IEC TR 60601-4-3

Edition 1.0 2015-04

TECHNICAL REPORT

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

IEC TR 60601-4-3:2015-04(en)

IEC Central Office
3, rue de Varembé
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
Fax: +41 22 919 03 00
info@iec.ch
www.iec.ch

About the IEC
The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

About IEC publications
The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigenda or an amendment might have been published.

IEC Catalogue - webstore.iec.ch/catalogue
The stand-alone application for consulting the entire bibliographical information on IEC International Standards, Technical Specifications, Technical Reports and other documents. Available for PC, Mac OS, Android Tablets and iPad.

IEC publications search - www.iec.ch/searchpub
The advanced search enables to find IEC publications by a variety of criteria (reference number, text, technical committee,…). It also gives information on projects, replaced and withdrawn publications.

IEC Just Published - webstore.iec.ch/justpublished
Stay up to date on all new IEC publications. Just Published details all new publications released. Available online and also once a month by email.

Electropedia - www.electropedia.org
The world's leading online dictionary of electronic and electrical terms containing more than 30 000 terms and definitions in English and French, with equivalent terms in 15 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

IEC Glossary - std.iec.ch/glossary
More than 60 000 electrotechnical terminology entries in English and French extracted from the Terms and Definitions clause of IEC publications issued since 2002. Some entries have been collected from earlier publications of IEC TC 37, 77, 86 and CISPR.

IEC Customer Service Centre - webstore.iec.ch/csc
If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: csc@iec.ch.

IEC TR 60601-4-3

Edition 1.0 2015-04

TECHNICAL REPORT

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

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

ICS 11.040

ISBN 978-2-8322-2613-1

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

_____

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

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
6) All users should ensure that they have the latest edition of this publication.
7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

The main task of IEC technical committees is to prepare International Standards. However, a technical committee may propose the publication of a technical report when it has collected data of a different kind from that which is normally published as an International Standard, for example "state of the art".

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.

The text of this technical report is based on the following documents:

Enquiry draft	Report on voting
62A/951/DTR	62A/973A/RVC

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

Terms used throughout this technical report that have been defined in Clause 3 of IEC 60601-1:2005 and IEC 60601-1:2005/AMD 1:2012 are printed in SMALL CAPITALS.

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

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

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

INTRODUCTION

At the Sydney meeting in August 1994, 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 first edition of IEC TR 60601-4-3 contains 93 recommendations, numbered 101 to 193. All these recommendations are based upon IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012.

The numbering starts with 101 instead of just 1 to ensure that these WG 14 recommendations (101 to 193) will not accidentally be confused with previous issued WG 14 recommendations 1 to 63, which are based on the second edition of IEC 60601-1 and published in IEC TR 62296.

This technical report 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 and object

1.1 Scope

This technical report contains a series of recommendations developed by an expert working group of IEC subcommittee 62A in response to questions of interpretation of the third edition of IEC 60601-1.

This technical report 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 and IEC 60601-1:2005/AMD1:2012, and

– 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 a future revision of IEC 60601-1.

1.2 Object

The object of this technical report is to make the recommendations/interpretations developed by the experts in IEC/SC 62A/WG 14 available to those interested in the application of the third edition of IEC 60601-1.

The reader is reminded that, although a majority of the National Committee members of IEC/SC 62A have approved publication of this technical report, the contents remain the opinion of the expert members of WG 14. 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, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

IEC 60601-1-8:2006, *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*

3 Recommendations

3.1 Template used for recommendations prepared by SC 62A/WG 14

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

WG 14 recommendation number	NNN [a]
Requirement, clause/ subclause number(s) [b]	
Source/problem [c]	
Discussion/comment [d]	
Submitter proposed recommendation [e]	
WG 14 recommendation [f]	

[a] The numbering of the recommendations in the Technical Report starts with 101 instead of just 1 to ensure that these WG 14 recommendations will not accidentally be confused with previously issued WG 14 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.

[c] A description of the problem as submitted to WG 14.

[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 WG 14.

3.2 Recommendation sheets

3.2.101 Total PATIENT LEAKAGE CURRENT of a ME SYSTEM

WG 14 recommendation number	101
Requirement, clause/ subclause number(s)	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	–
WG 14 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. WG 14 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 subclauses 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 subclause 8.7.4.7 h) separately for each individual ME EQUIPMENT belonging to the ME SYSTEM? WG 14 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, but WG 14 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.

3.2.102 Pollution degree for MOPP

WG 14 recommendation number	102
Requirement, clause/ subclause number(s)	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.
WG 14 recommendation	It is recommended to use Table 12 for MOPP for pollution degrees 1, 2 and 3. NOTE Pollution degree 4 is not allowed.

3.2.103 Transients on d.c. mains

WG 14 recommendation number	103
Requirement, clause/ subclause number(s)	8.9, 8.9.1.1
Source/problem	Transients on d.c. mains (e.g. ambulance power source).
Discussion/comment	The tables are based on a.c. mains transients. What about ME EQUIPMENT that operates from a d.c. mains such as an ambulance?
Submitter proposed recommendation	Apply Tables 12 through 16 as provided for ME EQUIPMENT connected to the d.c. mains.
WG 14 recommendation	It is recommended to apply Tables 12 through 16 for ME EQUIPMENT connected to the d.c. mains. Examples: a) Pure external battery power: no MAINS TRANSIENT VOLTAGE exists. b) If the external d.c. power is derived out of an a.c. MAINS VOLTAGE (e.g. 230 V a.c.): use the concept already described in IEC 60601-1. c) If the external d.c. power is locally generated by a local generator (i.e. not derived out of MAINS VOLTAGE 230 V a.c.), e.g. by a generator of the ambulance, then use transient level Table 10, line 50 V r.m.s. for primary d.c. circuit.

