced) secondary circuits; – CLASS II ME EQUIPMENT with FUNCTIONAL EARTH CONDUCTOR according to 8.6.9 and with floating (non-earth referenced) secondary circuits. Measure the mains derived TOUCH CURRENT by applying the limits in 8.7.3 c) from the connectors described above in: – NORMAL CONDITION, and – SINGLE FAULT CONDITION (respectively open neutral conductor; open PROTECTIVE EARTH CONDUCTOR (if applicable), open FUNCTIONAL EARTH CONDUCTOR (if applicable).

Recommendation 191 *(continued)*

SC 62A recommendation	NOTE 3 If the SIP/SOP circuit is completely isolated from the floating (non-earth referenced) secondary circuit by an own insulation barrier of at least 1 MOOP based on MAINS VOLTAGE, i.e. a SEPARATION DEVICE according to 16.5, the measurement of the SIP/SOP connector to earth TOUCH CURRENT does not need to be conducted. In such cases, it is sufficient to evaluate the effectiveness of the SEPARATION DEVICE by measurement according to 8.7.4.7 c). NOTE 4 For CLASS I ME EQUIPMENT with earth referenced SECONDARY CIRCUITS, the MAINS derived LEAKAGE CURRENT will in NORMAL CONDITION be superimposed by the secondary extra low voltage generated current. However, the MAINS derived LEAKAGE CURRENT will usually be equal to the TOUCH CURRENT measured on parts connected to the PROTECTIVE EARTH TERMINAL both in NORMAL CONDITION and in SINGLE FAULT CONDITION (open neutral conductor; open PROTECTIVE EARTH CONDUCTOR). If in doubt, the measurement can usually be done by setting the voltage meter to AC-measurement only or by using an oscilloscope or any other equivalent method to assure that the secondary voltage will not influence the measurement result. Additional hint for work on a future revision of IEC 60601-1: Within a ME SYSTEM, non-ME EQUIPMENT (such as a display equipment) approved according IEC 60950-1 could have accessible pins in the PATIENT ENVIRONMENT, and LEAKAGE CURRENTS from such pins to earth, when the connector is disconnected from the ME EQUIPMENT, might exceed 0,1 mA, because IEC 60950-1 limits go up to 3,5 mA.

4.2.192 Overbalancing

Recommendation number	192
Clause(s) number (only)	9.4.2.3 b)
Source/problem	"ME EQUIPMENT or its parts, other than FIXED ME EQUIPMENT, that is intended to be used on the floor or on a table shall be permanently marked with a CLEARLY LEGIBLE warning of this RISK, e.g. by use of safety signs ISO 7010-P018 (2011-05) or ISO 7010-P019 (2011-05) as appropriate (see Table D.2, safety signs 6 and 7), or it shall not overbalance due to being sat or stepped upon." This requirement means that either the equipment does not overbalance when carrying out the test or it is marked. There is no explicit exception for equipment for which overbalancing due to a static force cannot be assumed (e.g. small equipment or equipment with no potential stepping or sitting misuse).
Discussion/comment	Does the wording "as appropriate" refer to the application of the requirement or to the labelling?
Submitter proposed recommendation	Marking in the case of overbalancing should be done, if potential stepping or sitting misuse can be assumed.
SC 62A recommendation	The word "as appropriate" refers solely to the correct selection of the safety sign. The compliance paragraph in 9.4.2.3 b) contains the solution requested, because it mentions *"offering an obvious foothold or sitting surface of a minimum 20 cm by 20 cm area".* SC 62A suggests that, during work on a future revision of IEC 60601-1, the solution in the compliance paragraph be inserted in the requirement part above as well.

4.2.193 MAINS VOLTAGE on APPLIED PART

Recommendation number	193
Clause(s) number (only)	8.7.4.7 b)
Source/problem	PATIENT CONNECTIONS of functions of a ***single*** APPLIED PART circuit other than those under test are not connected to earth in the SINGLE FAULT CONDITION of mains on APPLIED PART.
Discussion/comment	Consider an ME EQUIPMENT with a single APPLIED PART circuit of two functions. The PATIENT CONNECTIONS of one function are connected to a PATIENT and the PATIENT CONNECTIONS of the other function are hanging free from the ME EQUIPMENT. If MAINS VOLTAGE is applied to the PATIENT and the unconnected PATIENT CONNECTIONS become earthed, an excessive LEAKAGE CURRENT will flow from PATIENT to earth (if there is no isolation between the two functions). 8.7.4.7 b) does not address this situation of two functions of one single APPLIED PART circuit, but only addresses earthing of PATIENT CONNECTIONS of ***other*** APPLIED PARTS (which therefore have to be isolated from the one under test). This is clearly a gap in IEC 60601-1.
Submitter proposed recommendation	–
SC 62A recommendation	The described HAZARDOUS SITUATION occurs if both functions of a single APPLIED PART circuit are conductive at the PATIENT CONNECTION, for example such as ECG and EEG on one common circuit. In the meaning of IEC 60601-1 as a whole, the functions could be different from those covered by IEC 60601-2-49. It is recommended to apply the solution from IEC 60601-2-49:2011, 201.8.5.2.3, for all kind of functions including those not covered by IEC 60601-2-49. A future revision of IEC 60601-1 should be considered if some requirements from IEC 60601-2-49 could be transferred to IEC 60601-1. Figure AA.1 in IEC 60601-2-49:2011 could be improved to clearly show if a detached PATIENT CONNECTION concerns only the connector to, for example, an ECG-electrode, or if the adhesive electrode itself is also included. If the electrode itself is not included, a black spot without lead should remain on the PATIENT.

4.2.194 TYPE B vs TYPE BF SFC limits

Recommendation number	194
Clause(s) number (only)	Limit of PATIENT LEAKAGE CURRENT TYPE BF APPLIED PART in special SINGLE FAULT CONDITION (external voltage on the APPLIED PART) = 5,000 µA IEC 60601-1:2005, Table 3 and Table 4
Source/problem	The limit of 5 mA PATIENT LEAKAGE CURRENT with TYPE BF APPLIED PART in SFC is too high and not acceptable/logical regarding the PATIENT RISK, in comparison to the LEAKAGE CURRENT limit in SFC of TYPE B APPLIED PART.
Discussion/comment	Regarding the PATIENT safety, the TYPE BF APPLIED PART is situated in the middle between TYPE B and TYPE CF. Type BF suggest a higher safety then Type B, therefore it is not logical that the PATIENT LEAKAGE CURRENT in any SFC of TYPE BF is 10 times higher than the limit for SFC of TYPE B (BF = 5 000 µA, B = 500 µA) The LEAKAGE CURRENT in SFC of TYPE B is flowing out of the medical device, through the PATIENT CONNECTION, through the PATIENT, to the ground.

Recommendation 194 *(continued)*

Discussion/comment (continued)	The LEAKAGE CURRENT of TYPE BF in the special SFC (= external voltage on the APPLIED PART) is flowing in the other direction, from an external voltage, through the PATIENT, through the PATIENT CONNECTION, into the medical device (and inside the ME device to ground). If you look from the RISK situation of a PATIENT, it does not matter in which direction the current is flowing through him and which of the possible SFC's causes the current. That means either the 5 mA in SFC for TYPE BF APPLIED PART are much too high for the PATIENT, or they are ok. If the 5 mA value is acceptable, then it is not understandable why the LEAKAGE CURRENT limit for an TYPE B APPLIED PART, with lower safety, has to be 10 times lower than that of a TYPE BF APPLIED PART. The limit of the PATIENT LEAKAGE CURRENT has to belong only to the effect the current is resulting in, while the current is flowing through the PATIENT. The limit has not to belong to a certain high of voltage, to a certain reason of the voltage or to the direction of the current. Current and not voltage is danger, and current is the result of voltage and internal impedance! High voltage by itself is not danger, if the internal impedance is so high that the resulting current is below the limit. The direction, how the PATIENT LEAKAGE CURRENT is flowing (from or to the PATIENT), is totally unimportant too. And last but not least: the reason of a voltage, which is driving A PATIENT LEAKAGE CURRENT, is totally unimportant as well, for the effect of the current and for the limit. In summary: Nothing else is important then the limit of the current through the PATIENT (including information AC, DC and perhaps frequency). No reason of the voltage, no high of the voltage, no direction the current is flowing. Table 3 has a lot of lines but mostly with the same values. That makes easy things looking more complicate then they are. In general, this is a lot of paper with less information on. We should stay more professional in the standard.
Submitter proposed recommendation	Change the limit of the PATIENT LEAKAGE CURRENT of TYPE BF APPLIED PARTS in all SFC general to 500 µA, not matter which kind of SFC, including mains voltage on the APPLIED PART. Bring Table 3 and Table 4 of IEC 60601-1:2005 together in one simple table and delete all the reasons of the voltages in the descriptions of that table. If necessary, you can explain some additional information in the informative annex about possible reasons of voltages.
SC 62A recommendation	There is no ambiguity of the requirements in this respect in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012. The informative Annex A, Subclause 8.7.3, clearly describes how the limits are derived. The values are based on probability of occurrence of the different SINGLE FAULT CONDITION or even double failure of protective means in other equipment. The issue of whether 5 mA is a reasonable value for all kind of PATIENTS, for example children, should be subject for the work on future editions. See IEC TS 60479-2.

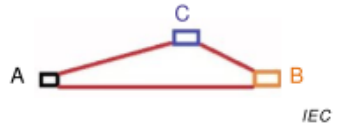
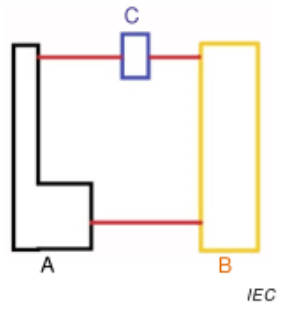
4.2.195 Split up of BI, SI, DI, RI barriers

Recommendation number	195
Clause(s) number (only)	8.5.1.1 versus 8.9.4
Source/problem	Contradiction between these subclauses implies that DOUBLE INSULATION in the form of two distances practically does not exist or at least is unnecessary. Is this assumption correct?

Recommendation 195 *(continued)*

Discussion/comment	A distance which is interrupted by a floating conductive part is strictly a double insulation and 8.5.1.1 reads: "Any insulation, CREEPAGE DISTANCE, AIR CLEARANCE, component or earth connection that does not comply with the requirements of 8.5.1.2 and 8.5.1.3 shall not be considered as a MEANS OF PROTECTION. Failure of any or all such parts shall be regarded as NORMAL CONDITION." However, 8.9.4 reads: "If CREEPAGE DISTANCE or AIR CLEARANCE for one or two MEANS OF PROTECTION are interrupted by one or more floating conductive parts, the minimum values specified in Table 12 to Table 16 (inclusive) apply to the sum of the sections, except that distances less than 1 mm are not taken into consideration." Only for the reason of better clarity, in the following, the terms BASIC INSULATION, SUPPLEMENTARY INSULATION, DOUBLE INSULATION or REINFORCED INSULATION are used instead of MOPP's. A DOUBLE INSULATION can only consist of A) two solid insulations or B) one solid insulation + a distance. A DOUBLE INSULATION can theoretically consist of two distances, but only if both distances meet the requirements, and this is practically of no interest. If one of the distances is shorter than required but the other one is extra long, one simply rename it from DOUBLE INSULATION to REINFORCED INSULATION and thus the design is accepted because it will be a REINFORCED INSULATION, interrupted by a floating conductive part. It could be worth mentioning that the IEC safety philosophy is that DOUBLE INSULATION should be the first hand choice and that REINFORCED INSULATION can be used where it is impractical to achieve DOUBLE INSULATION. Examples for a working voltage of < 250 V RMS in Table 12: – in line with 8.9.4, a basic insulation can be 2 mm + 2 mm, and supplementary insulation can be 1 mm + 3 mm; – in line with 8.5.1.1, a double insulation cannot be 3 mm + 5 mm; – in line with 8.9.4, a reinforced insulation can be 3 mm + 5 mm. If this REINFORCED INSULATION instead would be regarded as DOUBLE INSULATION, the BASIC INSULATION of 3 mm will be short-circuited in line with 8.5.1.1 and thus it would be a fail. Conclusion: In line with this, a transformer with an E-core practically does not have any DOUBLE INSULATION (primary – core and core – secondary). It only has REINFORCED INSULATION, and the only thing that matters is the total distance primary – secondary, on condition that none of the interrupted distances are less than 1 mm. Question 1: If the conclusion is correct, it remains unclear why 15.5.1.1 states that the frame shall be included when doing dielectric strength test. It is my assumption that "frame" is intended to mean "core". However, this is inconsistent with 15.5.2 in which the word "core" is used. Question 2: Is the above conclusion correct and, if so, does it apply also for complete electronic intermediate floating circuits? For example: – first transformer 230 V primary – 12 V secondary = 3 mm, followed by – floating intermediate circuit 12 V – 12 V, followed by – second transformer 12 V primary – 5 V secondary = 5 mm. The following example (see Figure 2 illustrations a) and b) below) is intended to reflect the problem in a visual form.

Recommendation 195 *(continued)*

	Example drawing:  a)  b) **Key** A primary part B secondary part C floating conductive part, like screw on PCB or core in transformer, but not earthed Primary to secondary require 2 MOPP. Each of them shall be at least 4 mm. The red line is the creepage distance. CR: A to B is 8 mm A to C is 7 mm B to C is 3 mm **Figure 2 – Example of creepage measurement**
Submitter proposed recommendation	Submitter has no proposal at this point.
SC 62A recommendation	It is recommended to transfer the issue to the work on future editions of the standard.

4.2.196 ALARM PULSE RISE TIME

Recommendation number	196
Clause(s) number (only)	IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012, 6.3.3.1, Table 4 on auditory alarm signals
Source/problem	The PULSE RISE TIME (t_r) is specified 10 % to 40 % of PULSE duration (t_d), with a recommendation in NOTE 2 that the rise time should not be less than 10 ms to prevent speaker noise.
Discussion/comment	According to Table 4, the minimum PULSE duration for an auditory HIGH PRIORITY ALARM SIGNAL is 75 ms. Following the 10 % specification, a RISE TIME of 7,5 ms is allowed, then. According to Annex A, the main reason for the 10 % specification is that "very short RISE TIMES can cause mechanical distortion arising from the speaker". So, the allowed rise time of 7,5 ms seems not to cause such problems. Question: Why should a RISE TIME of e.g. 12 ms in case of a 150 ms PULSE duration (= 8 %) cause mechanical distortion from the speaker when a 7,5 ms RISE TIME does not? And why does NOTE 2 of Table 4 explain the 10 ms specification with a "should" (as well as in Annex A only "should" is used)? Hint: In the field, there are a lot of MEDICAL ELECTRICAL EQUIPMENT with ALARM SYSTEMS with shorter rise times than 10 % of t_d, especially MEDICAL ELECTRICAL EQUIPMENT. Up to now, no problems with their RISE TIMES have been reported by hospitals. The shorter RISE TIMES are typically generated by equipment that does not incorporate additional electronics and/or software for a stepwise or smooth increase of PULSE amplitude.

Recommendation 196 *(continued)*

Submitter proposed recommendation	It should be clarified that lower RISE TIMES than 10 % of PULSE duration can be accepted as long as evidence is given that the chosen RISE TIME does not cause mechanical distortion arising from the speaker. For future Amendment 2: The minimum RISE TIME should be specified not by percentages, but either by an absolute value, for example $t_r \geq 7{,}5$ ms, to prevent speaker noise, or by a more generic requirement that the minimum RISE TIME needs to be long enough to avoid mechanical distortion arising from the speaker.
SC 62A recommendation	The topic belongs to the IEC 60601-1-8 standard committee. It was confirmed by the JWG 2 convener of IEC 60601-1-8 that the issue will be solved in the future edition of IEC 60601-1-8 planned for 2019. In the meantime, it is recommended to follow submitter's proposal above.

4.2.197 Non-frequency-weighted measurement

Recommendation number	197
Clause(s) number (only)	8.7.3 e)
Source/problem	Non-frequency-weighted measurement for the PATIENT AUXILIARY CURRENT
Discussion/comment	8.7 describes the requirements for LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS. This subclause distinguishes the requirements for LEAKAGE CURRENTS (EARTH LEAKAGE CURRENT, TOUCH CURRENT and PATIENT LEAKAGE CURRENT) and PATIENT AUXILIARY CURRENT exactly by wording. 8.7.3 e) requires the non-frequency-weighted measurement only for LEAKAGE CURRENTS. The PATIENT AUXILIARY CURRENT is in accordance with 3.47 not a LEAKAGE CURRENT. Shall the non-frequency-weighted measurement be performed for the PATIENT AUXILIARY CURRENT?
Submitter proposed recommendation	
SC 62A recommendation	It is recommended to read 8.7.3 e) as follows: "Additionally, regardless of waveform and frequency, no LEAKAGE CURRENT or PATIENT AUXILIARY CURRENT shall exceed 10 mA RMS in NORMAL CONDITION or in SINGLE FAULT CONDITION when measured with a non-frequency-weighted device."

4.2.198 Printed circuit boards meeting UL 796

Recommendation number	198
Clause(s) number (only)	8.9.3.3 and 8.9.3.4
Source/problem	Unclear if 8.9.3 as a whole needs to be applied to multilayer PC-boards meeting the UL 796.
Discussion/comment	PC-boards are often recognized to UL 796, and the pre-conditioning treatment shown in Table 30.1 seems equivalent to 8.9.3.4. However, UL 796 does not use the multiple of 1,6 for the dielectric strength, which should be applied between tracks, within the same inner layer, not meeting the normal CREEPAGE DISTANCE requirement. Even though the dielectric strength test should be done directly after the pre-conditioning, the question is if it can be accepted that it is done without repeating the pre-conditioning.
Submitter proposed recommendation	Multilayer PC-boards meeting UL 796 need not be pre-conditioned according to the thermal cycling test of 8.9.3.4 before performing the dielectric strength test according to 8.9.3.3.
SC 62A recommendation	UL 796 does not call out for a complete finished board test, but only require to test the generic materials of the printed circuit board. Therefore, it is recommended not to regard UL 796 as an acceptable replacement for thermal cycling tests specified in 8.9.3.

4.2.199 Y1 caps bridging 2 MOPP

Recommendation number	199
Clause(s) number (only)	8.8.3. 8.5.1.2
Source/problem	In 8.5.1.2, it is required that, where two Y1 caps are used in series, each of them shall be rated for the total working voltage across the pair. Y1 caps are available with rated voltage up to 500 V RMS and withstand voltage of 4 kV RMS and 8 kV impulse. Is it sufficient to have only two Y1 caps in series (rated 500 V RMS each) when the working voltage is 330 V RMS but the test voltage based on the peak working voltage is 5,55 kV RMS (based on a measured WVp of 900 Vp)?
Discussion/comment	Because peak working voltage is now used for dielectric test on MOPP, the issue above regarding Y1 caps seems relevant.
Submitter proposed recommendation	No proposal at this point.
SC 62A recommendation	According to IEC 60384-14, a Y1 capacitor is rated up to 500 V RMS, which means it could have a rating of 250 V RMS or even 125 V RMS. The principle idea of IEC 60601-1 regarding INSULATION COORDINATION is to ensure that if a DOUBLE INSULATION is used, such as two MOPP, then it should be ensured that, if one MOPP fails, the remaining other one MOPP will ensure safety. Consequently, if one Y1 rated e.g. 250 V RMS would fail, the remaining serial other Y1 capacitor rated as well for 250 V RMS would be overstressed in the example above by 330 V RMS This should be avoided by adequate Y1 voltage ratings. Table 6 states that each Y1 capacitor of this example should withstand 2 273 V RMS, but both Y1 capacitors used in series should withstand 5 546 V RMS. The above principles should be applied as well for Y2 capacitors.

4.2.200 PORTABLE, STATIONARY and TRANSPORTABLE ME EQUIPMENT

Recommendation number	200
Clause(s) number (only)	3.85, 3.118 and 3.130
Source/problem	Unclear how to establish if an ME EQUIPMENT is intended to be moved.
Discussion/comment	PORTABLE, STATIONARY and TRANSPORTABLE are defined. It is necessary to establish if the ME EQUIPMENT belongs to one of these categories because there are different safety requirements for them. However, it is nowhere in 7.9 required to state such information in the ACCOMPANYING DOCUMENTS. So, if it is not obvious, how would a testing laboratory know and how would the RESPONSIBLE ORGANIZATION and the OPERATOR know of possible restrictions regarding movement? Normally, it is obvious that equipment with handles is PORTABLE. However, whether equipment without any handle is PORTABLE or STATIONARY is not obvious. Example: A small table-top unit without handle but that can easily be moved from one room to another but is not intended to be moved. – Is this a STATIONARY unit even though it most likely will be moved occasionally or is it PORTABLE or by default TRANSPORTABLE? – Shall the instructions for use state that it is not intended to be moved? – Does "installed and placed into service" mean only when clinically used on a patient or does it include movement between clinical uses? – Should reasonable foreseeable misuse be considered? – Can equipment that is not MOBILE nor PORTABLE be TRANSPORTABLE?
Submitter proposed recommendation	Whether ME EQUIPMENT is PORTABLE, STATIONARY or TRANSPORTABLE should be evident from the RISK MANAGEMENT FILE and should be stated in the ACCOMPANYING DOCUMENTS.
SC 62A recommendation	For work on a future edition of the standard, the classification clause 6 should include the categories as shown in Figure A.20. According to 7.9.2.1, all classifications are included in the instructions for use. Starting point to determine which defined term applies should be the INTENDED USE.

4.2.201 Opposite polarity and philosophy of IEC 60601-1

Recommendation number	201
Clause(s) number (only)	8.1 a), 8.1 b), 8.9.1.1, 8.9.2 a), 8.11.5, 15.4.3.5 and 15.5.1.1
Source/problem	Inconsistency between subclauses regarding insulation philosophy between opposite polarity.
Discussion/comment	– 8.1 a) clearly says that insulation and distances not meeting the requirements shall be short-circuited in NORMAL CONDITION. – 8.1 b), first and second dashes, clearly say that one MOP shall be short-circuited in SINGLE FAULT CONDITION. – 8.9.1.1 clearly requires only one MOOP between opposite polarity before any mains fuses. – The rationale to 8.9.2 a) says that the opening of a branch circuit breaker is not acceptable. Even though all above is common in many standards, it is in fact contradictive because – when following 8.1 a), with a short-circuit after the mains fuses, the fuses will open making the equipment non-functional in NORMAL CONDITION, and – when following 8.1. b), with short-circuit before the mains fuses, the branch circuit breaker will open in SINGLE FAULT CONDITION (found no exception for opposite polarity under 8.1 b)). NOTE For secondary circuits it has been deemed necessary to require two MOP between opposite polarity as laid out in 15.4.3.5 and 15.5.1.1. 8.11.5 states that, if two MOP are present between opposite polarity within the MAINS PART, and between the MAINS PART and earth, then the fuses can be omitted. The rationale says that fuses reduces the risk that a fault will cause a protective device in the installation to operate thus removing power to for example life supporting ME EQUIPMENT. Following the standard, general safety philosophy would mean that - two MOOP before the mains fuses is required to assure that the protective device in the installation will not operate due to short-circuit between opposite polarity before the mains fuses (where the fuses are not mounted directly at the input, for example in an appliance inlet assembly, the area up to the mains fuses is an area where fuses are omitted), and - one MOOP after the mains fuses is required to assure that the fuses do not open in NORMAL CONDITION due to short-circuit between opposite polarity after the mains fuses; at least this is reasonable, for example for life-supporting equipment. Such an approach would also align with the philosophy in 15.4.3.5 and 15.5.1.1. If this is not too much to ask, there should at least be a rationale explaining why one MOOP is sufficient between opposite polarity and between mains and PROTECTIVE EARTH before the mains fuses. In addition, there should be a rationale explaining why one MOOP is not required between opposite polarity after the mains fuses.
Submitter proposed recommendation	Hint for the Amendment 2 work: Establish which route to go and add a rationale stating any deviations to the general safety philosophy in the standard and the reason thereto.

Recommendation 201 *(continued)*

SC 62A recommendation	SC 62A recommends to implemented rationales in the standard to solve identified inconsistencies above in the work on a future edition of the standard. – Before ME EQUIPMENT mains fuses: The standard requires 1 MOOP. The rationale for 8.9.2 a) says that the opening of the installation fuse is not acceptable. This could be read that 2 MOOP are needed. But it also says that, in front of the equipment, over-current device basic requirements for parts of opposite polarity are sufficient. It is recommended in the work on a future edition of the standard to improve this rationale. NOTE There are many certified components which do not comply with 2 MOOP at this barrier. – After ME EQUIPMENT mains fuses: The standard does not have requirements for an opposite polarity barrier at this location. 8.9.2 a) requires that a short-circuit does not lead to HAZARDOUS SITUATION as described in 13.1. There is no problem with BASIC SAFETY if the equipment fuses will open in any fault condition behind the ME EQUIPMENT fuses. – Faults before secondary fuses according 15.4.3.5 and 15.5.1.1: The standard requires 2 MOP or short-circuit test to be applied. No need for further clarification of 15.4.3.5 and 15.5.1.1.

4.2.202 Separation device

Recommendation number	202
Clause(s) number (only)	16.5
Source/problem	Limited access to IT-components meeting IEC 60601-1
Discussion/comment	The requirement for a SEPARATION DEVICE according to 16.5 is 1 MOOP. This normally means 2 mm CLEARANCE, 2,5 mm CREEPAGE and 1 500 V RMS for 60 s and the leakage current limit maintained with mains voltage applied. Standardized IT components meeting IEC 60950-1 often passes the dielectric and the leakage requirement but rarely meets the distance requirements. One reason thereto can be that IEC 60950-1 in most cases requires only functional insulation. Still they often pass both the leakage current test with mains voltage applied and the dielectric test with 1 500 V RMS for 60 s. A SEPARATION DEVICE is used primarily to decrease leakage current from exterior equipment. Therefore, the distance requirements seem a bit overkill. The normal voltage on SIP/SOPs is less than 42 V peak/60 V DC. Question: Can the 1 MOOP requirement for a SEPARATION DEVICES be limited to the LEAKAGE CURRENT and the dielectric strength test by applying a higher dielectric strength test voltage, for example 1,6 x 1 500 V RMS = 2 400 V RMS for 60 s?
Submitter proposed recommendation	A SEPARATION DEVICE used to meet 16.5 need not meet the CLEARANCE and CREEPAGE requirements on condition that it complies with: – the LEAKAGE CURRENT limit with 1,1x the mains voltage applied. – the dielectric strength test with the test voltage multiplied by 1,6. – the component is rated for a withstand voltage of at least 2 500 V. – the connection is not intended for connection to a telephone network. – the proposal should not be used for MOPP barriers.
SC 62A recommendation	16.5 is clear and requires CREEPAGE DISTANCE and AIR CLEARANCE and dielectric strength test to be in compliance. Changes on the standard can only be done in a future amendment or new edition of IEC 60601-1.

4.2.203 Consult ACCOMPANYING DOCUMENTS

Recommendation number	203
Clause(s) number (only)	7.2.3
Source/problem	"When appropriate, symbol ISO 7000-1641 (2004-01) (see Table D.1, symbol 11) may be used to advise the operator to consult the ACCOMPANYING DOCUMENTS. When consulting the ACCOMPANYING DOCUMENTS is a mandatory action, safety sign ISO 7010-M002 (2011-05) (see Table D.2, safety sign 10) shall be used instead of symbol ISO 7000-1641."  ISO 7000-1641:2004-01  ISO 7010-M002:2011-05 The normative part of the standard is crystal clear: a) An "advice" to consult accompanying documents ➔ symbol ISO 7000-1641:2004-01. b) A "mandatory action" of consulting the accompanying documents ➔ safety sign ISO 7010-M002:2011-05. The reader of the normative part of the standard clearly understands that he is permitted to advice the operator to read the instructions for use (IFU) by the symbol ISO 7000-1641:2011-05. However, we all know advises are like recommendations or hints: they can be ignored, and even then there should be no unacceptable risk for the patient and the operator. It is the nature of "advices" that these are not a "must" to be followed. Being aware that "descriptive safety" is part of the integrated safety concept and almost all medical products contain warnings, precautions, etc., the second sentence of 7.2.3 fix the safety gap by requiring the safety sign ISO 7010-M002:2011-05 if following the IFU is a "mandatory action". So up to here, the standard wording is – perfectly correct, – unambiguous, – in line with the integrated safety concept of unconditional safety, conditional safety and descriptive safety, and – safe. However, some readers of the standard claim that the normative part of 7.2.3 is in contradiction with the informative part in Annex A, Subclause 7.2.3. "It is not intended in every case when the instructions for use contain warnings, that the ME EQUIPMENT be marked with ISO 7010-M002 (see Table D.2, safety sign 10). Too many warnings and unnecessary warnings are counterproductive. Only when the MANUFACTURER, as a RISK CONTROL measure for a specific RISK, decides to mark the ME EQUIPMENT to instruct the operator to read the instructions for use, should safety sign ISO 7010-M002 be used." ➔ In summary, some readers of the standard argue: "The use of symbol ISO 7010-M002:2011-05 is required when the user shall refer to the instructions for use each and every time they use the equipment."

Recommendation 203 *(continued)*

Discussion/comment	1. An information in the informative Annex A cannot overwrite a clear unambiguous requirement in the normative part of the standard. 2. The IFU is always used by the MANUFACTURER as RISK CONTROL measure. A few examples make that clear. a) Single use product, not for multiple uses. b) This machine shall exclusively be used by trained and professional users. c) Replace fuses only with the same rating. d) Disconnect the applied parts before defibrillation. e) STERILE, verify that the protective cover is not damaged before use. f) Only to be used under constant supervision of the operator. ➔ These few risk control measures (a) to f)) in the IFU (descriptive safety level) should convince everybody that MEEs always contain such risk control measure and therefore the safety sign ISO 7010-M002:2011-05 is required. 3. The claim that the safety sign ISO 7010-M002:2011-05 is only required when the user shall refer to the IFU "each and every time" when they use the ME EQUIPMENT seems a little bit speculation. The words "each and every time" are not found in the standard and therefore we do not know where they really come from in this context.
Submitter proposed recommendation	Follow the standard as it was approved by the National Committees.
SC 62A recommendation	The meaning of the blue-white coloured safety sign ISO 7010-M002:2011-05 and its use is regarded as clear in the standard. The standard requires the use of the safety sign ISO 7010-M002:2011-05 if consulting the accompanying documents is a mandatory action. See the rationale above in the problem and discussion row for the link between "mandatory action" and "RISK CONTROL measure". It is recommended to clarify the use of the black and white symbol ISO 7000-1641:2004-01 (see Table D.1, symbol 11), including examples, in the work on a future edition of the standard.

4.2.204 AP-ENCLOSURE requirements

Recommendation number	204
Clause(s) number (only)	15.3
Source/problem	Is housing of applied parts considered as ENCLOSUREs as defined in 3.26 and Figures 2 to 4?
Discussion/comment	3.26 and Figures 2 to 4 could be read in a way that tests of 15.3 are not applicable.
Submitter proposed recommendation	3.26 should be read that all housings, including the housing of the applied part of ME EQUIPMENT, are considered as ENCLOSURE and therefore should fulfil the requirements of 15.3.
SC 62A recommendation	Within IEC 60601-1, the term ENCLOSURE could be read in the way that it sometimes is used for inclusion of APPLIED PARTS and sometimes APPLIED PARTS are specifically not included (example TOUCH CURRENT versus PATIENT LEAKAGE CURRENTS). Figures 2 to 4 should not be used to generally exclude APPLIED PARTS from ENCLOSURE requirements. In case of 15.3, all housings, including the housing of the APPLIED PART of ME EQUIPMENT, are considered as ENCLOSURE and therefore should fulfil the requirements of 15.3 as applicable. 15.3 uses words such as ENCLOSURE, ACCESSORIES, equipment parts. In the work on a new edition of the standard, it should be considered if the wording of 15.3 should be improved with respect to including APPLIED PARTS or not.