3.2.104 Altitude factor for DEFIBRILLATION-PROOF APPLIED PARTS

WG 14 recommendation number	104
Requirement, clause/ subclause number(s)	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 subclause 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 subclause 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 subclause 8.9.1.15. Also, bump the CREEPAGE DISTANCE requirements to equal those of the AIR CLEARANCE as is done throughout this edition of IEC 60601-1.
WG 14 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.

3.2.105 Defibrillation energy protection for MOOP / MOPP

WG 14 recommendation number	105
Requirement, clause/ subclause number(s)	8.9, 8.9.1.1
Source/problem	APPLIED PART separation MOP type.
Discussion/comment	Is APPLIED PART separation, for example in subclause 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.
WG 14 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.

3.2.106 Overvoltage categories III and IV

WG 14 recommendation number	106
Requirement, clause/ subclause number(s)	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 is overvoltage category I under certain conditions as defined in subclause 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 or IEC 61010 for requirements of CREEPAGE DISTANCE, AIR CLEARANCE and DIELECTRIC STRENGTH for ME EQUIPMENT connected to SUPPLY MAINS of overvoltage category III or IV.
WG 14 recommendation	Subclause 8.9.1.11 deals with this issue, therefore, there is no need for a WG 14 recommendation.

3.2.107 Pollution degree related to different micro/macro environments

WG 14 recommendation number	107
Requirement, clause/ subclause number(s)	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	–
WG 14 recommendation	The answer can be found in IEC 60601-1:2005/AMD1:2012, Annex M.

3.2.108 Warnings versus ALARM SIGNALS

WG 14 recommendation number	108
Requirement, clause/ subclause number(s)	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 – e.g. 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.
WG 14 recommendation	It is recommended to use IEC 60601-1:2005, subclause 7.8.1 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 subclause 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, subclause 7.8.1, Table 2 related to the meaning of warnings and cautions seems to be in conflict with definition 3.141 in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 for ALARMS CONDITION. This should be clarified in a future revision of IEC 60601-1.

3.2.109 Single Y1 capacitor for MOPP

WG 14 recommendation number	109
Requirement, clause/ subclause number(s)	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 Amendment 1.
Submitter proposed recommendation	–
WG 14 recommendation	The issue is already addressed in IEC 60601-1:2005/AMD1:2012.

3.2.110 WORKING VOLTAGE > 14 140 V peak

WG 14 recommendation number	110
Requirement, clause/ subclause number(s)	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	WG 14 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	–
WG 14 recommendation	Usually particular standards address the issue. For example, see IEC 60601-2-2, -22, -28, -36, -44, -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.

3.2.111 CREEPAGE DISTANCE and AIR CLEARANCE for dental equipment

WG 14 recommendation number	111
Requirement, clause/ subclause number(s)	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, which is a horizontal safety standard 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 subclause 8.9 of IEC 60601-1:2005 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. 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	–
WG 14 recommendation	WG 14 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.

3.2.112 Short circuiting of one constituent part of DOUBLE INSULATION

WG 14 recommendation number	112
Requirement, clause/ subclause number(s)	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	Above the reference clause, 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), subclause 8.4.2 does not describe EARTH LEAKAGE CURRENT limit.
Submitter proposed recommendation	–
WG 14 recommendation	The issue is clearly addressed in subclause 8.7.2 second and third dashes.

3.2.113 Instability in transport position

WG 14 recommendation number	113
Requirement, clause/ subclause number(s)	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.
WG 14 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.

3.2.114 When to conduct leakage current tests after humidity preconditioning treatment

WG 14 recommendation number	114
Requirement, clause/ subclause number(s)	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	–
WG 14 recommendation	After humidity preconditioning treatment, LEAKAGE CURRENT testing should be conducted immediately after the DIELECTRIC STRENGTH test has been completed (no delay time).

3.2.115 DEFIBRILLATION-PROOF TYPE B APPLIED PARTS

WG 14 recommendation number	115
Requirement, clause/ subclause number(s)	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 subclause 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	–
WG 14 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, e.g. the operating table legs. Consequently, if the operating table legs are not isolated from the operating table top surface (=APPLIED PART), this design fails.

3.2.116 Instability excluding transport position

WG 14 recommendation number	116
Requirement, clause/ subclause number(s)	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 have 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)"
WG 14 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.*"

3.2.117 DIELECTRIC STRENGTH of two serial MOPP barrier parts

WG 14 recommendation number	117
Requirement, clause/ subclause number(s)	8.8.3 Table 6
Source/problem	The fact that each MOPP of 2 MOPP's 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	–
WG 14 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 2500 V. In the case that 1MOPP 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 1MOPP 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 500V, **and** b) The whole 2 MOPP should be tested with 4 000V.

3.2.118 Overheating transformer

WG 14 recommendation number	118
Requirement, clause/ subclause number(s)	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 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	–
WG 14 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.

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

WG 14 recommendation number	119
Requirement, clause/ subclause number(s)	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? Maintenance test equipment is usually designed for: – periodic safety checks when the medical device is already on the market. – MANUFACTURER production line end tests. – 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 WG 14/23, which usually is 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 8.7.4.4 requires to use a voltage measuring instrument (not the measuring device) which is able to indicate true r.m.s. 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 works 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.

WG 14 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 must 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 must contact e.g. 100 medical manufacturers and request a retesting of their product free of charge (image damaged). – Sometimes it is questionable if "T r.m.s." measurements will be conducted. – Not all switch conditions of IEC 60601-1 are possible, e.g. testing during stand-by, etc. – Testing with a MD independent from waveform and frequency according subclause 8.7.3.e is not possible. – Such devices are not suited to test high power (16A) – 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 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 d.c./a.c. 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), than the protective earth test shall be conducted with e.g. 1,5 times of 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 WG 14 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, e.g. during IECEE audits or during IECEE proficiency tests.
Submitter proposed recommendation	Issue a WG 14 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 60601-1 requirements, e.g. those listed in the above overview, is given.
WG 14 recommendation	WG 14 is not responsible for dealing with suitable test equipment and possible testing errors based on selection of unsuitable test equipment.