4.2.205 Guidewire

Recommendation number	205
Clause(s) number (only)	8.5.2.3, 8.5.5, 8.7.4.7 b)
Source/problem	Application of the requirements from 8.5.2.3 (PATIENT leads or PATIENT cables), 8.5.5 (DEFIBRILLATION-PROOF APPLIED PARTS), and 8.7.4.7 b) (PATIENT LEAKAGE CURRENT for F-TYPE APPLIED PARTS – mains on APPLIED PART) to guidewires, as defined by ISO 11070:2014, when used with ME EQUIPMENT.
Discussion/comment	Guidewires that meet the definition of ISO 11070:2014 are used to gain access to vasculature during diagnostic and interventional procedures, including those in which ME EQUIPMENT is present in the operating environment or when a defibrillator may be used on the patient. The guidewire itself does not treat any medical condition. Guidewires are used by physicians that are trained in the use of these products, techniques, and procedures. The primary construction of standard guidewires is commonly composed of metal. Metal is used to provide the appropriate mechanical properties necessary for navigation of complex anatomies with 0,36 mm (0,014 inch) wire outer diameter constraints without damage to the wire. In the typical use, a portion of guidewire is inserted into the PATIENT and a portion remains outside the PATIENT. Since these guidewires have exposed metal that remains outside of the PATIENT (diameter 0,36 mm, length depending on how deep the other end is inserted in the PATIENT body – several centimetres), the application of the above references clauses of IEC 60601-1 to the exposed part of the guidewire would not comply, since there is direct electrical contact with the PATIENT. The normal procedure for use of guidewires states that the OPERATOR should not touch the guidewire while the PATIENT is being defibrillated, nor shall the guidewire make contact with conductive surfaces while inserted in the PATIENT. The training and standard practices for the use of standard guidewires addresses the risk of the metal exposed section of the guidewire being subjected to external voltages and contact during application of a defibrillation pulse in normal use. When a guidewire becomes a part of ME EQUIPMENT, there are no additional risks associated with the guidewire, as related to these three clauses of IEC 60601-1 specified. All requirements of IEC 60601-1 would still be applicable to everything other than the guidewire. This includes meeting these three clauses from the connection to the guidewire to the rest of the ME EQUIPMENT.
Submitter proposed recommendation	The complete guidewire, as defined in ISO 11070:2014, should be considered the APPLIED PART when connecting to ME EQUIPMENT. As the APPLIED PART, 8.5.2.3, 8.5.5, and 8.7.4.7b) would not be applied to the exposed section of the exposed guidewire that remains outside the PATIENT. All requirements of IEC 60601-1 would still be applicable to everything other than the guidewire. This includes meeting these three clauses from the connection to the guidewire to the rest of the ME EQUIPMENT.
SC 62A recommendation	Guidewires are largely used in the medical field. It is recommended to regard the whole guidewire as part of the APPLIED PART. The guidewire itself (in the PATIENT body inserted part and external part of the guidewire) should not be subject of tests in the following subclauses: a) 8.5.2.3: Location at the external part of the guidewire. Explanatory note: Some guidewires have an internal sensor and contain a connecting ring at the distal end of the external part of the guidewire towards the ME EQUIPMENT. This ring contact – still has a diameter of around 0,36 mm – is recommended to be excluded from 8.5.2.3. However, external connection and extension cables should not be excluded from the requirements, because the prevention of the RISKS addressed in 8.5.2.3 applies. See recommendation 185.

Recommendation 205 *(continued)*

SC 62A recommendation (continued)	b) 8.5.5: Measuring point at the external part of the guidewire. Explanatory note: Because the guidewire housing is almost completely conductive metal, there is no chance to apply on that metal part the defibrillation energy and not to have the defibrillation energy available on that same metal part a few centimeters further towards the ME EQUIPMENT. This situation is comparable to ECG gluing electrodes for ECG measurements. The necessary isolation barriers are used inside the ME EQUIPMENT or inside the PATIENT cable. c) 8.7.4.7 b): Measuring point at the external part of the guidewire. Explanatory note: See note under b) above (similar case). Metal endoscopes with ACCESSIBLE metal PARTS outside the PATIENT body not isolated from its metal parts inside the PATIENT body are reflecting the same situation. Therefore, it is recommended to treat guidewires in a comparable way. See IEC 60601-2-18.

4.2.206 H or L mains fuses

Recommendation number	206
Clause(s) number (only)	8.11.5
Source/problem	Various interpretations among test houses regarding whether H-fuses are recommended or required.
Discussion/comment	Examples of problems with L-fuses: – explosion, causing conductive debris over insulation barriers; – arcing with continued current flow, causing interruption of the branch circuit; – arcing with continued current flow, causing overheating in the ME EQUIPMENT. Quote 4.8: "All components, including wiring, the failure of which could result in a HAZARDOUS SITUATION shall be used in accordance with their specified ratings […]". Quote 8.11.5: "Protective devices shall have adequate breaking capacity […]. 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 (1 500 A)." Since the mentioning of H-fuses is in a note only, it opens for different interpretations whether H-fuses are required anyway based on the requirement in 4.8 and 8.11.5. For some reason, the note text is reproduced as a requirement text in the IECEE CB TRF No. IEC60601_1K, which makes it even more confusing. The text is copied from IEC 60950-1. Many test houses accept L-fuses in plug connected IT-equipment even though the fault current, at least for a short period, can be over 10 x or 35 A. If the L-fuse does not explode during SFC testing, with a 16 A fused branch circuit, it is usually accepted for plug connected equipment. This philosophy is also applied for IEC 60601-1 by some test houses. Is such testing sufficient to conclude whether H-fuses are required?
Submitter proposed recommendation	No proposal for the moment.

Recommendation 206 *(continued)*

SC 62A recommendation	It is recommended to delete the note in 8.11.5 due to the following reasons: a) The note is linked to IEC 60127 with a reference number 20, which is linked to miniature fuses only. b) The successor of IEC 60950-1, IEC 62368-1, has deleted this note. The normative requirement "Protective devices shall have adequate breaking capacity" is correct. One way to ensure adequate breaking capacity is using mains fuses with rated high breaking capacity calculated from the source impedance. NOTE A breaking capacity of up to 35 A is usually regarded as not sufficient for mains circuits rated 100 V AC to 240 V AC and up to 16 A.

4.2.207 APPLIED PART temperature

Recommendation number	207
Clause(s) number (only)	11.1.2.2
Source/problem	How to deal with temperature on APPLIED PART that starts on a higher value and then decreasing?
Discussion/comment	An internally powered BODY-WORN MEE with plastic ENCLOSURE is charged before its use. Immediately after charging, when the MEE is placed on the PATIENT, the ENCLOSURE is relatively hot, but still below 60 °C. After 1 min, the temperature has decreased below 48 °C and after 10 min the temperature has decreased below 43 °C.
Submitter proposed recommendation	For each of these isolated time intervals, the temperature limits for applied parts in Table 24 are met. But if the total contact time is considered, no temperatures higher than 43 °C is allowed even for a short duration. The accumulated heat transfer to the PATIENT shall be considered and therefore the total contact time shall be considered and therefore the actual test is failing.
SC 62A recommendation	Table 24 is intended to cover temperature limits depending on the total duration of contact with the APPLIED PART. So the situation above would not be compliant with the standard. For work on a future edition of the standard, it should be checked if an APPLIED PART with a time dependent temperature is also addressable by Table 24.

4.2.208 Cecon plug as permanently installed MEE

Recommendation number	208
Clause(s) number (only)	8.7
Source/problem	Has switch S7 to be used at MEE provided with an IEC 60309 connector (industrial plugs and socket outlets)?
Discussion/comment	Due to the construction of pluggable TYPE B connector according to IEC 60309, a protection against reverse polarity is given. Furthermore a permanent connection to protective earth is ensured and connection between plug and socket is mechanically secured against unintended loosing.
Submitter proposed recommendation	Protective earth connection can be considered as reliable and S7 can be closed for all measurements according to 8.7.
SC 62A recommendation	It is recommended to regard the standard to be correct as it is. The standard already requires to use S7 in both conditions. NOTE It is a plug connected ME EQUIPMENT where the PROTECTIVE EARTH CONDUCTOR could break.

4.2.209 Biocompatibility for enclosures and other parts

Recommendation number	209
Clause(s) number (only)	11.7
Source/problem	Is biocompatibility needed to be evaluated according to ISO 10993 (all parts) for other parts than APPLIED PARTS?
Discussion/comment	11.7 says that ME EQUIPMENT and their parts or ACCESSORIES intended to come into direct or indirect contact with biological tissues, cells or body fluids shall be assessed and documented according to the guidance and principles given in ISO 10993 (all parts). That would include not only applied parts but also all other accessible parts like the ENCLOSURE of the ME EQUIPMENT. When reading the scope of ISO 10993-1:2009, it says: "This part of ISO 10993 does not cover testing of materials and devices that do not come into direct or indirect contact with the patient's body, nor does it cover biological hazards arising from any mechanical failure." Reading the above sentence, it sounds like OPERATOR accessible parts do not fall into the scope of ISO 10993-1. But it says "direct or indirect contact with the PATIENT's body" which means that parts falling under 4.6 of IEC 60601-1:2005/AMD1:2012 might need to be considered.
Submitter proposed recommendation	It makes no sense to evaluate the biocompatibility of the enclosure or similar accessible parts (including those falling under 4.6) of the ME EQUIPMENT, since the risk for the PATIENT to be in contact with these parts is no higher than other electrical devices. The expected contact time with those parts is normally also very limited. Only biocompatibility of parts which are classified as APPLIED PARTS (parts that necessarily come into physical contact with the patient for ME EQUIPMENT to perform its function) is needed to be evaluated according to ISO 10993 (all parts). This should be clarified in Clause A.2 of IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012.
SC 62A recommendation	Application of 11.7: For parts considered to be quasi APPLIED PARTS according to 4.6, it is advised to see recommendation number 175. Parts other than APPLIED PARTS or quasi APPLIED PARTS according to 4.6: Even though 11.7 does not exclude ENCLOSURES, SC 62A recommends, due to practical reasons, that it is not necessary to test all ENCLOSURES according to ISO 10993. NOTE ISO 10993-1:2009, Clause 1, last paragraph, says: "This part of ISO 10993 does not cover testing of materials and devices that do not come into direct or indirect contact with the PATIENT'S body, nor does it cover biological hazards arising from any mechanical failure." Improvement of the wording of 11.7 in the work on a future edition of the standard should be done. 11.7 should be more precise as to what parts it applies.

4.2.210 Safety relevant LEDs

Recommendation number	210
Clause(s) number (only)	10.4 and 10.5
Source/problem	LEDs were removed from 10.4 in IEC 60050-1:2005/AMD1:2012, and 10.5 excludes LEDs
Discussion/comment	There are no requirements for LEDs – which can be hazardous.
Submitter proposed recommendation	Interpret 10.5 to include LED radiation.
SC 62A recommendation	SC 62A recommends that the cross-reference to 10.4 in 10.5 to 10.7 has been forgotten to be removed within the amendment work, because LEDs were excluded from 10.4 within the amendment work. The rationale in Annex A, Subclause 10.4, refers to IEC 62471 related to LEDs. Amendment 2 should consider if the parts of Annex A, Subclause 10.4, referring to IEC 62471 for LEDs should become normative within 10.5 to 10.7. IEC 62471 should be considered when using LEDs or other lamps in a ME EQUIPMENT. Low power LEDs (with low luminance), for example used for indicator lights, should not be required to be evaluated according IEC 62471. The work on a future edition of the standard should reflect this aspect in detail.

4.2.211 Lithium coin cells

Recommendation number	211
Clause(s) number (only)	15.4.3.4
Source/problem	Are the requirements of 15.4.3.4 also applied to lithium coin cells (e.g. CR2032)? Common application of such lithium coin cells is, for example, real time clock of computer backup system, or other applications.
Discussion/comment	Very few of these lithium coin cells are tested and certified according to IEC 60086-4 (primary) or IEC 62133 (secondary). The most of these lithium coin cells are tested according to UL 1642. These lithium coin cells have a very small power (approx. 250 mAh, 3 V DC).
Submitter proposed recommendation	For those lithium coin cells, a certification according to UL 1642 is considered suitable for use.
SC 62A recommendation	It is recommended to regard compliance with UL 1642 for lithium coin cells (primary or secondary) as an alternative RISK CONTROL measure according to 4.5 of IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012. NOTE 1 IECEE document CTL DSH 616B dated 2013 supports this clarification. NOTE 2 This recommendation is intended for limited energy lithium coin cells typically used for memory backup systems.

4.2.212 Motor capacitors

Recommendation number	212
Clause(s) number (only)	13.2.9
Source/problem	IEC 60601-1 does not distinguish between the various safety protection classes of motor capacitors, now called S0 to S3. Further, a coroner's report relating to domestic freezer fires concluded that the requirement of motor capacitors to comply with safety class P2 (now S2) of IEC 60252-1 is not good enough to protect against fire.
Discussion/comment	In IEC 60252-1, S0 and S1 compliant capacitors are assumed to fail short-circuit test; IEC 60601-1 excludes this test for IEC 60252-1 capacitors regardless of safety protection class. Therefore, these components may not be tested sufficiently.
Submitter proposed recommendation	Interpret the test specification (paragraph before the last of 13.2.9) as either: 1) "The test with a short-circuited capacitor is not performed if the motor is provided with a capacitor complying with IEC 60252-1 **safety protection class S2 or S3** and the ME EQUIPMENT is not intended for unattended use (including automatic or remote control)", or 2) Ignore this paragraph so that the short-circuit test is always performed, on the basis of evidence that "additional safety requirements from IEC series [is] necessary" (Figure 5 of IEC 60601-1:2005).
SC 62A recommendation	It is recommended that the test with a short-circuited capacitor is not needed if the motor is provided with a capacitor complying with IEC 60252-1 safety protection class S2 or S3 and the ME EQUIPMENT is not intended for unattended use (including automatic or remote control).

4.2.213 Warning, caution, safety notice

Recommendation number	213
Clause(s) number (only)	7.1.2, first dash, et al.
Source/problem	Many subclauses of the standard (see below) require warnings, caution hints or safety notices. However. these terms are never defined in the standard, and also not in ISO 14971: 7.1.2: warning statements 7.2.13: warning statements 7.3.3: warning 7.5: warning, prohibition or mandatory action signs, safety notice 7.8.1, Table 2: warning, caution 7.9.2.1: warning 7.9.2.2: warning and safety notices, warning statement 7.9.2.4: warning statement 7.9.2.9: warning statements 7.9.3.1: warning statement, warning and safety notices 7.9.3.2: warning 8.11.1: warning notice 9.2.1: warnings 9.4.2.2; warning notice 9.4.2.3: warning 9.7.2: warning label 11.6.2: warning or safety notice 16.2 c): warning How to treat them? In ACCOMPANYING DOCUMENTS or as markings (not safety signs or symbols) on the ME EQUIPMENT? Always with a signal word like WARNING or CAUTION at the beginning? Or incorporating the word "warning" or "caution" in the instructive text? Or is an appropriate instructive text without use of the word "warning" or "caution" sufficient? And what is the difference between use of warnings, safety notices, and caution statements?
Discussion/comment	Common rules would be helpful to avoid misinterpretation of these requirements.

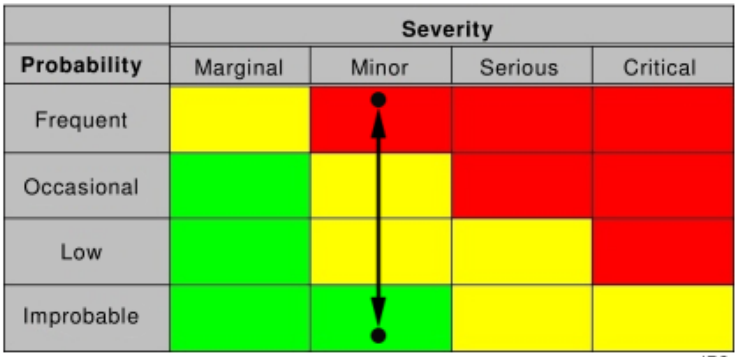
Recommendation 213 *(continued)*

Submitter proposed recommendation	Specify in a recommendation the recommended use of a warning in difference to the use of a caution and to the use of safety notices. Specify if the use of the signal words "warning" and/or "caution" is mandatory at the beginning or at least within the text of a warning/caution statement or not.
SC 62A recommendation	Signal words (WARNING, DANGER, CAUTION, etc.) are not defined within IEC 60601-1. The used terms within IEC 60601-1 for warnings etc. (see list above) should be harmonized in the work on a future edition of the standard.

4.2.214 ESSENTIAL PERFORMANCE related to RM (P1 and P2)

Recommendation number	214
Clause(s) number (only)	4.3
Source/problem	4.3 gives instruction and guidance on how to determine ESSENTIAL PERFORMANCE. However, the described concept possibly might not include probability aspects as they are used in ISO 14971 for the RESIDUAL RISK ASSESSMENT. In case of a component or functional failure, ISO 14971 takes into account the severity S of HARM, the probability P_1 of occurrence of a failure that results in a HAZARDOUS SITUATION and the probability P_2 by which the HAZARDOUS SITUATION leads to HARM. The combined product of the two mentioned probabilities ($P_1 \times P_2$) is sometimes taken as one term P and compared with the severity S (see Figure E.1 of ISO 14971:2007). So, a higher severity S may be acceptable if the probability P is very low, but the same severity S may be unacceptable if the probability P is higher. According to ISO 14971, the severity level S alone is not sufficient to judge if the residual risk is unacceptable or not. Taking the concept of 4.3, "the MANUFACTURER shall [...] specify performance limits between fully functional and total loss of the identified performance in both NORMAL CONDITION and SINGLE FAULT CONDITION. [He] shall then evaluate the RISK from the loss or degradation of the identified performance beyond the limits specified by the MANUFACTURER. If the resulting RISK is unacceptable, then the identified performance constitutes an ESSENTIAL PERFORMANCE of the ME EQUIPMENT or ME SYSTEM." These "performance limits" are often specified in particular standards, implicitly taking into account severity of potential HARM, but typically no information is given regarding generally acceptable severities or their dependencies of probabilities. For products without a particular standard, how should a manufacturer first specify performance limits and then "evaluate the RISK from the loss or degradation of the identified performance beyond the limits"? If using the ISO 14971 approach in applying probabilities, the tolerable performance limit could depend on the probability P and thus on intervals of safety checks, maintenance intervals, duration of a treatment, etc., for one and the same clinical function. Is that meant with the text in 4.3? Or does 4.3 address, in difference to ISO 14971, a fault condition disregarding the probability P (P = 1)? In that case, even a low severity S is usually not acceptable, though it might occur very unlikely in reality. 4.3 would then cover almost all functional failures that could lead to HARM. See Figure 3 below which illustrates that a minor severity could lead to both acceptable or unacceptable RISK estimation depending on the related probability values.

Recommendation 214 *(continued)*

Discussion/comment	It should be clarified if probability aspects (P_1, P_2) as used in ISO 14971 are included or excluded in the determination of performance limits according to 4.3 for the ESSENTIAL PERFORMANCE.  **Figure 3 – Same severity could result in an acceptable or unacceptable RISK, depending on the probability factor**
Submitter proposed recommendation	Depending on what is meant, clarify the inclusion or exclusion of probability aspects (P_1 and P_2) in the determination of performance limits according to 4.3 for the ESSENTIAL PERFORMANCE. If probability aspects are not intended to be included, the standard should be read/interpreted as if it refers to HARM rather than to RISK, for example in the third paragraph: "The MANUFACTURER shall then evaluate the potential HARM from the loss or degradation of the identified performance beyond the limits specified by the MANUFACTURER. If the potential HARM is unacceptable [...]".
SC 62A recommendation	It is recommended to regard the intended application of 4.3 to include both the determination of SEVERITIES and of probabilities (P_1 x P_2 of Figure A.8 of IEC 60601-1:2005) of the HARM (see also Annex A, Subclause 4.3). When determining the allowed degradation of a clinical function, a probability aspect has to be regarded, too.

4.2.215 IEC 60601-1-8 symbol color

Recommendation number	215
Clause(s) number (only)	IEC 60601-1-8
Source/problem	Colours of alarm related symbols.
Discussion/comment	The alarm related symbols are shown in black on white background. Is it acceptable to display them in white on black background or any other colour combination, for example yellow on grey background? The fourth paragraph of Annex D in the general standard states "Consistent use of these symbols and safety signs in all fields of use (e.g., medical, consumer products, and general transportation) will help ME EQUIPMENT OPERATORS to become familiar with their meaning. Conversely, any inconsistent use will lead to confusion and mistakes and jeopardize safety". It is also stated, in the sixth paragraph, "The colours of symbols are not specified, except [...]". In Annex C of IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012, it is stated "The symbol graphics of Table C.1 required by this collateral standard shall conform to the IEC or ISO referenced standard, as indicated". Indicated standards are IEC 60417 and ISO 7000; no colour requirements have been found in these standards.
Submitter proposed recommendation	A specific colour combination for symbols is not specified by IEC 60601-1-8 and hence any colour combination can be used. Relevant usability studies shall be evident from the USABILITY ENGINEERING FILE.
SC 62A recommendation	See IEC 60601-1-8:2006, informative Annex A, Subclause 6.3.2, where the different colour aspect is clarified. NOTE IEC 60601-1-8 does not refer to safety signs, only to symbols.

4.2.216 Indicator lights for standby switch

Recommendation number	216
Clause(s) number (only)	15.4.4, 7.4.1
Source/problem	There are sometimes disputes with manufacturers regarding the interpretation of 15.4.4 and 7.4.1 in relation to ME EQUIPMENT without a mains switch but with a standby switch and no indication by other unambiguous means. In such cases, is an indicator light required in the standby off-position or the standby on-position, or both?
Discussion/comment	If no indicator light is present in standby off-position, there is no way of knowing whether or not electrical circuits (for example a power supply subunit) is energized, as mentioned in informative Annex A, Subclause 15.4.4. Is such awareness not required?
Submitter proposed recommendation	For ME EQUIPMENT without a mains switch and without any other unambiguous means to indicate if circuits are energized, but with a standby switch, both switch positions should be indicated with an indicator light or other unambiguous means.
SC 62A recommendation	There is a mismatch between the normative part of 15.4.4, which speaks about "ready for NORMAL USE" and the informative Annex A, Subclause 15.4.4, which additional brings in the aspect about "to be energized". This mismatch should be clarified in the work on a future edition of the standard. It is recommended for the time being to follow the normative part of the standard.

4.2.217 CLASS II symbol

Recommendation number	217
Clause(s) number (only)	6.2
Source/problem	ME EQUIPMENT energized from an external electrical power source shall be classified as CLASS I OR II. Other ME EQUIPMENT shall be classified AS INTERNALLY POWERED ME EQUIPMENT. ME EQUIPMENT which is powered from an USB port cannot be classified according to this requirement, if the class of the external computer is not specified.
Discussion/comment	If the ME EQUIPMENT would be classified as CLASS II, because there is neither a protective earth nor an internal power source, the marking according to 7.2.6 would be necessary and could lead to misinterpretations, because the identification as CLASS II usually refers to the mains part of the equipment.
Submitter proposed recommendation	–
SC 62A recommendation	For the specific case that a ME EQUIPMENT without internal battery is powered by an external CLASS II power supply, the ME EQUIPMENT itself should normally not contain the CLASS II symbol, but the external power supply should contain the CLASS II symbol. It is recommended for the very specific case that the ME EQUIPMENT could either be powered by the external power supply unit or by an external DC/AC SUPPLY MAINS, it might contain the CLASS II symbol. Background is that 7.2.6 refers to the defined term "supply mains" and the SUPPLY MAINS does not include the power supply output DC voltage. For the work on a future edition of the standard: There is a conflict between the definition of CLASS II in 3.14 (not referring to SUPPLY MAINS) and the normative requirement in 7.2.6 (referring to SUPPLY MAINS).

4.2.218 Authorized SERVICE PERSONNEL

Recommendation number	218
Clause(s) number (only)	For example 7.3.3, 7.3.4 and 8.11.4
Source/problem	The standard sets out certain design requirements to facilitate for SERVICE PERSONNEL to repair the equipment without impairing safety. This includes, for example, exchange of internal battery (identification, warning and polarity), exchange of mains cord-set (clear how to install and connect a cord without special preparation) and exchange of internal fuses (identification or rating). However, it is often seen in test reports that the verdicts are not applicable because service is only done by authorized persons.
Discussion/comment	Some test laboratories and manufacturers interpret the standard as if the ACCOMPANYING DOCUMENTS state that service/repair is only allowed to be performed by "authorized persons", without going into detail on what is meant by "authorized"; the design requirements are deemed not applicable. This might for example lead to fuses not being identified, warning text for lithium batteries missing and the fact that the mains cord cannot be installed without special preparation. Hospital technicians, i.e. SERVICE PERSONNEL working in the maintenance and service department in the hospital, are, at least in some countries, seen as "authorized" based on the fact that they have an education on medical engineering before allowed to repair medical equipment in general. Is such a generic authorized hospital technician deemed authorized to repair a product not meeting all design requirements but the ACCOMPANYING DOCUMENTS state "Only to be serviced by authorized persons". I would say no, this is not the intent of the standard. Only if the MANUFACTURER states that repair is only allowed to be done by personnel that have passed the specific training program held by the MANUFACTURER, and received authorization from the MANUFACTURER, they are allowed to perform service and repair on that specific product.
Submitter proposed recommendation	Design requirements aimed to facilitate for service/repair, with maintained safety, is applicable except when the manufacturer states in the ACCOMPANYING DOCUMENTS that service/repair is only allowed to be done by the MANUFACTURER or by personnel that have passed the specific training program held by the MANUFACTURER and who have received the MANUFACTURER's written authorization.
SC 62A recommendation	It is recommended that the design and marking requirements of IEC 60601-1 should apply whenever service/repair is intended by the MANUFACTURER to be done by any kind of SERVICE PERSONNEL.

4.2.219 Scope of IEC 62133 and requirement in 15.4.3.4 related to PORTABLE batteries

Recommendation number	219
Clause(s) number (only)	15.4.3.4
Source/problem	15.4.3.4 says that all secondary (rechargeable) lithium batteries shall comply with the requirements of IEC 62133. But the scope of IEC 62133 only covers batteries for use in portable applications. What shall be required for lithium batteries used in non-portable applications?
Discussion/comment	IEC 62133 specifies portable battery as: "a battery for use in a device or appliance which is conveniently hand carried". IEC 60601-1 has six different mobility classifications: hand-held, body-worn, portable, mobile, fixed and stationary equipment. When comparing with the definition of "portable battery" in IEC 62133, only "hand-held" in IEC 60601-1 does 100 % matches this definition. So, shall compliance with IEC 62133 only be required for secondary lithium batteries used in "hand-held" equipment (possibly also "body-worn", "portable"), and if so, what shall be required for other equipment types? Or can IEC 60601-1 as an end-product standard override the scope of the component standard IEC 61233, and thus compliance with IEC 62133 shall be required for all secondary lithium batteries no matter of mobility classification as the subclause is currently written?
Submitter proposed recommendation	–
SC 62A recommendation	IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 requires to apply IEC 62133 for all secondary lithium batteries independent from its use classification "HAND-HELD" or otherwise. Note there are safety requirements in IEC 62133 which are not covered by other clauses of IEC 60601-1.

4.2.220 IT-NETWORK requirements

Recommendation number	220
Clause(s) number (only)	14.13
Source/problem	The IT-NETWORK related requirements are limited to descriptive information (in the accompanying documentation). The check of compliance is limited to "inspection of the accompanying documents".
Discussion/comment	These limitations seem to be inadequate/insufficient, as a) it is not consistent with the "safety principles" of MDD Annex I, section 1 (i.e. inherent safety, technical safety, descriptive safety), b) it is not consistent with the RISK MANAGEMENT "philosophy" of EN 14971 (e.g. section 6.2 "RISK CONTROL option analysis"), c) it is not consistent with the state-of-the art, see for example required RISK ANALYSIS/RISK counter measures in related scientific publications, such as regulatory requirements (e.g. IEC 60601-1:2005 and IEC 60601-1:2005, Clause H.7; IEC 80001-1; IEC 80001-2-x; FDA guidance "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices"), and legal laws (e.g. Germany: "Bundesdatenschutzgesetz", USA "HIPAA", IEC 27002, and IEC 62443). d) it is not consistent with the required manufacturer disclosure statement (MDS) of IEC 80001-1:2010, 4.1.

Recommendation 220 *(continued)*

Submitter proposed recommendation	The requirements of 14.13 should be extended with the following. a) Requirement that the ME EQUIPMENT shall have technical means against IT-NETWORK related risks according to the manufacturer`s risk management file. b) *Compliance is checked by inspection of the RISK MANAGEMENT FILE, and if necessary inspection of the ME EQUIPMENT and product accompanying documents.* Note to b): The standard`s appendix H.7 should include information about how the medical device manufacturer can provide important information to the health care provider in order to assist them in assessing the vulnerability and mitigating the risks with regard to cybersecurity (e.g. via the manufacture disclosure statement form "MDS").
SC 62A recommendation	Case 1: The MANUFACTURER of the ME SYSTEM should validate the whole software, because the software is developed by that MANUFACTURER. Therefore, for the PEMS MANUFACTURER of the ME EQUIPMENT or ME SYSTEM, the complete Clause 14 (including 14.6.1 and 14.8) apply. Case 2: For unknown IT-NETWORKS, the ME EQUIPMENT MANUFACTURER should follow 14.13, and 14.6.1 and 14.8. Note that 14.6.1 and 14.8 already specify protective measures also for interfaces to unknown software. For the MANUFACTURER of the IT-NETWORK, other standards should be taken into account, for example IEC 80001 series. NOTE IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, Clause 14 is clear as it is.

4.2.221 Non-lithium batteries

Recommendation number	221
Clause(s) number (only)	15.4.3.4
Source/problem	15.4.3.4 covers exclusively lithium batteries. The referenced standard IEC 62133 is not limited to lithium batteries and covers other kind of batteries as well. How should other kind of batteries, for example NiMH, be handled within IEC 60601-1? Batteries of high energy level are for example used in medical wheel-chairs. Strictly according the wording of 4.8, component standards shall be applied only if the component is a MEANS OF PROTECTION. However batteries are not MEANS OF PROTECTION, because if they fail there is usually no electric shock hazard. NOTE IECEE has identified the gap and has issued an INF document IECEE-CMC/1232/INF dated 2011-12-13. IEC 60601-1 covers this gap via the general subclause 4.2 related to risk management (RM). However, it should be considered for Amendment 2 to address the issue explicitly within the standard with a clear pass/fail requirement. A SC 62A recommendation could cover the time until Amendment 2, but Amendment 2 should cover the aspect finally.
Discussion/comment	It seems appropriate for IEC 60601-1 to explicit implementation requirements for non-lithium and non acid (non lead) rechargeable batteries such as NiMH batteries (except small batteries such as button cell batteries).
Submitter proposed recommendation	IEC 62133 is not limited to lithium batteries. Apply IEC 62133 as well for non-lithium battery cell and battery pack other than acid and button cell batteries.
SC 62A recommendation	IEC 62133 should be applied to batteries of all types within its scope. Within a future update of IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 15.4.3.4 is recommended to be updated to cover all types of batteries.