3.2.120 Tolerances of apparatus

WG 14 recommendation number	120
Requirement, clause/ subclause number(s)	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 Amendment 1), 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 (SC62A, 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'd like to suggest that there be a WG 14 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
WG 14 recommendation	Clause 9.4.2.4.3 specifies tolerances as specified in IEC 60601-1, which is ± 0,5 mm for a 10 mm threshold. WG 14 recommends the following proposal: ± 5 % should be applied as the tolerance of values from subclauses 15.3.5.a, 15.3.5.b, and 15.3.5.c. NOTE Due to humidity reasons a very small tolerance is not practical.

3.2.121 FUNCTIONAL EARTH CONDUCTOR and ESSENTIAL PERFORMANCE

WG 14 recommendation number	121
Requirement, clause/ subclause number(s)	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 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 subclause 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 does not allow green/yellow).
Discussion/comment	–
Submitter proposed recommendation	Allow disconnections of mains earth connections that comply with IEC 60601-1 subclauses 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.
WG 14 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. NOTE 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 must be green yellow, because it speaks about the POWER SUPPLY CORD.

3.2.122 A.c. motors

WG 14 recommendation number	122
Requirement, clause/ subclause number(s)	8.5.4
Source/problem	Resonance voltage on start capacitors on motors subclause 8.5.4 and CREEPAGE DISTANCE & 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 subclause 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.
WG 14 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 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 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 a.c. 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.

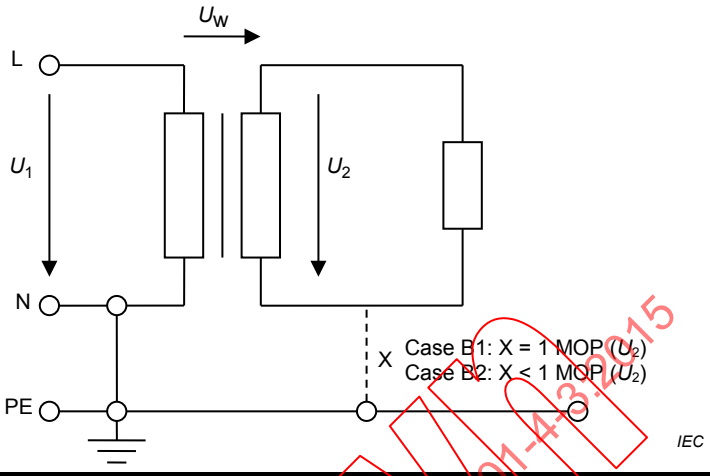
3.2.123 Operational insulation

WG 14 recommendation number	123
Requirement, clause/ subclause number(s)	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)
WG 14 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, WG 14 supports that it could make sense to document the "operational insulation" in the TRF, e.g. at the insulation diagram.

3.2.124 WORKING VOLTAGE measurement

WG 14 recommendation number	124
Requirement, clause/ subclause number(s)	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, subclause 1.4.9 (excerpted below)
WG 14 recommendation	It is recommended to measure WORKING VOLTAGE according the procedure in IEC 60950-1:2005 subclause 2.10.2: <u>Case A (estimated to cover >95 % of all cases):</u> 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, than 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. <u>Case B (estimated to cover <5 % of all cases):</u> Two different possibilities exists (see the following diagram): 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.

WG 14 recommendation 124 *(continued)*

WG 14 recommendation	

3.2.125 Defibrillation test

WG 14 recommendation number	125
Requirement, clause/ subclause number(s)	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 subclause 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.
WG 14 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 3.2.115.

3.2.126 Oil containers for moving parts

WG 14 recommendation number	126
Requirement, clause/ subclause number(s)	15.4.9
Source/problem	There is fixed equipment with multiple movement and axis, where components under questions are moved in such a way that it 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 'partly sealed'?
Discussion/comment	–
Submitter proposed recommendation	WG 14 recommendation shall make clear how to handle such components.
WG 14 recommendation	Subclause 15.4.9 item c applies. Clause 15.4.9 items 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 Standard and then to apply subclause 15.4.9 items a) and b) but ignoring the words PORTABLE and MOBILE. NOTE See as well the RISK MANAGEMENT requirement in subclause 13.2.6 about leakage and liquids.

3.2.127 PERMANENTLY INSTALLED ME EQUIPMENT in the HOME HEALTHCARE ENVIRONMENT

WG 14 recommendation number	127
Requirement, clause/ subclause number(s)	3.84 of IEC 60601-1 7.5.1 of IEC 60601-1-11
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 must be very well dimensioned. I think Part 1 is too vague in the definition of PERMANENTLY INSTALLED."

WG 14 recommendation 127 *(continued)*

Discussion/comment	WG 14 discussion: This answer applies only to the home care environment, not to the hospital environment. The WG 14 interpretation of the wording of IEC 60601-1:2005 and 60601-1-11:2010 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 WG 14 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	–
WG 14 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) offers 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 rational of Clause 6 of IEC 60601-1-11 and the state of the art would not be a CLASS I SUPPLY MAINS connection. 3) As of today 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.

WG 14 recommendation 127 *(continued)*

WG 14 recommendation	WG 14 additional information: To fix a mains plug with screws to the wall is against the national electrical code in some countries. Separation from mains must be ensured by suitable mains switches or DETACHABLE POWER SUPPLY CORD.

3.2.128 Polystyrene plate for LEAKAGE CURRENT tests

WG 14 recommendation number	128
Requirement, clause/ subclause number(s)	8.7.4.3 d) 1)
Source/problem	Subclause 8.7.4.3 d) 1) Measuring arrangements. Background: Subclause 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 subclause 8.7.4.3 d) 1) testing setup/requirements?
Discussion/comment	The questioned raised a number of additional questions related to whether the clause 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, Subclause 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 200mm? 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 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: The standard 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: The standard 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.
Submitter proposed recommendation	Suggested revision to subclause 8.7.4.3 d) 1) or it's 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 must 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)

WG 14 recommendation 128 *(continued)*

WG 14 recommendation	WG 14 is not aware of the origin of the test set-up as described in subclause 8.7.4.3.d) 1). WG 14 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 subclause 8.7.4.3.d) 1), in order to ensure reproducibility of test results for these sensitive measurements.

3.2.129 Push buttons

WG 14 recommendation number	129
Requirement, clause/ subclause number(s)	7.4.2
Source/problem	Push buttons usually do not have different 'working positions' (e. g. switches).
Discussion/comment	Is subclause 7.4.2 applicable for push buttons? How to fill in verdict in Test Report Form (TRF)?
Submitter proposed recommendation	—
WG 14 recommendation	The issue is already addressed in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 subclause 7.4.2. A push button could be a control device / switch.

3.2.130 Temperature limit at the ENCLOSURE in SINGLE FAULT CONDITION

WG 14 recommendation number	130
Requirement, clause/ subclause number(s)	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.

WG 14 recommendation 130 *(continued)*

WG 14 recommendation	See Interpretation Sheet ISH 03 published 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 Subclause 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-W018 () 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 this Interpretation Sheet 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.

3.2.131 Optic coupler requirements

<table>
<tr><td>WG 14 recommendation number</td><td>131</td></tr>
<tr><td>Requirement, clause/ subclause number(s)</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 subclause 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 subclause 8.8.2, nor does it require the 30 day cemented joint requirement in subclause 8.9.3. It does require a partial discharge test for solid insulation, including cemented joints, and presumably there’s aging/conditioning done prior to partial discharge. The standard presumably isn’t appropriate for the CR, CL, DS requirements considered necessary for MOPP.
According to Figure 5, which is associated with 4.8.a), there’s a decision box at end that says after complying with component standard, “are additional end product requirements necessary?” I’m not sure how the flow chart matches with the wording of 4.8, but it would seem it’s 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’s 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>R(240 V r.m.s.)</td><td>8 mm CR,
5 mm CL,
4 kV r.m.s. DS,
0,4 mm DTI*,
30 d thermal cycling for cemented joint*</td><td>5 mm CR,
4 mm CL,
3 kV r.m.s. DS,
0,4 mm DTI*,
30 d thermal cycling for cemented joint*</td></tr>
<tr><td colspan="3">* Perhaps represented by IEC 60747-5-5:2007 partial discharge testing with pre-conditioning.</td></tr>
</table>
</td></tr>
</table>

WG 14 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 day 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's my understanding that IEC 60950-1:2005, requires IEC 60747-5-5:2007 compliance, and does NOT require the 30 d 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's 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.
WG 14 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; – Compliance with IEC 60747-5-5:2007 or its predecessor standards (IEC 60747-1, -2, -3). NOTE 1 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, 5.5.4. / 5.4.4.4. NOTE 2 DTI (0,4mm) and thermal cycling testing are not required because compliance with the component standards addresses the RISK of pin holes and thermal effects on the insulating compound.

3.2.132 Eye-verification of tester before legibility test

WG 14 recommendation number	132
Requirement, clause/ subclause number(s)	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 amendment 1)? 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; or. 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 e.g. 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 weren't, 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.

WG 14 recommendation 132 *(continued)*

	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?
Submitter proposed recommendation	Possible alternatives: – Reading the Jaeger card as a single requirement for the tester. – Using ISO 8596:2009 (Landolt rings). (Advantage: Standard contains pass-fail-criteria.) Provide a definition of fixed letter sizes for markings.
WG 14 recommendation	WG 14 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.

3.2.133 End stops to prevent overtravel

WG 14 recommendation number	133
Requirement, clause/ subclause number(s)	9.2.3.2
Source/problem	Amendment 1 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	–
WG 14 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 must 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 subclause 4.7 and subclause 5.1. Tests under SINGLE FAULT CONDITION or component faults should be conducted once.

3.2.134 MOPP barrier with low WORKING VOLTAGE r.m.s. and high WORKING VOLTAGE peak

WG 14 recommendation number	134
Requirement, clause/ subclause number(s)	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 r.m.s. was used for creepage, clearance and DIELECTRIC STRENGTH. Ed. 2 use: $2 \times (2 \times U$ r.m.s. + 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 ed. 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 r.m.s. 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	–
WG 14 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 e.g. 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 subclause 8.9.1.15. 2) CREEPAGE DISTANCE: Table 12 WORKING VOLTAGE r.m.s. should be applied. 3) AIR CLEARANCE: IEC 60601-1 requires to use Table 12 for WORKING VOLTAGE r.m.s. However, this is in conflict to IEC 60664 where AIR CLEARANCE is based on U_{peak}. This conflict should be addressed during the preparation of a future revision of IEC 60601-1. The 3rd edition of IEC 60601-1 is not sufficiently detailed to explicitly address the very special case of a low WORKING VOLTAGE such as 5 V d.c. that is present for a long time with an occasional superimposed peak occurring, e.g. 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.

WG 14 recommendation 134 *(continued)*

WG 14 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 r.m.s. value of Table 12 and add the corresponding peak value of Table 14.

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

WG 14 recommendation number	135
Requirement, clause/ subclause number(s)	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.

WG 14 recommendation 135 *(continued)*

Source/problem	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 clauses 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	–
WG 14 recommendation	Subclauses 7.2.2 and 7.2.4 should be read by considering defined terms and notes in IEC 60601-1. **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 subclauses 7.2.2 and 7.2.4 in the context of IEC 60601-1 as a whole, as follows:

WG 14 recommendation 135 *(continued)*

WG 14 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 subclause 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 subclause 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 subclause 3.63. Those ACCESSORIES are defined in 3.3 and indicated by the word "**additional**". Those items must comply with subclause 7.2.4.