4.2.222 AP and APG

Recommendation number	222
Clause(s) number (only)	11.4 and Annex G
Source/problem	11.4 and normative Annex G specify requirements if flammable anaesthetics are used. The requirements lead to AP or APG requirements. However, flammable anaesthetics are not used any longer since over 35 years. Over 40 years ago, there have been used Cyclopropan and Aether as anaesthetic gases for medical purposes. These gases are highly explosive. Therefore, a need for AP or APG protection was required long time ago. However, in our days these gases are not used any longer since over 40 years. Therefore, there are almost no requests any longer for AP and APG testing. In our days, Halophan and Desfloran will be used as anaesthetic gases, which are not so explosive. Furthermore, these gases are not used in critical amounts for explosion. Halophan and Desfloran are also much lighter than the heavy Cyclopropan and Aether. Therefore, these gases volatilize in air instead of gathering around the equipment. In summary, AP and APG tests including the resistance test are not ordered any longer. Based on the fact that there is no need to classify medical equipment any longer as AP and APG, the test in 11.4 and Annex G could be deleted.
Discussion/comment	This aspect has already been discussed when working on edition 3.0 (between 1995 and 2005), as explained in Annex A, Subclause 11.4 (and also in the rationale of Annex G):
Discussion/comment	"While the use of flammable anaesthetics is uncommon, it was determined during the writing of this edition that some MANUFACTURERS might still want to rate their ME EQUIPMENT as CATEGORY AP or CATEGORY APG. In order to make this 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. Requirements related to CATEGORY AP and CATEGORY APG are found in Annex G (see also the rationale for Annex G)." Annex A, rationale of Annex G: "Section six of the second edition of this standard 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."
Submitter proposed recommendation	Delete 11.4 and normative Annex G. Alternatively change the normative Subclause 11.4 and normative Annex G to informative parts in Annex A.
SC 62A recommendation	The term PATIENT covers human being and animals. Within the veterinarian field, the flammable anaesthetics are still used. No change of the standard needed.

4.2.223 Non-weighted 10 mA PATIENT AUXILIARY CURRENT

Recommendation number	223
Clause(s) number (only)	3.47, 3.77, 8.7.3 e)
Source/problem	In 8.7.3 e) of IEC 60601-1:2005, the standard says: "Additionally, regardless of waveform and frequency, no LEAKAGE CURRENT shall exceed 10 mA RMS [...].when measured with a non-frequency-weighted device". We know that patient auxiliary current is not taken as LEAKAGE CURRENT. Does this mean that 8.7.3 e) is not applicable to PATIENT AUXILIARY CURRENT?
Discussion/comment	From my point of view, PATIENT AUXILIARY CURRENT and PATIENT LEAKAGE CURRENT are both PATIENT related; if 8.7.3 e) is applicable to PATIENT LEAKAGE CURRENT but not applicable to PATIENT AUXILIARY CURRENT, it seems not reasonable.
Submitter proposed recommendation	Rewrite 8.7.3 e) as follows: "Additionally, regardless of waveform and frequency, no LEAKAGE CURRENT or PATIENT AUXILIARY CURRENT shall exceed 10 mA RMS. .[...] when measured with a non-frequency-weighted device."
SC 62A recommendation	It is recommended to include the term PATIENT AUXILIARY CURRENT in 8.7.3 e) in the work on a future edition of the standard.

4.2.224 IPX test and test criteria

Recommendation number	224
Clause(s) number (only)	11.6.5, and IEC 60601-1-11:2015, 8.3.1
Source/problem	Question related to IEC 60601-1 only: An INTERNALLY POWERED ME EQUIPMENT without ESSENTIAL PERFORMANCE passes the test of 11.6.5 although there is no function after the IPXY test any longer due to inserted water. The compliance paragraph of 11.6.5 says: "*Compliance is checked by the tests of IEC 60529 with the ME EQUIPMENT placed in the least favourable position of NORMAL USE and by inspection.* *After these PROCEDURES, the ME EQUIPMENT is to show no signs of bridging of insulation (or electrical components) that is likely to result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE 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.*" Whilst the procedure of the test follows IEC 60529, the pass-fail criteria is defined here in 11.6.5 of the general standard. The pass-fail criteria focuses on maintaining of BASIC SAFETY and ESSENTIAL PERFORMANCE. This kind of ME EQUIPMENT does not have ESSENTIAL PERFORMANCE (or missing function is regarded as a safe state). Due to the low internal voltage (battery 3 V DC) and the short-circuit of battery plus and minus pole due to inserted water, there is no voltage measurable on the enclosure outside after the IP test. Therefore, there is no loss of BASIC SAFETY. Does the MEE comply with 11.6.5 because BASIC SAFETY and ESSENTIAL PERFORMANCE are either "maintained" or "N/A", even though the function of the device is not given any longer due to inserted water? Question related to IEC 60601-1 used together with IEC 60601-1-11: In another specific case of mandatory application of IEC 60601-1-11, the MEE (without carry case) shall comply with a specific IPXY rating (e.g. IPX1). Is it acceptable, if the IPX1 label will not be used on the ME EQUIPMENT, due to misleading the operator, because of inserted water leads to loss of the function? BASIC SAFETY is passed and ESSENTIAL PERFORMANCE is either N/A or missing function leads to a safe state.
Discussion/comment	
Submitter proposed recommendation	Question related to IEC 60601-1 only: The compliance criteria of BASIC SAFETY and ESSENTIAL PERFORMANCE should be regarded as sufficient. Function of the ME EQUIPMENT should not be required in any case. If water enters the MEE in such an amount that the function is not guaranteed any longer, the device should be classified IPX0. Question related to IEC 60601-1 used together with IEC 60601-1-11: The compliance criteria of BASIC SAFETY and ESSENTIAL PERFORMANCE should be regarded as sufficient. Function of the ME EQUIPMENT should not be required in any case. If water enters the MEE in such an amount that the function is not guaranteed any longer, it is recommended that the device should not be labelled according IPX1 or IPX2 due to potential misleading the operator. However, the mandatory conducted IPX1 or IPX2 test remains PASS, due to the passed test criteria of BASIC SAFETY and ESSENTIAL PERFORMANCE.
SC 62A recommendation	IEC 60601-1: For the work on a future edition of the standard, it is recommended to consider if, beyond the existing standard pass/fail criteria of BASIC SAFETY and ESSENTIAL PERFORMANCE, further criteria operations of the ME EQUIPMENT which are not ESSENTIAL PERFORMANCE should be as well be maintained to avoid misunderstanding of the IP rating.

Recommendation 224 *(continued)*

SC 62A recommendation	It is recommended to be very careful before you conclude that BASIC SAFETY is not concerned. For BASIC SAFETY and ESSENTIAL PERFORMANCE, the effects of ingress of water over time should be considered. If the kind of liquid in real medical use is different from water, effects on BASIC SAFETY and ESSENTIAL PERFORMANCE based on these liquids should be considered. IEC 60601-1 together with IEC 60601-1-11: Because IEC 60529 does not specifically address the pass/fail criteria, these are transferred to the writers of product standards. Therefore, in the current editions of IEC 60601-1 and IEC 60601-1-11, the pass/fail criteria is BASIC SAFETY and ESSENTIAL PERFORMANCE. Therefore, the marking should not be skipped. For the next edition of those standards, we recommend the compliance criteria should be reconsidered to include normal operation. For next editions of IEC 60601-1 and IEC 60601-1-11, the aspects over time with regard to BASIC SAFETY and ESSENTIAL PERFORMANCE should be considered particularly in regard to repeated wetting and drying of components.

4.2.225 ALARM SETTINGS, alarm presets, default alarm presets

Recommendation number	225
Clause(s) number (only)	IEC 60601-1-8:2006, 6.5.1 a), 6.5.3.2 g), 6.5.4.2 g)
Source/problem	In the three subclauses listed above, the storage and later selection of retained ALARM SETTINGS from the previous use are mentioned as an option. But it is not clearly expressed which requirements for this specific set of ALARM SETTINGS exist when recalling them: – that set might be recalled automatically after a power failure; – that set might be recalled automatically when activating the MEE from standby/off mode, if it is the only available ALARM SETTING of the MEE; – that set might be recalled only by confirmation of the operator even if it is the only available ALARM SETTING the MEE offers; – that set might be recalled only by confirmation of the operator if further available ALARM SETTINGS of the MEE exist. NOTE Depending on the intended use and on MANUFACTURER configured restrictions of possible ALARM SETTINGS, the retained ALARM SETTINGS can or cannot result in a HAZARDOUS SITUATION for a next PATIENT.
Discussion/comment	Specify in an appropriate way how retained ALARM SETTINGS from the previous use should be activated. Question: Is it acceptable if the change of a PATIENT would be addressed in the usability specifications and tests and to regard this not only related to ALARM SETTINGS? Is it acceptable if, depending on the use cases, means have to be implemented to avoid hazardous settings when changing the PATIENT? Should the RESPONSIBLE ORGANIZATION take care of procedures when changing PATIENTS including the aspects of ALARM SETTINGS? Should it be recommended for future update of usability standards to include name or identification of PATIENT in the user profile (see IEC 62366:2007, 5.1)

Recommendation 225 *(continued)*

Submitter proposed recommendation	Add following clarification to 6.5: If, after powering on the MEE, the activation of retained ALARM SETTINGS could result in a HAZARDOUS SITUATION, this activation needs to be confirmed by the OPERATOR. Alternatively, according to 6.5.4.2.e), a (non-hazardous) DEFAULT ALARM PRESET may be activated automatically. NOTE Automatic activation of retained ALARM SETTINGS after a loss of power is not deemed to result in a HAZARDOUS SITUATION as the same PATIENT is still present. If the MEE is powered on from off or standby state, usually a different PATIENT is connected to the MEE. In this case, it depends on the intended use of the MEE and on careful restriction of parameter ranges for the ALARM SETTINGS if retained ALARM SETTINGS might result in a HAZARDOUS SITUATION or not.
Submitter proposed recommendation	The change of a PATIENT should be addressed in the usability specifications and tests and is not only related to alarm settings. Depending on the use cases, means have to be implemented to avoid hazardous settings when changing the PATIENT. The RESPONSIBLE ORGANIZATION should take care of procedures when changing PATIENTS including the aspects of ALARM SETTINGS. It is recommended for future update of SC 62A to include name or identification of PATIENT in the user profile (see IEC 62366:2007, 5.1).
SC 62A recommendation	This recommendation has been developed and issued by responsible standard committee for standards IEC 60601-1-8 and IEC 60601-1-6. It is recommended not to include the name of the PATIENT into the description of a user profile. A user profile by definition is to describe a distinct group of users and not any individual. The user interface specification is the most appropriate place when it is needed to have a data point such as a PATIENT name that might be used in a PATIENT specific alarm profile.

4.2.226 AUDIBLE ALARM SIGNALS

Recommendation number	226
Clause(s) number (only)	IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012, 6.3.3.1
Source/problem	Over defined (not hearable criterion)
Discussion/comment	Timing (t_s): According to Table 3, the variation of this parameter does not exceed 5 %. For short t_s intervals in case of high priority alarm (50 ms up to 125 ms), there will be no hearable effect with more than 5 % variation. Up to 10 % variation shows no real hearable effect in operational environment. Furthermore, there can be differences in similar dimensions depending on measuring method. The electrical timing (connection to loudspeaker) can be different to "real" acoustical timing. It seems so as it is difficult to measure the parameter in a laboratory. The standard seems clear in theory, but not for the test house for evaluation. Question: Could, in a future edition of IEC 60601-1-8, pulse sequences that sound similar as in usability test be regarded as sufficient?
Submitter proposed recommendation	Timing (e.g. t_s): Increase tolerance to 10 % for variation of t_s, or change tolerance to absolute values, for example 10 ms. It is very difficult to measure the parameter in a laboratory. The standard is clear in theory, but not for the test house for evaluation. In future edition of IEC 60601-1-8, pulse sequences that sound similar in usability test should be regarded as sufficient.
SC 62A recommendation	This recommendation has been developed and issued by responsible standard committee for IEC 60601-1-8. It is working on the issue within the Amendment 2 project, solution expected 2019.

4.2.227 ISO 8820-3 fuses

Recommendation number	227
Clause(s) number (only)	15.4.3.5
Source/problem	ISO 8820-3 (low-voltage fuse-links with tabs (blade type) for fuses in road vehicles) used as over current protection in secondary circuits.
Discussion/comment	Can ISO 8820-3 fuses (low-voltage fuse-links with tabs (blade type) for fuses in road vehicles) be used as over current protection in secondary circuits? Furthermore, there are some requirements in ISO 8820-3 for a) breaking capacity (5.9 of ISO 8820-3:2010), and b) time rating test (Table 2, 5.5.1 and 5.7.2 of ISO 8820-3:2010). Furthermore, if such fuses would not be regarded as appropriate, does that mean that vehicles where MEE are powered by the vehicle battery shall change their ISO 8820-3 fuses to IEC 60127 fuses? In addition, 15.4.3.5 is not so restrictive. See also 3.120 for SUPPLY MAINS. 15.4.3.5 does not even require a fuse, but only an appropriately RATED device.
Submitter proposed recommendation	ISO 8820-3 has no specific breaking capacity and time-current behaviour. Therefore, these fuses should not be used.
SC 62A recommendation	Fuses according ISO 8820-3 are not excluded for secondary circuits, (e.g. in 15.4.3.5). If those fuses are used for protection against HAZARDOUS SITUATIONS in SECONDARY CIRCUITS, then they should have adequate rating including breaking capacity. 15.4.3.5 states: "Protective devices shall have adequate breaking capacity to interrupt the maximum fault current (including short-circuit current) which can flow." Fuses according ISO 8820-3 are fast acting because they are designed for DC currents and therefore it should be regarded that these fuses do not need to have a specification for time-current behaviour. Using DC-fuses for AC-purposes (and vice versa) should not be done without further evaluation.

4.2.228 Luminous colour of ambient light

Recommendation number	228
Clause(s) number (only)	IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012, 6.3.2.2.2
Source/problem	Conditions for perceptibility of visual alarm and information signals incomplete.
Discussion/comment	The luminous colour of ambient light is not defined. Particularly with regard to visual medium priority alarm signal (yellow light/indicator), there is a problem. If the ambient light at the test place is "too yellow", the indicator can be not visible; if the ambient light is "too cold", even you can perceive very bad indicator lights. Furthermore, depending on luminous colour, the differentiation of red and yellow colour can be difficult. The best differentiation is possible with neutral white. Are there any problems known on the market? Should colour temperature and index of ambient illumination during test be specified? Should usability test give evidence if the legibility is given?
Submitter proposed recommendation	Additional test condition should be used: – Ambient luminous colour: neutral white (3 300 up to 5 300 K)
SC 62A recommendation	After discussion with standard committee JWG2 (alarms) for the standard IEC 60601-1-8, it was determined that this technical issue is a general question as well in IEC 60601-1:2005, 7.8.1 (indicator lights). If ambient light during final use of the ME EQUIPMENT has a significant impact on the visibility of indicator lights or ALARM SIGNALS, the use scenarios for USABILITY design specifications should give instructions in which ambient light the visibility test (see 7.8.1 in IEC 60601-1:2005 or 6.3.2.2 in IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012) has to be performed.