3.2.136 Protective earth impedance of ME SYSTEM >200 mΩ

WG 14 recommendation number	136
Requirement, clause/ subclause number(s)	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, subclause 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 10-20 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.
WG 14 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 subclause 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.

3.2.137 Ball pressure test

WG 14 recommendation number	137
Requirement, clause/ subclause number(s)	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 – 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 subclause 52.4.1 is pointing only to subclauses 52.5.10 d) – 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 – 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.
WG 14 recommendation	MT 30 has confirmed that there is a gap in IEC 60601-1. SINGLE FAULT CONDITION or component faults which do not fall in the described subclauses 13.2.13.2-13.2.13.4 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 subclause 13.2. Subclause 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 isn't limited to motors/heaters, it applies to all ME EQUIPMENT.

3.2.138 Magnesium alloy ENCLOSURE

WG 14 recommendation number	138
Requirement, clause/ subclause number(s)	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.
WG 14 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.

3.2.139 Instability with initial movement

WG 14 recommendation number	139
Requirement, clause/ subclause number(s)	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, the subclauses 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 and 9.4.3.1 c) and 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) and 9.4.3.2 a) and 9.4.3.2 b)). Therefore, it is not clear if e.g. 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 subclause 9.4) has been done intentionally in order to avoid too many references to RISK MANAGEMENT activities where they are not necessary, e.g. 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.
WG 14 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.

3.2.140 Ball pressure test

WG 14 recommendation number	140
Requirement, clause/ subclause number(s)	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 subclause 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, subclause 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, e.g.: 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, 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 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

WG 14 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	–
WG 14 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 subclause 13.2.13.1 as meaning: 1) The temperature as measured in 13.2.13.2 – 13.2.13.4 (using the test conditions described in subclause 11.1) that the thermoplastic material relied upon as a MOP will be exposed to. 2) PLUS 25 °C as a safety factor. NOTE 1 The test condition as described in subclause 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. NOTE 2 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.

3.2.141 DIELECTRIC STRENGTH test values

WG 14 recommendation number	141
Requirement, clause/ subclause number(s)	8.8.3 and 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 (r.m.s.) 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 (r.m.s.) according to the formula. **Problem 2, example:** For *U* (peak) = 10 000 V the solid insulation has to be tested with a Voltage (r.m.s.) 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 (r.m.s.) 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 (r.m.s.) The elimination of "/ √2" only causes a new conflict, because with 1,06 × 10 001 V (peak) = 10 601 V (r.m.s.), the test-voltage is still below the value of Table 7 for 10 000 V (peak) = 10 607 V (r.m.s.). **Problem 2:** Change the formula into: *U* (peak) + 2000 WG 14 acknowledges the issues as valid. NOTE The answer should be based on the base standard, IEC 60664-1.
WG 14 recommendation	WG 14 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.

3.2.142 SECONDARY CIRCUITS

WG 14 recommendation number	142
Requirement, clause/ subclause number(s)	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: For SECONDARY CIRCUITS isolated by two MOP from mains, Table 15 and 16 apply.”
WG 14 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 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. NOTE 4 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.

3.2.143 LEAKAGE CURRENTS in SINGLE FAULT CONDITION and during component faults

WG 14 recommendation number	143
Requirement, clause/ subclause number(s)	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	—
WG 14 recommendation	IEC 60601-1:2005, subclause 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 subclause 5.1.

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

WG 14 recommendation number	144
Requirement, clause/ subclause number(s)	8.6.4 second paragraph
Source/problem	The requirement in subclause 8.6.4.a) paragraph 6 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 (3x28). 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.
WG 14 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.

3.2.145 Time delay of the 100 VA limit

WG 14 recommendation number	145
Requirement, clause/ subclause number(s)	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 sec = 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 CB TRF 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.
WG 14 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 MT 30.

3.2.146 Test voltage multiplied by factor 1,6

WG 14 recommendation number	146
Requirement, clause/ subclause number(s)	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) Must the test voltage be multiplied by 1,6 or B) must 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/ AMD1:2012. However in several other clauses of IEC 60601-1: 2005/ AMD1:2012, the referenced edition of IEC 60950 is not that of 2001 but rather 2005. 2) Subclause 2.10.5.3 makes reference to subclause 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.
WG 14 recommendation	Exception of the factor 1,6 applies to the test voltage only, but **not** to the test duration of 1 min.

3.2.147 Overflow, spillage, …

WG 14 recommendation number	147
Requirement, clause/ subclause number(s)	11.6.2, 11.6.3
Source/problem	Overflow, 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	–
WG 14 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 subclause 11.6 need to be conducted.

3.2.148 DIELECTRIC STRENGTH test of transformers without accessible frame

WG 14 recommendation number	148
Requirement, clause/ subclause number(s)	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	–
WG 14 recommendation	Normally follow the compliance paragraph of subclause 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.

3.2.149 Expected voltage on SIP/SOPs

WG 14 recommendation number	149
Requirement, clause/ subclause number(s)	8.1 a), 8.7.4.6 and Figure 14
Source/problem	8.1 a): "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)? 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 subclause 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 d.c. etc. for IEC 60601-1 and IEC 609501-1 compliance equipment)? Between ± 5 V and ± 60 V d.c. 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	–
WG 14 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.

3.2.150 Flammability rating for transformer bobbin

WG 14 recommendation number	150
Requirement, clause/ subclause number(s)	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
WG 14 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.

3.2.151 COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS

WG 14 recommendation number	151
Requirement, clause/ subclause number(s)	4.9
Source/problem	1) What is a COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS? One perfect example is a Y capacitor bridging 2 MOPs, 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) Subclause 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, subclause 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 must 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 subclause 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 subclause 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.
WG 14 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 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.