4.2.229 WITHDRAWN

4.2.230 WITHDRAWN

4.2.231 Assumed typing errors in several clauses

Recommendation number	231
Clause(s) number (only)	8.8.3, 8.9.4, 8.11.4.4,10.5, Annex K
Source/problem	Several issues numbered 1) to 5): 1) Table 6 does not include the V peak 42,V and V DC 60 V values in the first and second column. 2) In 8.9.4, many requirements of 1 mm CREEPAGE DISTANCE remained instead of X mm CREEPAGE DISTANCE. 3) In 8.11.4.4, "compliance is checked by [...] after the test of 8.11.3.4", while 8.11.3.4 is the requirement of APPLIANCE COUPLERS. 4) 10.5: "[...], other than that produced by lasers and light emitting diodes (see 10.4)". In clause 10.4, IEC 60601-1:2005/AMD1:2012 has deleted the light emitting diodes requirement. So in 10.5, light emitting diodes should be deleted accordingly. 5) In Figure K.5, the APPLIED PART itself is not protectively earthed. There is no need to explain BF. The title seems to have been copied from Figure K.4: "ME EQUIPMENT with a PATIENT connection of a TYPE B APPLIED PART that is not PROTECTIVELY EARTHED", where B has been changed to BF.
Discussion/comment	This could be an overlooked mistake of 8.9.4, 8.11.4.4,Table 6 and 10.5.
Submitter proposed recommendation	Table 6: PEAK WORKING VOLTAGE (*U*) V peak | PEAK WORKING VOLTAGE (*U*) V DC *U* ≤ 42,4 | *U* ≤ 60 8.9.4: use X mm instead of 1 mm in the subclause. 8.11.4.4: "*Compliance is checked by [...] after the test of 8.11.**4.3**.*" 10.5: "[...], other than that produced by lasers ~~and light emitting diodes~~ (see 10.4)." Figure K.5: "ME EQUIPMENT with a PATIENT CONNECTION of a TYPE BF APPLIED PART ~~that is not protectively earthed~~".
SC 62A recommendation	1) It is recommended to read the first line of Table 6 as "less than or equal to" 42,4 V peak and 60 V DC 2) It is recommended to replace 1 mm by X mm in 8.9.2 and 8.9.4 at the following locations: 8.9.2 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 23 to Figure 31 [inclusive]). 8.9.4: *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 25).* *Where the distance across the top of a groove is **1 mm** or more, no CREEPAGE DISTANCE exists across the air space (see Figure 24).* *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 24). In all other cases the groove is neglected.*

Recommendation 231 *(continued)*

SC 62A recommendation	In addition, Figure 23 specifies "mm" without an "X" used. It is recommended to correct it in a future edition of the standard. 3) There is an editorial error in the compliance paragraph of 8.11.4.4. It is recommended to read "8.11.**4.3**" instead of "8.11.**3.4**". 4) The issue related to 10.5 is covered by recommendation 210 and is additional. It will be subject of the work on a future edition. 5) It is recommended to change the title of Figure K.5 as follows: Figure K.5 – ME EQUIPMENT with a non-PROTECTIVELY EARTHED part and with a PATIENT CONNECTION of a TYPE BF APPLIED PART In addition, a similar change for the title of Figure K.4 is recommended as follows: Figure K.4 – ME EQUIPMENT with a non-PROTECTIVELY EARTHED part and with a PATIENT CONNECTION of a TYPE B APPLIED PART that is not PROTECTIVELY EARTHED

4.2.232 Indicator lights

Recommendation number	232
Clause(s) number (only)	7.8
Source/problem	Indicator lights are not defined, and as such, the requirements noted in 7.8.1 and 7.8.2 can be applied to lights that are not intended to provide an indication function.
Discussion/comment	Lack of a definition for indicator light causes confusion when lights are used for other purposes. The standard already recognizes that dot-matrix and alphanumeric displays are not considered to be indicator lights, but this still leaves other types of lights that the MANUFACTURER does not intend to be used as an indication open for discussion. The definition proposed below comes from a result of reviewing the following standards: IEC 62271-1:2007 (Ed 1.0), IEC 60947-1:2007 (Ed. 5.0), IEC 60073:2002 (Ed. 6.0) and IEC 60079 (Ed. 6.0)
Submitter proposed recommendation	**Add in Clause 3 a definition for indicator light:** INDICATOR LIGHT: lamp used to provide a visual indication of the operating state of the device. **Add Note to exclusion statement in 7.8.1 (above Table 2):** "NOTE A yellow or red light that is not necessary for the OPERATOR to identify equipment that requires a response is not considered to be an INDICATOR LIGHT." Please note that if the proposal is accepted, "indicator light" will need to be changed throughout the standard to small caps to identify this as a defined term. [References in 7.4.1 (3 places), 7.8, 7.8.1, 7.8.2, 7.9.2.9, 8.4.2 Example 2, 15.4.4 (5 places), etc.] **Alternate proposal:** Do not add the definition for indicator light, but still add the proposed note to help clarify the use of coloured lights that are not meant to function as indicator lights.
SC 62A recommendation	The real case of the issue is a phototherapy equipment. For such ME EQUIPMENT, IEC 60601-2-50 is applicable. It is recommended that the submitter submits the request for clarification to the maintenance team responsible for the relevant material in IEC 60601-1. NOTE Not all indicator lights require OPERATOR response.

4.2.233 PEMS

Recommendation number	233
Clause(s) number (only)	14.1
Source/problem	This subclause is ambiguous in two aspects: Aspect 1: "The requirements in 14.2 to 14.12 (inclusive) shall apply to PEMS unless: – none of the PROGRAMMABLE ELECTRONIC SUBSYSTEM (PESS) provides functionality necessary for BASIC SAFETY or ESSENTIAL PERFORMANCE; or – the application of RISK MANAGEMENT as described in 4.2 demonstrates that the failure of any PESS does not lead to an unacceptable RISK. [...] NOTE 2 If a RISK CONTROL measure is implemented within the PESS, it is necessary to apply Clause 14 to demonstrate that the failure of the PESS does not lead to an unacceptable RISK." Question 1: "Freedom from unacceptable risk" is directly used for the definition of "safety" (in IEV International Electrotechnical Vocabulary/ ISO/IEC Guide 51) as well as for the definition of "basic safety" and "essential performance" in IEC 60601-1. What is the difference between both dashes? In cases where dash 1 condition is given, dash 2 condition should be given, too. Same vice versa (taking into account note 2, i.e. no risk control measure used in PESS itself). Can the "or" at the end of dash 1 be read like "i.e.:"? So that the 2 dashes can be read as only one? Answer from the maintenance team responsible for the relevant material of IEC 60601-1: The first dash covers the situation where a ME EQUIPMENT has software but that software cannot contribute to a hazardous situation. For instance, the software may log a use of the ME EQUIPMENT for the purpose of billing or to provide information to help the manufacturer improve the device. The software cannot impact delivery of the therapy and the logged information is not used for the purpose of patient diagnosis or treatment. The requirements in 14.2 to 14.12 are not necessary. The second dash covers the situation where a ME EQUIPMENT has software that can contribute to a hazardous situation, but the application of risk management at a system level reduces the risk from the software to an acceptable level. For instance, an external pacemaker could have software that controls the rate of the pacing. The software could fail and try to pace at an unsafe rate. If the pacemaker hardware would not pace at the unsafe rate, the risk from the software failure would be acceptable due to the application of risk management to the system, and the requirements in 14.2 to 14.12 would not be necessary (note that if the risk control that limited the pacing rate was implemented by software, the requirements in 14.2 to 14.12 would still be required to provide assurance that the risk control was implemented safely). It is correct that if dash one is true dash two will also be true, but dash two is not just an example of dash one, it can describe a different situation where dash one is not true. The maintenance team responsible for the relevant material of IEC 60601-1 felt it was valuable to identify both types of situations where the requirements of the section were not needed.

Recommendation 233 *(continued)*

Source/problem (continued)	Aspect 2: "The requirements in 14.13 are applicable to any PEMS intended to be incorporated into an IT-NETWORK whether or not the requirements in 14.2 to 14.12 apply. […] When the requirements in 14.2 to 14.13 apply, the requirements in 4.3, Clause 5, Clause 7, Clause 8 and Clause 9 of IEC 62304:2006 shall also apply to the development or modification of software for each PESS." The quoted sentences create a contradiction. Sentence 1 says that 14.13 is applicable to PEMS intended to be incorporated into an IT-NETWORK independent of applicability of 14.2 to 14.12. But sentence 2 says that, if for example 14.13 applies, the same clauses of IEC 62304 are applicable that are addressed by 14.2 to 14.12 (except of IEC 62304 new subclause 4.4 "LEGACY SOFTWARE", and Clause 6 "Software maintenance PROCESS" which is addressed by 14.12; both exceptions have nothing to do with the IT system integration). This does not make sense as 14.13 is just applicable in cases where the combination of the PEMS with an (unknown, though specified) IT system cannot be/is not validated in advance (see sentence 1 of 14.13). Question 2: Can the sentence "When the requirements in 14.2 to 14.13 apply…" be read like "When the requirements in 14.2 to 14.12 apply…"? I.e., is "14.13" in that sentence a typo to be read as "14.12"? Answer from the maintenance team responsible for the relevant material of IEC 60601-1: Well, perhaps this was not written as clearly as it could have been. The intent was that the reference to IEC 62304 was necessary if 14.2 to 14.12 apply to the PEMS or if 14.13 applies. It is not a typo, it was intended to include 14.13. The reference is to a dated version of IEC 62304, so 4.4 introduced in the Amendment 1 (2015) of IEC 62304:2006 is not included. Clause 6 of IEC 62304 is excluded for the same reason that the post-market requirements in ISO 14971 are not included for risk management in 4.2.
Discussion/comment	
Submitter proposed recommendation	Clarify as appropriate. For example (if SC 62A agrees), read both dashes as only one, reading the "or" as an "i.e.". And (if SC 62A agrees), read "14.2 to 14.13" as "14.2. to 14.12" and declare the wrong digit to be a typo.
SC 62A recommendation	Aspect No. 1: 14.1, first dash: The first dash covers the situation where a ME EQUIPMENT has PESS but that PESS cannot contribute to a hazardous situation. In this case, no RISK mitigation is needed. For instance, the PESS may log a use of the ME EQUIPMENT for the purpose of billing or to provide information to help the manufacturer improve the device. The PESS cannot impact delivery of the therapy and the logged information is not used for the purpose of PATIENT diagnosis or treatment. The requirements in 14.2 to 14.12 are not necessary.

Recommendation 233 *(continued)*

SC 62A recommendation	14.1 second dash: The second dash covers the situation where a ME EQUIPMENT has PESS that can contribute to a hazardous situation, but the application of risk management at a system level reduces the RISK from the PESS to an acceptable level. Consequently, a RISK mitigation is needed, but it is implemented external to PESS (hardware risk control measures). For instance, a surgical lamp is not allowed to exceed a certain luminance limit. If hardware limits the luminance below the allowed value in NORMAL CONDITION and SFC, any software setting or failures cannot overcome the hardware protection. Aspect No. 2: Question 2: Can the sentence "When the requirements in 14.2 to 14.13 apply…" be read like "When the requirements in 14.2 to 14.12 apply…"? i.e., is "14.13" in that sentence a typo to be read as "14.12"? Answer: The references in the sentence below Note 4 in 14.1 is not a typo, it was intended to include 14.13, because additional HAZARDOUS SITUATIONS can result from a connection to an IT-NETWORK. Those have to be assessed to the procedure described in 14.1 and as appropriate 14.2 to 14.12. Hint: The reference is to a dated version of IEC 62304:2006, so 4.4 (legacy software) introduced in the Amendment 1(2015) of IEC 62304:2006 is not included. Clause 6 of IEC 62304:2006 and IEC 62304:2006/AMD1:2015 is excluded for the same reason that the post-market requirements of ISO 14971:2007, Clause 9, are not included for risk management in 4.2.

4.2.234 PEMS validation

Recommendation number	234
Clause(s) number (only)	14.11
Source/problem	The last sentence of 14.11 is ambiguous: "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." Typically, PEMS VALIDATION team members participate in one or more product design teams and may collaborate with other members of a specific design team also in further design teams. So, "professional relationships" may be manifold. What exactly is meant with "all professional relationships", and what exactly needs to be documented? Only complete role descriptions of the PEMS VALIDATION team member(s) within the specific design team of the product under test?
Discussion/comment	
Submitter proposed recommendation	Read the sentence that way that all roles of the PEMS VALIDATION team member(s) within the design team of the product under test need to be documented.
SC 62A recommendation	It is recommended that the term "professional relationship" from the normative part of the standard in 14.11 will be added in a future edition of the standard in the informative Annex A for 14.11 at the part addressing "independence" to make the link clearer.

4.2.235 Instability excluding transport

Recommendation number	235
Clause(s) number (only)	9.4.3.2
Source/problem	There is no minimum weight limit specified for this test as there is in 9.4.2.3.
Discussion/comment	Devices that are deemed too light for the "instability from horizontal forces" test in 9.4.2.3 are still tested in 9.4.3.2. Pushing with a force equal to 15 % of the weight of the device can lead to a tipping over of the device before the 15 % force is reached, especially when the locking devices prevent movement of the wheels.
Submitter proposed recommendation	In 9.4.3.2, add in the minimum weight exclusion just as in 9.4.2.3.
SC 62A recommendation	The standard is clear as it is and does not need improvement. Rationale: Both 9.4.2.3 (overbalance issue) and 9.4.3.2 (checking the wheels and breaking system moving issue) test different aspects of the ME EQUIPMENT and have therefore different requirements. NOTE 9.4.3.2 has incorporated in IEC 60601-1:2005/AMD1:2012 the wording "*that does not lead to overbalancing*" to make it clear.

4.2.236 Separating transformer output voltage accuracy

Recommendation number	236
Clause(s) number (only)	7.2.8.1, 16.9.2.1 b)
Source/problem	The accuracy of the voltage on auxiliary outputs, supplied from a separating transformer, is not specified. A product rated 220-240 V has a built-in separating transformer with the output supplying 3 auxiliary outlets with a max load of 2 A each but max 4 A total. With no output load and an input voltage of 240 V, the output is 250 V (264 V input generates 275 V output). This is approximately a 4 % difference. At 50 % output load, the output voltage is 245 V (2 %), and at 100 % load the output is 242 V (1 %). This means that exterior equipment will be supplied by an over-voltage for which they are not designed or tested. It should be noted that also an under-voltage might be a safety issue. To maintain the same voltage on the output, at any rated load, one would need either a very large transformer or a voltage stabilization circuit. Is this the intention or can a certain output voltage difference be accepted? The same problem exists for stand-alone separating transformers tested to IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2016, 16.9.2.1 b).
Discussion/comment	The MEE shall be safe at any mains supply voltage fluctuations of ±10 %. Exterior equipment connected to mains auxiliary outputs are also supposed to be safe at ±10 % (in some cases only +6 % to –10 %). Examples are IEC 60601-1, IEC 60950-1 and IEC 62368-1. Even with solutions as very large transformers or voltage stabilization circuits that would increase size, weight and costs, there should still be a maximum accuracy value stated.
Submitter proposed recommendation	A maximum of +3 % difference between the MAINS SUPPLY input voltage and the auxiliary output voltage at no-load conditions and a maximum of –3 % difference at full-load conditions is recommended.
SC 62A recommendation	It is recommended to include in edition 4 of IEC 60601-1 a margin for the output voltage of power outlets including MSO, in addition to the rated input voltage. This limit should take into account the margin for open circuit voltage and maximum load voltage.

4.2.237 CLASS I ME EQUIPMENT in EMS environment

Recommendation number	237
Clause(s) number (only)	IEC 60601-1-12
Source/problem	IEC 60601-1-12 requires a class II MEE if used during transport. Our MEE (console in particular) was originally designed as class I with a metal housing and a PE connector several years ago. It can be run on internal battery during transport, but the foreseeable misuse that the system is connected to mains (via a connected mains power cord to the appliance inlet) is given. The design of the system is that the MEE has an appliance inlet for connection of a standard 3 pole mains connector and the switched mode power supply is inside the MEE (no external power supply used).
Discussion/comment	A redesign of the system is not possible at the moment since the current design will be submitted for PMA approval at FDA soon. The system is a blood pumping MEE (VAD) that is mainly used in hospitals. Usually, the transport of the device (together with a PATIENT being supported) is limited to transfers between operating room (OR) and intensive care unit (ICU), and in some cases, it is used for transports between two hospitals. It is not an emergency device that is used in the domestic area or that is set up into operation in the ambulance. In all cases, the surgical intervention which is needed to connect a PATIENT to the system and to set it into operation is done in suitable infrastructure (e.g., OR) where the whole system remains immobile. Please check 3.1 of IEC 60601-1-12:2014, if this MEE is really used under EMS or not.
Submitter proposed recommendation	Can this system be excluded from IEC 60601-1-12:2014 based on the explanation given above? If not, what are the options to pass IEC 60601-1-12:2014 even with the current class I design? Is the understanding really correct that each MEE in the EMS ENVIRONMENT which is not permanently fixed by a tool (or which is permanently installed, but the operator is intended to use the tool to disconnect the MEE from the ambulance installation) and which contains a standard 3 pole MAINS appliance inlet connector (class I design MEE) does fail IEC 60601-1-12:2014, Clause 5? Please confirm or explain otherwise.
SC 62A recommendation	"This recommendation has been developed and issued by the responsible standard committee for the standard IEC 60601-1-12:2014". It is recommended to regard the described ME EQUIPMENT or ME SYSTEM as clearly within the scope of IEC 60601-1-12:2014, due to the definition in 3.1 of IEC 60601-1-12:2014, EMERGENCY MEDICAL SERVICES ENVIRONMENT. This definition explicitly includes transport "between professional healthcare facilities". If this ME EQUIPMENT or ME SYSTEM would be labelled "exclusively for transport within a hospital", then it is recommended to regard IEC 60601-1-12:2014 as not applicable. However, If the hospital area is so big that an ambulance for transportation is needed between building 1 and building 2, it is recommended that the ME EQUIPMENT or ME SYSTEM still is within the scope of IEC 60601-1-12:2014. IEC 60601-1-12:2014 allows one to FIX or PERMANENTLY INSTALL the charging system to the ambulance so when the PATIENT is transported now the ME EQUIPMENT or ME SYSTEM is compliant of this aspect of the standard. See IEC 60601-1-12:2014, Clause 5. However, as long the ME EQUIPMENT or ME SYSTEM is detachable from the power cord without the use of a TOOL and a standard MAINS VOLTAGE CLASS I APPLIANCE INLET is available on the ME EQUIPMENT or ME SYSTEM, it is recommended to regard the ME EQUIPMENT or ME SYSTEM as not compliant with IEC 60601-1-12:2014, because common POWER CORDS are available almost everywhere and it is foreseeable that those will be used. Other solutions may be achieved through a reading of the rationale related to Clause 5.