3.2.152 Peak and r.m.s. WORKING VOLTAGES

WG 14 recommendation number	152
Requirement, clause/ subclause number(s)	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 d.c. and V r.m.s. are contradictory, because for a d.c. voltage without ripple the r.m.s. value has, per definition, the same numerical value (e.g. 17 V d.c. = 17 V r.m.s.). ➔ Due to the fact that most a.c. voltages will be rectified by diodes, the higher d.c., value in Table 12 is regarded as correct. See also IEC 60664-1 subclause 6.1.1, where a.c. values are equivalent to d.c. values when the a.c. values are multiplied by a factor of 1,414. 2) If, for example, a constant voltage of 16 V d.c. (first line of Table 12) turns into a rectangular pulsing voltage (0 V...16 V) with 15 V r.m.s: ➔ For this low voltage, the issue is not related to MAINS transients: Take the 15 V r.m.s. for CREEPAGE DISTANCE and interpolate if possible. Take the 16 V d.c. 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 d.c.), even though the r.m.s. value has decreased? – What, if the rectangular voltage range is -0,5..+16 V? – What about an a.c. voltage with a very low frequency, e.g. changing polarity 1 time per minute or per hour? Is there a frequency limit, where an a.c. voltage has to be considered d.c. 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 r.m.s. values for creepage. Interim solution: Application of the r.m.s. column for sinusoidal voltages only; usage of the d.c. 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).
WG 14 recommendation	For this low voltage, the issue is not related to MAINS TRANSIENT VOLTAGE: It is recommended to use 15 V r.m.s. for CREEPAGE DISTANCE and interpolate if possible. It is recommended to use 16 V d.c. for AIR CLEARANCE. This subject should be reconsidered when preparing a future revision of IEC 60601-1. See also WG 14 recommendation 3.2.134.

3.2.153 Critical components

WG 14 recommendation number	153
Requirement, clause/ subclause number(s)	–
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	–
WG 14 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. WG 14 is unable to make a recommendation at this time. NOTE 1 IECEE – OD 2020 includes examples, such as: a.c. inlet, fuse, fuse holder, ENCLOSURE, X-capacitor, line filter, triple insulation wire, transformer, bobbin of transformer, switch. See also IECEE – OD 2039. NOTE 2 WG 14 recommends that a future revision of IEC 60601-1 consider developing a definition for the term “critical component” and take into consideration other technical areas outside the medical field and/or provide a critical component list.

3.2.154 LEAKAGE CURRENT test for ME EQUIPMENT with multiple APPLIED PARTS

WG 14 recommendation number	154
Requirement, clause/ subclause number(s)	8.7.4.9, A.8.7.4.9, 3.8, 3.78, 8.5.2.1, A.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*
WG 14 recommendation	Subclause 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 subclause 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.

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

WG 14 recommendation number	155
Requirement, clause/ subclause number(s)	8.8.2 d) and 8.8.2 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 subclause 8.8.3. Therefore, for 2 MOPP and a WORKING VOLTAGE of 570 V peak as above, we have 4 612 V a.c. × 1,6 = 7 380 V a.c. This seems quite excessive.
Discussion/comment	–
Submitter proposed recommendation	Remove the 1,6 times factor from Annex L.
WG 14 recommendation	A) For extruded TIW: Subclause 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: Subclause 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 must 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.

3.2.156 DIELECTRIC STRENGTH test after thermal cycling test

WG 14 recommendation number	156
Requirement, clause/ subclause number(s)	8.9.3.4
Source/problem	Subclause 8.9.3.4 was taken from IEC 60950-1 but it omits the voltage stress of 500 V a.c. 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 r.m.s. 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."
WG 14 recommendation	While it is noted that the requirements in IEC 60601-1 and IEC 60950-1 differ, WG 14 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, 8.9.3.4.

3.2.157 Required MOOP values higher than MOPP values

WG 14 recommendation number	157
Requirement, clause/ subclause number(s)	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 a.c. r.m.s. / 570 V a.c. 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 r.m.s. 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	–
WG 14 recommendation	Figure A.12 should be regarded as normative.

3.2.158 Optocouplers

WG 14 recommendation number	158
Requirement, clause/ subclause number(s)	8.9.3
Source/problem	Subclause 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 subclause 8.8.3. In switched mode power supplies, the optocoupler typically has a WORKING VOLTAGE of 240 V a.c. giving 340 V peak. The DIELECTRIC STRENGTH voltage is then 4 000 V a.c. for 2 MOPPs times 1,6, giving 6 400 V a.c. 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 must be sure that it forms a cemented joint. That is what subclause 8.9.3 deals with.
Submitter proposed recommendation	Remove the 1,6 times factor from the subclauses in 8.9.3.
WG 14 recommendation	WG 14 recommendation number 3.2.131 deals with this topic.

3.2.159 Impact test

WG 14 recommendation number	159
Requirement, clause/ subclause number(s)	15.3.3
Source/problem	Impact test on BODY WORN ME EQUIPMENT was introduced by AMD1. 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 3V 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 AMD1. 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 d.c. 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 d.c. 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.
WG 14 recommendation	The impact test according to subclause 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 subclause 4.5.

3.2.160 Spillage test in NORMAL CONDITION and in SINGLE FAULT CONDITION

WG 14 recommendation number	160
Requirement, clause/ subclause number(s)	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	—
WG 14 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.

3.2.161 TYPE B APPLIED PART connected to ACCESSIBLE PARTS

WG 14 recommendation number	161
Requirement, clause/ subclause number(s)	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 must 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.
WG 14 recommendation	The two normative requirements in subclause 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 subclause 8.7.4.7 d) ban this solution completely. The link to RISK MANAGEMENT in subclause 8.5.2.2 should be regarded as priority and should be used as well for subclause 8.7.4.7 d).