Recommendation 237 *(continued)*

SC 62A recommendation	See also particular standards for specific solutions. In addition, it is recommended to regard the following solution as in compliance with the standard: The MAINS PLUG should be FIXED and used with a special style MAINS CONNECTOR that is not commonly available preventing the use of a standard commonly available MAINS CONNECTOR. As an alternative, it is recommended to use the following solution based on 4.5 of the general standard as alternative RISK CONTROL measure: If there are two MOOP and two MOPP between SUPPLY MAINS and any ACCESSIBLE PART and any APPLIED PART, independent of PROTECTIVE EARTH CONNECTION, the PROTECTIVE EARTH CONNECTION could be allowed. However, if this case is used, the tests of IEC 60601-1-2:2014 should be performed without the PROTECTIVE EARTH CONDUCTOR connected.

4.2.238 Fire ENCLOSURE top cover

Recommendation number	238
Clause(s) number (only)	11.3 b)
Source/problem	In 11.3 b), the requirements on the bottom [in 11.3 b) 1) and 11.3 b) 3], the sides [in 11.3 b) 2)] and the material [in 11.3 b) 3)] of fire enclosures are listed. There is no specification for the top side of fire enclosures. Literally, according to 11.3 b), the top side of a fire enclosure might even be completely open (at least for a sub-assembly; for a complete equipment, further aspects like ingress of liquids, spillage, electrical safety, etc. need to be regarded). In IEC 61010-1:2010, 9.3.2 c), bottom and sides of a fire ENCLOSURE are specified in detail in a similar way, but in addition, the defined term ENCLOSURE is used. That term defined in 3.2.4 of IEC 61010-1:2010 makes ENCLOSURE to a part for protection against direct contact from all directions, with a subsequent note that such an ENCLOSURE might also be part of fire protection. The allowed openings of the defined term ENCLOSURE are shown in Figure 1 of IEC 61010-1:2010 (ingress of a 4 mm test finger is not allowed). In IEC 62368-1:2014, 6.4.8.3.3, the top side is dealt with: either no openings on top side exceed 5 mm in any dimension or 1 mm in width regardless of length, or openings keep a vertical distance to ignition sources (6.4.7.2: 50 mm), or cheesecloth covering the openings shall not be ignited by a needle flame burner (IEC 60695-11-5:2004) in a 7 mm distance. Question: Has a specification for the top side of a fire enclosure intentionally or unintentionally been dropped when 11.3 b) has been written? And what is recommended for the top side? IEC 61010-1 solution? IEC 62368-1 solution? Or one of both selectable? Or just no requirement at all?
Discussion/comment	None
Submitter proposed recommendation	It might be adequate to use a state-of-the-art restriction for top side openings in a fire enclosure according to 11.3 b), for example the solution of IEC 61010-1:2010 or the solution of IEC 62368-1:2014.
SC 62A recommendation	It is recommended to include an appropriate specification for the top of fire ENCLOSURES in a future edition of IEC 60601-1. Currently, this issue is also being discussed in other safety standard maintenance teams (e.g. IEC 62368-1), and the future solution should take notice of that.

4.2.239 Unacceptable RISK – Mechanical strength

Recommendation number	239
Clause(s) number (only)	15.3
Source/problem	Confusing and contradicting requirement
Discussion/comment	IEC 60601-1:2005/AMD1:2012 removed the statement "unacceptable RISK" in 15.3.1. However, in 15.3.2 and 15.3.3 to 15.3.5, Compliance is check by checking damage that "results in unacceptable RISK". Additionally, there is no clear definition of the term "unacceptable RISK" in Clause 3.
Submitter proposed recommendation	Remove the term "unacceptable RISK" from all subclauses of 15.3 and refine the compliance as BASIC SAFETY. I would also argue that ESSENTIAL PERFORMANCE should be added to the compliance verification as exampled in IEC 60601-1-11:2015, Clause 10.
SC 62A recommendation	It is recommended to replace in a future edition of the standard the term "unacceptable RISK" from all subclauses compliance paragraphs of 15.3 by "no loss of BASIC SAFETY or ESSENTIAL PERFORMANCE". For the time being, it is recommended to regard compliance with BASIC SAFETY and ESSENTIAL PERFORMANCE as an alternative RISK CONTROL measure according to 4.5, instead of having "no unacceptable RISK".

4.2.240 PE plus 1 MOP for non-medical components

Recommendation number	240
Clause(s) number (only)	8.5 and 8.1 b), 3.84
Source/problem	Non-medical automation components (e.g. power supplies, power rectifiers, frequency converters, motor controller, motors, position sensors) comply with their applicable component standards. The insulation requirements (air CLEARANCE/CREEPAGE distances as well as dielectric strength) of those standards are in some cases less strict as required by IEC 60601-1 for one MOOP/MOPP to PROTECTIVELY EARTHED parts. Such components are sometimes used in MEE (e.g. automated patient couches). If the MEE concerned is CLASS I **AND** PERMANENTLY INSTALLED according definition 3.84, would a kind of alternative RISK CONTROL according 4.5 be acceptable to use these non-medical automation components (e.g. power supplies, power rectifiers, frequency converters, motor controller, motors, position sensors) in a MEE?
Discussion/comment	Undercutting the insulation, requirements of IEC 60601-1 of the barrier between a working voltage in a circuit and PROTECTIVELY EARTHED part should be acceptable, if following conditions are fulfilled. a) MEE is PERMANENTLY INSTALLED **AND** CLASS I, so that PE can be considered as CWHIC (= no degradation during lifetime/not subject to SFC according to 8.1 b), fourth dash). b) Short-circuit of the concerned barrier does not lead to 1) an exceeded leakage current, and 2) a HAZARDOUS SITUATION as described in 13.1.2, and 3) any violation of ESSENTIAL PERFORMANCE according 4.3. c) Any insulation barrier which does not comply with the requirements of IEC 60601-1 shall at least comply with the individual applicable component standard to ensure a minimum of reliability requirements. NOTE This is already common practice for such situations.

Recommendation 240 *(continued)*

Submitter proposed recommendation	**Justification**
	Item a) above: According 8.5.1.1, ME EQUIPMENT shall have two MEANS OF PROTECTION to prevent APPLIED PARTS and other ACCESSIBLE PARTS from exceeding the limits specified in 8.4. Normally PE is regarded as 1 MOPP or MOOP. As for PERMANENTLY INSTALLED MEE of CLASS I, the PE is not subject to SFC assumption (= CWHIC as no degradation during lifetime shall be assumed). It is a matter of a logical consequence to count the fixed wired PE for 2 MO(O/P)P and hence to fulfil the requirement of 8.5.1.1. Item b) above: Short-circuit of the concerned barrier does not lead to exceeding of any relevant LEAKAGE CURRENT under NORMAL CONDITION, HAZARDOUS SITUATION according 13.1.2 and violation of ESSENTIAL PERFORMANCE. The LEAKAGE CURRENT test shall be conducted after 50 ms to allow a protection device (fuse) to activate. Transient currents occurring during the first 50 ms following the short-circuit are disregarded (comparable to 8.6.4 b) compliance paragraph). Item c) above: The isolation barrier between a WORKING VOLTAGE in a circuit and the PROTECTIVELY EARTHED part shall at least comply with the individual applicable component standard. If in doubt, re-testing according the individual applicable component standard is required! (NO other experimental testing!) Result: It is recommended to regard the above mention additional safety measures (PERMANENTLY INSTALLED PROTECTIVE EARTH, short-circuit test and compliance with LEAKAGE CURRENTS AND ESSENTIAL PERFORMANCE and no resulting HAZARDOUS SITUATIONS according to 13.1.2, compliance with the component standard regarding insulation barriers) as alternative RISK CONTROL measures according 4.5. Consequently, compliance with IEC 60601-1 requirements for the concerned barrier between a WORKING VOLTAGE in the component and the protective earth is not required.
SC 62A recommendation	It is recommended to regard 4.5 as always applicable if it is applied correctly. Based on SC 62A discussion, the real practical issue for MANUFACTURERS and test houses is mainly related to motors and motor controllers. It is recommended to regard the following alternative RISK CONTROL measures as alternative RISK CONTROL for the specific case where 1 MOOP/1 MOPP to a PROTECTIVELY EARTHED part is not met: a) PROTECTIVELY EARTHED ME EQUIPMENT which is PERMANENTLY INSTALLED in accordance with 3.84, so that opening the PROTECTIVE EARTH CONDUCTOR should not considered necessary as stated in 8.1 b), fourth dash); and b) short-circuit of this barrier is a special case and should not result in 1) an exceeded applicable LEAKAGE CURRENT for NORMAL CONDITION, and 2) a HAZARDOUS SITUATION as described in 13.1.2, and 3) a loss of ESSENTIAL PERFORMANCE according 4.3; and c) the insulation barrier to PROTECTIVELY EARTHED parts which does not comply with the requirements of IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 should at least comply with the individual applicable component safety standard to ensure a minimum of reliability requirements; if no component standard requirements exist, then IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 should be applied.

4.2.241 Resistance temperature method for non-copper windings

Recommendation number	241
Clause(s) number (only)	11.1.3 d)
Source/problem	The RESISTANCE method in IEC 60601-1 standard is only applicable for the temperature rise of copper winding by following the formula, while regardless the copper content of the winding contains. $$\Delta T = \frac{R_2 - R_1}{R_1}(234{,}5 + T_1) - (T_2 - T_1)$$ Nowhere IEC 60601-1 tackles with the temperature rise on such a scenario that the winding is made of aluminium windings or copper/aluminium windings
Discussion/comment	The formula for resistance method in IEC 60601-1 could mislead the MANUFACTURERS that only copper windings are allowed for medical electrical power supply. However, in practice, more or less often, for the sake of cost saving, MANUFACTURERS may intend to select a transformer which uses the enamelled copper and aluminium wire or aluminium enamelled wire for coiling windings.
Submitter proposed recommendation	Provide a further clarification that the thermal coefficient *k* (234,5) is only for copper windings and copper/aluminium windings with a copper content ≥ 85 %. If the windings have less copper content, thus, adopt the coefficient and formula from IEC 60335-1 $$\Delta t = \frac{R_2 - R_1}{R_1}\ (k + t_1) - (t_2 - t_1)$$ where *k* is equal to • 225 for aluminium windings and copper/aluminium windings with an aluminium content ≥ 85 %, • 229,75 for copper/aluminium windings with a copper content > 15 % to < 85 %.
SC 62A recommendation	It is recommended to allow a *k*-factor (thermal coefficient of resistance) related to the actual winding material used if known. NOTE The current used *k*-factor (234,5) represents the worst case for all copper and copper-aluminium and aluminium winding.

4.2.242 DUPLICATE / WITHDRAWN

4.2.243 Drop test during INTENDED USE

Recommendation number	243
Clause(s) number (only)	3.37, 15.3.4.1
Source/problem	Drop test on MEE, accessories and parts intended to be hand-held when installed and "placed into service". The defined term NORMAL USE was, via IEC 60601-1:2005/AMD1:2012, changed to "placed into service" which makes it unclear. Does it mean only during INTENDED USE, i.e. clinical use on a PATIENT, or does it also mean NORMAL USE, i.e. configuration, set-up, preparation, inspection, adjustments, maintenance, transport, etc.?
Discussion/comment	Examples: – Should the drop test be applied on an OPERATOR accessible battery pack, intended to be exchanged by the OPERATOR between the INTENDED USE occasions? What if intended to be exchanged also during INTENDED USE? – Should the drop test be applied on an OPERATOR accessible vaporizer for anaesthetic liquid, intended to be exchanged by the OPERATOR between INTENDED USE occasions? What if intended to be exchanged during INTENDED USE? – Should the drop test be applied on a disposable container with bio hazardous body fluids, intended to be exchanged by the OPERATOR between INTENDED USE occasions? Even a big table top MEE, which is not HAND-HELD during INTENDED USE, can of course be accidently dropped during handling in NORMAL USE when moved from one table/location to another. There can be many things that sometimes are HAND-HELD during NORMAL USE. These parts might by themselves generate a hazardous situation when dropped or might have an impact on BASIC SAFETY or ESSENTIAL PERFORMANCE due to non-detected damages on the parts after a drop. Is it realistic to expect such parts being designed to withstand a free fall from 1 m, which might lead to quite expensive design requirements?
Submitter proposed recommendation	The drop test should be applied to MEE, accessories and parts intended to be HAND-HELD during INTENDED USE. The wording "placed into service" should be understood as used according to the INTENDED USE.
SC 62A recommendation	It is recommended to read the term "placed into service" in definitions 3.37 and 3.85 as "ready for INTENDED USE". Consequently, for example maintenance and service repair are not covered by the drop test.

Annex A
(informative)

Overview of the recommendations developed by SC 62A

Table A.1 provides cross-references to IEC 60601:2005 and IEC 60601:2005/AMD1:2012 in numerical order, along with the relevant recommendation number.

Table A.1 – Cross-references to IEC 60601-1:2005 and IEC 60601:2005/AMD1:2012 in numerical order

Clause/subclause of IEC 60601:2005 and IEC 60601:2005/ AMD1:2012	Recommendation number	Contents	Page
Clause 2	**190**	Reference to IEC 62304:2006	85
	153	Critical components	57
3.8	**154**	LEAKAGE CURRENT test for ME EQUIPMENT with multiple APPLIED PARTS	57
3.37, 15.3.4.1	**243**	Drop test during INTENDED USE	133
3.44	**167**	MOBILE and STATIONARY ME EQUIPMENT with wheels	66
3.47, 3.77, 8.7.3 e)	**223**	Non-weighted 10 mA PATIENT AUXILIARY CURRENT	115
3.65	**167**	MOBILE and STATIONARY ME EQUIPMENT with wheels	66
3.71	**167**	MOBILE and STATIONARY ME EQUIPMENT with wheels	66
3.78	**154**	LEAKAGE CURRENT test for ME EQUIPMENT with multiple APPLIED PARTS	57
3.84	**127**	PERMANENTLY INSTALLED ME EQUIPMENT in the HOME HEALTHCARE ENVIRONMENT	30
3.85, 3.118 and 3.130	**200**	PORTABLE, STATIONARY and TRANSPORTABLE ME EQUIPMENT	95
3.118	**167**	MOBILE and STATIONARY ME EQUIPMENT with wheels	66
4.3	**214**	ESSENTIAL PERFORMANCE related to RM (P1 and P2)	107
4.6	**175**	Biocompatibility for quasi APPLIED PARTS	71
4.7 a)	**172**	Examples of SINGLE FAULT CONDITION	70
4.8	**131**	Optic coupler requirements	35
4.8	**168**	Varistors installed in the MAINS PART	67
4.9	**151**	COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS	55
5.9.2.1	**180**	Infrared lamps	76
6.2	**217**	CLASS II symbol	110
7.1.2	**132**	Eye-verification of tester before legibility test	37
7.1.2, first dash	**213**	Warning, caution, safety notice	106
7.2.2	**135**	Labeling: spare parts vs. detachable parts vs. ACCESSORIES	40
7.2.3	**203**	Consult ACCOMPANYING DOCUMENTS	98
7.2.4	**135**	Labeling: spare parts vs. detachable parts vs ACCESSORIES	40
7.2.5	**164**	Specification of the allowed power supply	63
7.2.7	**162**	Current/power labeling	62
7.2.8.1, 16.9.2.1 b)	**236**	Separating transformer output voltage accuracy	127
7.3.3, 7.3.4 and 8.11.4	**218**	Authorized SERVICE PERSONNEL	111

Table A.1 – Cross-references to IEC 60601-1:2005 and IEC 60601:2005/AMD1:2012 in numerical order *(continued)*

Clause/subclause of IEC 60601:2005 and IEC 60601:2005/ AMD1:2012	Recommendation number	Contents	Page
7.3.4	**181**	Identification of internal fuses	77
7.4.2	**129**	Push buttons	33
7.8	**232**	Indicator lights	123
7.8.1 Table 2	**108**	Warnings versus ALARM SIGNALS	16
7.9.2.3	**163**	Separate power supply part of ME EQUIPMENT or ME SYSTEM	63
8.1	**123**	Operational insulation	28
8.1 a)	**149**	Expected voltage on SIP/SOPs	54
8.1 a) last dash	**121**	FUNCTIONAL EARTH CONDUCTOR and ESSENTIAL PERFORMANCE	26
8.1 a), 8.1 b), 8.9.1.1, 8.9.2 a), 8.11.5, 15.4.3.5 and 15.5.1.1	**201**	Opposite polarity and philosophy of IEC 60601-1	96
8.1 b) first dash note	**112**	Short-circuiting of one constituent part of DOUBLE INSULATION	19
8.1 b) last dash	**121**	FUNCTIONAL EARTH CONDUCTOR and ESSENTIAL PERFORMANCE	26
8.7.3 e)	**197**	Non-frequency-weighted measurement	93
8.4.2	**112**	Short-circuiting of one constituent part of DOUBLE INSULATION	19
8.4.2 c)	**180**	Infrared lamps	76
8.4.2 c)	**191**	The SIP/SOP pin to earth TOUCH CURRENT	85
8.5	**125**	Defibrillation test	29
8.5	**131**	Optic coupler requirements	35
8.5 and 8.1 b), 3.84	**240**	PE plus 1 MOP for non-medical components	130
8.5.1	**109**	Single Y1 capacitor for MOPP	16
8.5.1.2	**169**	Using Y2 capacitors for MOPP	67
8.5.2.1	**154**	LEAKAGE CURRENT test for ME EQUIPMENT with multiple APPLIED PARTS	57
8.5.2.2	**161**	TYPE B APPLIED PART connected to ACCESSIBLE PARTS	62
8.5.2.2	**188**	TYPE B APPLIED PART separated from ACCESSIBLE PARTS	83
8.5.2.3	**185**	PATIENT leads connectors	81
8.5.2.3, 8.5.5, and 8.7.4.7 b)	**205**	Guidewire	101
8.5.4	**122**	AC motors	27
8.5.4	**124**	WORKING VOLTAGE measurement	28
8.5.5	**115**	DEFIBRILLATION-PROOF TYPE B APPLIED PARTS	20
8.5.1.1	**195**	Split up of BI, SI, DI, RI barriers	90
8.6.4	**119**	Test equipment for recurrent tests according to IEC 62353 testing used within IEC 60601-1 type approval testing	23
8.6.4 a), second paragraph	**144**	Impedance of a PROTECTIVE EARTH CONDUCTOR within a DETACHABLE POWER SUPPLY CORD	51
8.6.4 a)	**189**	Protective earth test > 25A	84

Table A.1 – Cross-references to IEC 60601-1:2005 and IEC 60601:2005/AMD1:2012 in numerical order *(continued)*

Clause/subclause of IEC 60601:2005 and IEC 60601:2005/ AMD1:2012	Recommendation number	Contents	Page
8.6.4 b)	**136**	Protective earth impedance of ME SYSTEM >200 mΩ	43
8.6.9	**121**	FUNCTIONAL EARTH CONDUCTOR and ESSENTIAL PERFORMANCE	26
8.6.9	**183**	CLASS II ME EQUIPMENT with FUNCTIONAL EARTH CONDUCTOR	79
8.7	**119**	Test equipment for recurrent tests according to IEC 62353 testing used within IEC 60601-1 type approval testing	23
8.7	**176**	Floating reference earth	72
8.7	**208**	Cecon plug as permanently installed MEE	103
8.7.1	**114**	Delay time for conducting leakage current tests after humidity preconditioning treatment	20
8.7.2	**136**	Protective earth impedance of ME SYSTEM > 200 mΩ	43
8.7.2 third dash	**112**	Short-circuiting of one constituent part of DOUBLE INSULATION	19
Table 3 and 4	**194**	TYPE B vs TYPE BF SFC limits	88
8.7.4.3 d) 1)	**128**	Polystyrene plate for LEAKAGE CURRENT tests	32
8.7.4.6 and Figure 14	**149**	Expected voltage on SIP/SOPs	54
8.7.4.7 b)	**193**	MAINS VOLTAGE on APPLIED PART	88
8.7.4.9	**154**	LEAKAGE CURRENT test for ME EQUIPMENT with multiple APPLIED PARTS	57
8.8.2	**131**	Optic coupler requirements	35
8.8.2 d)	**155**	DIELECTRIC STRENGTH test value for extruded and spirally wrapped multi-layer wires	58
8.8.2 e)	**155**	DIELECTRIC STRENGTH test value for extruded and spirally wrapped multi-layer wires	58
8.8.3	**110**	WORKING VOLTAGE > 14 140 V peak	17
8.8.3	**131**	Optic coupler requirements	35
8.8.3	**134**	MOPP barrier with low working voltage RMS and high WORKING VOLTAGE peak	39
8.8.3	**146**	Test voltage multiplied by factor 1,6	53
8.8.3 and 8.5.1.2	**199**	Y1 caps bridging 2 MOPP	94
8.8.3, 8.9.4, 8.11.4.4,10.5, Annex K	**231**	Assumed typing errors in several clauses	122
8.8.3 Table 6	**117**	DIELECTRIC STRENGTH of two serial MOPP barrier parts	21
8.8.3 Table 6	**141**	DIELECTRIC STRENGTH test values	49
8.8.3 Table 7	**141**	DIELECTRIC STRENGTH test values	49
8.9	**102**	Pollution degree for MOPP	13
8.9	**103**	Transients on DC mains	13
8.9	**104**	Altitude factor for DEFIBRILLATION-PROOF APPLIED PARTS	14
8.9	**105**	Defibrillation energy protection for MOOP/MOPP	15
8.9	**106**	Overvoltage categories III and IV	15

Table A.1 – Cross-references to IEC 60601-1:2005 and IEC 60601:2005/AMD1:2012 in numerical order *(continued)*

Clause/subclause of IEC 60601:2005 and IEC 60601:2005/ AMD1:2012	Recommendation number	Contents	Page
8.9	**107**	Pollution degree related to different micro/macro environments	15
8.9	**110**	WORKING VOLTAGE > 14 140 V peak	17
8.9	**157**	Required MOOP values higher than MOPP values	59
8.9.1	**131**	Optic coupler requirements	35
8.9.1	**134**	MOPP barrier with low WORKING VOLTAGE RMS and high WORKING VOLTAGE peak	39
8.9.1	**171**	CREEPAGE DISTANCE and AIR CLEARANCE between input and output of fuse contacts	69
8.9.1.1	**102**	Pollution degree for MOPP	13
8.9.1.1	**103**	Transients on DC mains	13
8.9.1.1	**104**	Altitude factor for DEFIBRILLATION-PROOF APPLIED PARTS	14
8.9.1.1	**105**	Defibrillation energy protection for MOOP/MOPP	15
8.9.1.1	**106**	Overvoltage categories III and IV	15
8.9.1.1	**107**	Pollution degree related to different micro/macro environments	15
8.9.1.12	**142**	SECONDARY CIRCUITS	50
8.9.1.12	**165**	Mains transients for opposite polarity on the secondary side or battery pole to pole barrier	64
8.9.1.15 Table 12	**152**	Peak and RMS WORKING VOLTAGES	56
8.9.3	**131**	Optic coupler requirements	35
8.9.3	**158**	Optocouplers	59
8.9.3.2	**146**	Test voltage multiplied by factor 1,6	53
8.9.3.3	**198**	Printed circuit board passed UL 796	94
8.9.3.4	**156**	DIELECTRIC STRENGTH test after thermal cycling test	58
8.11.3.3 Table 17	**174**	Cross sectional area of POWER SUPPLY CORD for rated input current > 63 A	71
8.11.5	**206**	H or L mains fuses	102
9.2.3.2	**133**	End stops to prevent overtravel	38
9.2.3.2	**170**	Overtravel end stops – Specification of the speed	68
9.4.1	**139**	Instability with initial movement	46
9.4.2.2, compliance paragraph	**116**	Instability excluding transport position	21
9.4.3.2	**235**	Instability excluding transport	127
9.4.2.3 b)	**192**	Overbalancing	87
9.4.2.4.3	**120**	Tolerances of apparatus	25
9.4.3.1	**113**	Instability in transport position	19
9.4.3.1 c)	**139**	Instability with initial movement	46
9.4.3.2 a)	**139**	Instability with initial movement	46
9.4.3.2 b)	**139**	Instability with initial movement	46
10.4	**178**	Laser requirements	75
10.4 and 10.5	**210**	Safety relevant LEDs	105

Table A.1 – Cross-references to IEC 60601-1:2005 and IEC 60601:2005/AMD1:2012 in numerical order *(continued)*

Clause/subclause of IEC 60601:2005 and IEC 60601:2005/ AMD1:2012	Recommendation number	Contents	Page
11.1.2.1	**180**	Infrared lamps	76
11.1.2.2	**207**	Applied part temperature	103
11.2.3	**177**	SINGLE FAULT CONDITION in OXYGEN RICH ENVIRONMENT	73
11.3	**187**	Battery – Limited power	83
11.3 a)	**150**	Flammability rating for transformer bobbin	55
11.3 a)	**179**	Flammability rating of insulated wires	75
11.3 b)	**238**	Fire ENCLOSURE top cover	129
11.3 b) 3)	**138**	Magnesium alloy ENCLOSURE	45
11.4 and Annex G	**222**	AP and APG	114
11.6.2	**147**	Overflow and spillage	53
11.6.3	**147**	Overflow and spillage	53
11.6.3	**160**	Spillage test in NORMAL CONDITION and in SINGLE FAULT CONDITION	61
11.6.5, and IEC 60601-1-11:2015, 8.3.1	**224**	IPX test and test criteria	116
11.7	**175**	Biocompatibility for quasi APPLIED PARTS	71
11.7	**209**	Biocompatibility for enclosures and other parts	104
13.1.2	**130**	Temperature limit at the ENCLOSURE in SINGLE FAULT CONDITION	34
13.1.2	**145**	Time delay of the 100 VA limit	52
13.1.2	**187**	Battery – Limited power	83
13.1.3	**143**	LEAKAGE CURRENTS in SINGLE FAULT CONDITION and during component faults	50
13.2.9	**212**	Motor capacitors	106
13.2.13.1	**137**	Ball pressure test	44
13.2.13.1	**140**	Ball pressure test	47
Clause 14	**190**	Reference to IEC 62304:2006	85
14.1	**233**	PEMS	124
14.11	**234**	PEMS validation	126
14.13	**220**	IT-NETWORK requirements	112
15.3	**204**	AP-ENCLOSURE requirements	100
15.3	**239**	Unacceptable RISK – Mechanical strength	130
15.3.3	**159**	Impact test	60
15.3.5 a)	**120**	Tolerances of apparatus	25
15.3.5 b)	**120**	Tolerances of apparatus	25
15.3.5 c)	**120**	Tolerances of apparatus	25
15.4.3.4	**211**	Lithium coin cells	105
15.4.3.4	**219**	Scope of 62133 and requirement in 15.4.3.4 related to portable batteries	112
15.4.3.4	**221**	Non-lithium batteries	113
15.4.3.5	**165**	Mains transients for opposite polarity on the secondary side or battery pole to pole barrier	64

Table A.1 – Cross-references to IEC 60601-1:2005 and IEC 60601:2005/AMD1:2012 in numerical order *(continued)*

Clause/subclause of IEC 60601:2005 and IEC 60601:2005/ AMD1:2012	Recommendation number	Contents	Page
15.4.3.5	**227**	ISO 8820-3 fuses	120
15.4.4	**216**	Indicator lights for standby switch	109
15.4.9	**126**	Oil containers for moving parts	30
15.5.1	**148**	DIELECTRIC STRENGTH test of transformers without accessible frame	54
15.5.1.1	**118**	Overheating transformer	22
15.5.1.1	**165**	Mains transients for opposite polarity on the secondary side or battery pole to pole barrier	64
16.6.3	**101**	Total PATIENT LEAKAGE CURRENT of a ME SYSTEM	12
16.5	**202**	Separation device	97
16.9.2.1 b) first dash	**184**	Symbol ISO 7010-W001 (2011-05) on multiple socket-outlet (MSO)	80
16.9.2.2	**136**	Protective earth impedance of ME SYSTEM >200 mΩ	43
Annex A, Subclause 6.3	**186**	Rationale for IP2X	82
Table I.1	**173**	Examples of ME SYSTEMS	70
Annex L	**155**	DIELECTRIC STRENGTH test value for extruded and spirally wrapped multi-layer wires	58

Table A.2 provides cross-references to IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012 in numerical order, along with the relevant recommendation number.

Table A.2 – Cross-references to IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012 in numerical order

Clause/subclause of IEC 60601-1-8:2006 and IEC 60601-1-8:2006/ AMD1:2012	Recommendation number	Contents	Page
6.3.2.2.2	**228**	Luminous colour of ambient light	121
6.3.3.1	**196**	ALARM PULSE RISE TIME	92
6.3.3.1	**226**	AUDIBLE ALARM SIGNALS	119
6.5.1.a), 6.5.3.2.g) , 6.5.4.2.g)	**225**	Alarm settings, alarm presets, default alarm presets	117
Annex A, 6.3.2	**215**	IEC 60601-1-8 symbol color	109

Table A.3 provides cross-references to IEC 60601-1-11:2010 and IEC 60601-1-11:2015 in numerical order, along with the relevant recommendation number.

Table A.3 – Cross-references to IEC 60601-1-11:2010 and IEC 60601-1-11:2015 in numerical order

Clause/subclause of IEC 60601-1-11:2010 and IEC 60601-1-11:2015	Recommendation number	Contents	Page
7.2 and 8.3.1	**166**	Keep dry and umbrella symbol	65
7.5.1	**127**	PERMANENTLY INSTALLED ME EQUIPMENT in the HOME HEALTHCARE ENVIRONMENT	30

Table A.4 provides cross-references to IEC 60601-1-12:2014 in numerical order, along with the relevant recommendation number.

Table A.4 – Cross-references to IEC 60601-1-12:2014 in numerical order

Clause/subclause of IEC 60601-1-12:2014	Recommendation number	Contents	Page
Full standard	**237**	CLASS I ME EQUIPMENT in EMS environment	128

Bibliography

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

IEC 60073:2002, *Basic and safety principles for man-machine interface, marking and identification – Coding principles for indicators and actuators*

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[4] This publication has been replaced by IEC 80601-2-49:2018.

[5] This publication was withdrawn and replaced by IEC 60695-11-5:2016.

[6] This publication was withdrawn and replaced by IEC 62366-1:2015.

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[7] This publication was withdrawn and replaced in 2018.

[8] This publication was withdrawn and replaced by IEC 62368-1:2018.

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