3.2.162 Current/power labeling

WG 14 recommendation number	162
Requirement, clause/ subclause number(s)	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: 100-240 V, 4-2 A Equally safe is: 100-240 V, 4 A IEC 60601-1 requirement should be enforced only for high power consuming ME EQUIPMENT e.g. >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.
WG 14 recommendation	It is recommended that the rating "100 V - 240 V, XA" where X could go up maximum to 10 A, is sufficient to fulfil the requirement of subclause 7.2.7, because value XA is understood to be valid for both upper and lower voltage limit.

3.2.163 Separate power supply part of ME EQUIPMENT or ME SYSTEM

WG 14 recommendation number	163
Requirement, clause/ subclause number(s)	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.
WG 14 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.

3.2.164 Specification of the allowed power supply

WG 14 recommendation number	164
Requirement, clause/ subclause number(s)	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 AMD1 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.
WG 14 recommendation	It is recommended to apply 7.2.5 as well for external power supply which is part of ME EQUIPMENT.

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

WG 14 recommendation number	165
Requirement, clause/ subclause number(s)	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: Table 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 2-4 apply.
Submitter proposed recommendation	–
WG 14 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, – between plus and minus pole of a battery in front of the first protection device is not addressed within IEC 60601-1. WG 14 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; b) the electronic loads after the protection device (e.g. after the fuse).

3.2.166 Keep dry and umbrella symbol

WG 14 recommendation number	166
Requirement, clause/ subclause number(s)	IEC 60601-1-11:2010, subclauses 7.2 and 8.3.1
Source/problem	The first reference is in subclause 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 subclause 7.2 and states the requirement for all devices to be tested to IP21/22.
Discussion/comment	—
Submitter proposed recommendation	The position of the JWG 6 as expressed in IEC 60601-1-11 is clear and not at all at the way the request was presented. Subclause 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.
WG 14 recommendation	Subclause 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. 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.

3.2.167 MOBILE and STATIONARY ME EQUIPMENT with wheels

WG 14 recommendation number	167
Requirement, clause/ subclause number(s)	3.44 and 3.71 plus 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. Must 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.
WG 14 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.

3.2.168 Varistors installed in the MAINS PART

WG 14 recommendation number	168
Requirement, clause/ subclause number(s)	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 r.m.s. failed at 700 V r.m.s. 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 (1MOOP) is therefore in doubt. – If the protective earth in the POWER SUPPLY CORD is interrupted (1SINGLE FAULT CONDITION) plus the VDR fails (NORMAL CONDITION) we would have mains on the ENCLOSURE. – DELFT 20: 5 Varistors in MAINS PARTs SC 62A WG 14/Vienna/29 Varistors 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	
WG 14 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 be used only: a) after the MAINS fuse, and b) when it is used in series with a GDT (gas discharge tube) which fulfils the requirements for 1 MOP in accordance with subclause 4.8 of IEC 60601-1:2005, and c) the VDR should meet the requirements of Annex G.8 of IEC 62368-1:2014.

3.2.169 Using Y2 capacitors for MOPP

WG 14 recommendation number	169
Requirement, clause/ subclause number(s)	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 212-354 V peak.
Discussion/comment	–
Submitter proposed recommendation	–
WG 14 recommendation	It is recommended to read subclause 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 r.m.s. dielectric requirement, because in accordance with IEC 60384-14 a single Y2 capacitor complies with continuous 1 500 V r.m.s. 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.

3.2.170 Overtravel end stops – specification of the speed

WG 14 recommendation number	170
Requirement, clause/ subclause number(s)	9.2.3.2
Source/problem	In AMD1, 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.
WG 14 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.

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

WG 14 recommendation number	171
Requirement, clause/ subclause number(s)	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 MT 28 has remembered: This topic was discussed with MT 28 during the writing of AMD1. The result was that there are 2 extremes: a) not requiring 1MOOP 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. MT 28 was 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.
WG 14 recommendation	WG 14 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.

3.2.172 Examples of SINGLE FAULT CONDITION

WG 14 recommendation number	172
Requirement, clause/ subclause number(s)	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	Subclause 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	–
WG 14 recommendation	It is recommended to replace the example in subclause 4.7.a) by: "suspended masses without MECHANICAL PROTECTIVE DEVICES complying with Table 21, rows 1 to 4."

3.2.173 Examples of ME SYSTEMS

WG 14 recommendation number	173
Requirement, clause/ subclause number(s)	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 WG 14 meeting the following question was raised: Is the proposed solution, for example in 1a and 2a, always correct.
Discussion/comment	Example 2.c: 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	–
WG 14 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 is no possible LEAKAGE CURRENT issues in 2a.

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

WG 14 recommendation number	174
Requirement, clause/ subclause number(s)	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. The Table does not provide advice for ME EQUIPMENT operating at currents higher than 63 A.
Submitter proposed recommendation	–
WG 14 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.

3.2.175 Biocompatibility for quasi APPLIED PARTS

WG 14 recommendation number	175
Requirement, clause/ subclause number(s)	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	Clause 4.6 asks for an assessment to identify parts which are not APPLIED PARTS according subclause 3.8 but might come in contact with the PATIENT. If a part falls under the definition of subclause 4.6, all relevant requirements for TYPE B APPLIED PARTS shall be applied (except marking). Subclause 11.7 has to be applied for parts which are intended to come into direct/indirect contact with the PATIENT. Shall subclause 11.7 be applied for parts which fall under the definition of subclause 4.6?
Submitter proposed recommendation	–
WG 14 recommendation	WG 14 concurs that subclause 4.6 could be read and understood differently. Therefore our recommendation is to apply RISK MANAGEMENT, to find out if subclause 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 subclause 11.7 should apply or not.

3.2.176 Floating reference earth

WG 14 recommendation number	176
Requirement, clause/ subclause number(s)	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 of Subclause 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, e.g. due to high power consumption. Quote from the rationale of Subclause 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 ...."
WG 14 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.

3.2.177 SINGLE FAULT CONDITION in OXYGEN RICH ENVIRONMENT

WG 14 recommendation number	177
Requirement, clause/ subclause number(s)	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 this subclause deviates from the requirements given in IEC 60079-11 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 this subclause 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, 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.

WG 14 recommendation 177 *(continued)*

Discussion/comment	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. WG 14 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. WG 14 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 MT 30.
Submitter proposed recommendation	Re-word the failure condition specified in this subclause 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.
WG 14 recommendation	The issue was referred to MT 30, with the following result: MT 30 acknowledged that the issue needs to be clarified. However, due to the fact that the wording in subclause 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 within WG 14. WG 14 is unable to make a recommendation at this time. The issue is put on the agenda for a future revision of IEC 60601-1.

3.2.178 Laser requirements

WG 14 recommendation number	178
Requirement, clause/ subclause number(s)	10.4
Source/problem	Laser hazards not addressed
Discussion/comment	IEC 60601-1 addresses lasers in subclause 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). Clause 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, e.g. in the subclauses: 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 subclause 4.2 is applicable anyway, see 4.2.3.2 of IEC 60601-1:2005/AMD1:2012.
Submitter proposed recommendation	–
WG 14 recommendation	Gaps are to be handled according to subclause 4.2. The standard covers the issues of handling gaps.

3.2.179 Flammability rating of insulated wires

WG 14 recommendation number	179
Requirement, clause/ subclause number(s)	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 (>0,5mm^2) or IEC 60332-2-2 (≤ 0,5mm^2) can be used to show compliance with subclause 11.3 a) for insulating wires.
WG 14 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), – 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 subclauses 11.3 and 13.1.2.

3.2.180 Infrared lamps

<table>
<tr><td>WG 14 recommendation number</td><td colspan="2">180</td></tr>
<tr><td>Requirement, clause/ subclause number(s)</td><td colspan="2">IEC 60601-1 subclauses 11.1.2.1, 8.4.2.c, 5.9.2.1.
IEC 60601-1-11: Subclause 8.3.1.</td></tr>
<tr><td>Source/problem</td><td colspan="2">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.</td></tr>
<tr><td>Discussion/comment</td><td>2Ed IEC 60601-1:1988 + AMD1:1991 + AMD2:1995</td><td>3Ed IEC 60601-1:2005 + AMD1:2012</td></tr>
<tr><td></td><td>AP-temperature and ENCLOSURE temp:

Excluded by Clause 42 Table 10a.</td><td>AP-temperature:

If the glass = output of the light is regarded as “quasi AP” based on subclause 4.6 plus subclause 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.</td></tr>
<tr><td></td><td>Accessible voltage:

Excluded by subclause 16 e) 2) and WG 14rec12 for the 2nd Edition: Subclause 16 e) plus the WG 14rec12 allow access to LIVE parts during removal of lamps without any limitation to the voltage value, i.e. 240 V r.m.s. is included, and you find such 2nd Edition approved devices on the market.

IP-protection:

No requirement in the 2nd Edition.</td><td>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 subclause 8.4.2 c) and 5.9.2.1 of the 3rd Edition: subclause 8.4.2 c) allows access to parts which could produce touch currents of about 100 μA e.g. at lamp holder contacts, but ONLY if the voltage remains <42,4 V peak, i.e. 240 V r.m.s. is EXCLUDED. And therefore the infrared lamps FAIL the 3rd Edition.

IP-protection:

IEC 60601-1-11 requires IP21.
➔ FAIL, lamp could be adjusted in different positions, e.g. upwards.</td></tr>
</table>

WG 14 recommendation 180 *(continued)*

Discussion/comment	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 exist 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	–
WG 14 recommendation	The next revision of IEC 60601-1 should provide justification for banning lamp sockets with accessible voltages above of 60 V d.c. and 42,4 V peak (e.g. E27 socket) within IEC 60601-1 Annex A. Alternatively, under certain conditions, the banning of such sockets should be withdrawn by the next revision of IEC 60601-1.

3.2.181 Identification of internal fuses

WG 14 recommendation number	181
Requirement, clause/ subclause number(s)	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 subclause 7.9.3.3. This seems to be an internal contradiction in IEC 60601-1. There is also no explanation for the conflicting requirements, e.g. 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 f 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	–
WG 14 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.

3.2.182 Chargers for ME EQUIPMENT used at home

WG 14 recommendation number	182
Requirement, clause/ subclause number(s)	IEC 60601-1-11 general
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. ➔ WG 14: This is clarified in subclause 7.9.2.1 of IEC 60601-1:2005 and IEC 60601-1:2006/AMD1:2012. There is no clause for protection against electrical hazards ➔ WG 14: 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. ➔ WG 14: According to subclause 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 d.c. connector, and this could be > 0,1 mA. ➔ WG 14: Correct. The d.c. 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. ➔ WG 14: 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 should consider creating a new clause, or a new subclause 8.5, '**Protection against electrical HAZARDS**', containing the following text: "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. 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."
WG 14 recommendation	The issue is covered by IEC 60601-1 series.

3.2.183 CLASS II ME EQUIPMENT with FUNCTIONAL EARTH CONDUCTOR

WG 14 recommendation number	183
Requirement, clause/ subclause number(s)	8.6.9
Source/problem	Some CLASS II ME EQUIPMENT with a 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 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.
WG 14 recommendation	WG 14 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 subclause 8.6.9, IEC 60601-1 defines the required safety requirements that must be fulfilled. As long 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. WG 14 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.

3.2.184 Symbol D2-2 on MSO

WG 14 recommendation number	184
Requirement, clause/ subclause number(s)	16.9.2.1 b) first dash
Source/problem	The requirement to mark a 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 a 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.
WG 14 recommendation	WG 14 has the consensus that subclause 16.9.2.1 b) is clear.