



BSI Standards Publication

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

National foreword

This Published Document is the UK implementation of IEC TR 60601-4-3:2018. It supersedes [PD IEC/TR 60601-4-3:2015](#), which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/62/1, Common aspects of Electrical Equipment used in Medical Practice.

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

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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

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CONTENTS

FOREWORD.....	6
INTRODUCTION.....	8
1 Scope.....	9
2 Normative references	9
3 Terms and definitions	11
4 Recommendations.....	11
4.1 Template used for recommendations prepared by SC 62A	11
4.2 Recommendation sheets.....	12
4.2.101 Total PATIENT LEAKAGE CURRENT of a ME SYSTEM.....	12
4.2.102 Pollution degree for MOPP	13
4.2.103 Transients on DC mains	13
4.2.104 Altitude factor for DEFIBRILLATION-PROOF APPLIED PARTS.....	14
4.2.105 Defibrillation energy protection for MOOP/MOPP.....	15
4.2.106 Overvoltage categories III and IV.....	15
4.2.107 Pollution degree related to different micro/macro environments	15
4.2.108 Warnings versus ALARM SIGNALS	16
4.2.109 Single Y1 capacitor for MOPP	16
4.2.110 WORKING VOLTAGE > 14 140 V peak	17
4.2.111 CREEPAGE DISTANCE and AIR CLEARANCE for dental equipment.....	18
4.2.112 Short-circuiting of one constituent part of DOUBLE INSULATION.....	19
4.2.113 Instability in transport position	19
4.2.114 Delay time for conducting leakage current tests after humidity preconditioning treatment	20
4.2.115 DEFIBRILLATION-PROOF TYPE B APPLIED PARTS	20
4.2.116 Instability excluding transport position	21
4.2.117 DIELECTRIC STRENGTH of two serial MOPP barrier parts	21
4.2.118 Overheating transformer	22
4.2.119 Test equipment for recurrent tests according to IEC 62353 testing used within IEC 60601-1 type approval testing	23
4.2.120 Tolerances of apparatus	25
4.2.121 FUNCTIONAL EARTH CONDUCTOR and ESSENTIAL PERFORMANCE.....	26
4.2.122 AC motors	27
4.2.123 Operational insulation.....	28
4.2.124 WORKING VOLTAGE measurement.....	28
4.2.125 Defibrillation test.....	29
4.2.126 Oil containers for moving parts	30
4.2.127 PERMANENTLY INSTALLED ME EQUIPMENT in the HOME HEALTHCARE ENVIRONMENT	30
4.2.128 Polystyrene plate for LEAKAGE CURRENT tests	32
4.2.129 Push buttons	33
4.2.130 Temperature limit at the ENCLOSURE in SINGLE FAULT CONDITION.....	34
4.2.131 Optic coupler requirements.....	35
4.2.132 Eye-verification of tester before legibility test.....	37
4.2.133 End stops to prevent overtravel	38
4.2.134 MOPP barrier with low WORKING VOLTAGE RMS and high WORKING VOLTAGE peak.....	39
4.2.135 Labeling: spare parts vs. detachable parts vs. ACCESSORIES.....	40

4.2.136	Protective earth impedance of ME SYSTEM > 200 mΩ	43
4.2.137	Ball pressure test.....	44
4.2.138	Magnesium alloy ENCLOSURE.....	45
4.2.139	Instability with initial movement	46
4.2.140	Ball pressure test.....	47
4.2.141	DIELECTRIC STRENGTH test values	49
4.2.142	SECONDARY CIRCUITS	50
4.2.143	LEAKAGE CURRENTS in SINGLE FAULT CONDITION and during component faults	50
4.2.144	Impedance of a PROTECTIVE EARTH CONDUCTOR within a DETACHABLE POWER SUPPLY CORD.....	51
4.2.145	Time delay of the 100 VA limit	52
4.2.146	Test voltage multiplied by factor 1,6	53
4.2.147	Overflow and spillage	53
4.2.148	DIELECTRIC STRENGTH test of transformers without accessible frame	54
4.2.149	Expected voltage on SIP/SOPS	54
4.2.150	Flammability rating for transformer bobbin	55
4.2.151	COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS.....	55
4.2.152	Peak and RMS WORKING VOLTAGES	56
4.2.153	Critical components	57
4.2.154	LEAKAGE CURRENT test for ME EQUIPMENT with multiple APPLIED PARTS.....	57
4.2.155	DIELECTRIC STRENGTH test value for extruded and spirally wrapped multi-layer wires	58
4.2.156	DIELECTRIC STRENGTH test after thermal cycling test.....	58
4.2.157	Required MOOP values higher than MOPP values	59
4.2.158	Optocouplers	59
4.2.159	Impact test.....	60
4.2.160	Spillage test in NORMAL CONDITION and in SINGLE FAULT CONDITION	61
4.2.161	TYPE B APPLIED PART connected to ACCESSIBLE PARTS	62
4.2.162	Current/power labeling.....	62
4.2.163	Separate power supply part of ME EQUIPMENT or ME SYSTEM	63
4.2.164	Specification of the allowed power supply.....	63
4.2.165	Mains transients for opposite polarity on the secondary side or battery pole to pole barrier	64
4.2.166	Keep dry and umbrella symbol.....	65
4.2.167	MOBILE and STATIONARY ME EQUIPMENT with wheels.....	66
4.2.168	Varistors installed in the MAINS PART	67
4.2.169	Using Y2 capacitors for MOPP	67
4.2.170	Overtravel end stops – Specification of the speed.....	68
4.2.171	CREEPAGE DISTANCE and AIR CLEARANCE between input and output of fuse contacts	69
4.2.172	Examples of SINGLE FAULT CONDITION	70
4.2.173	Examples of ME SYSTEMS	70
4.2.174	Cross sectional area of POWER SUPPLY CORD for rated input current > 63 A.....	71
4.2.175	Biocompatibility for quasi APPLIED PARTS	71
4.2.176	Floating reference earth.....	72
4.2.177	SINGLE FAULT CONDITION in OXYGEN RICH ENVIRONMENT.....	73
4.2.178	Laser requirements.....	75
4.2.179	Flammability rating of insulated wires	75

4.2.180	Infrared lamps	76
4.2.181	Identification of internal fuses	77
4.2.182	Chargers for ME EQUIPMENT used at home	78
4.2.183	CLASS II ME EQUIPMENT with FUNCTIONAL EARTH CONDUCTOR	79
4.2.184	Symbol ISO 7010-W001 (2011-05) on a MULTIPLE SOCKET-OUTLET (MSO)	80
4.2.185	PATIENT leads connectors	81
4.2.186	Rationale for IP2X	82
4.2.187	Battery – Limited power	83
4.2.188	TYPE B APPLIED PART separated from ACCESSIBLE PARTS	83
4.2.189	Protective earth test > 25A	84
4.2.190	Reference to IEC 62304:2006	85
4.2.191	The SIP/SOP pin to earth TOUCH CURRENT	85
4.2.192	Overbalancing	87
4.2.193	MAINS VOLTAGE ON APPLIED PART	88
4.2.194	TYPE B VS TYPE BF SFC limits	88
4.2.195	Split up of BI, SI, DI, RI barriers	90
4.2.196	ALARM PULSE RISE TIME	92
4.2.197	Non-frequency-weighted measurement	93
4.2.198	Printed circuit boards meeting UL 796	94
4.2.199	Y1 caps bridging 2 MOPP	94
4.2.200	PORTABLE, STATIONARY and TRANSPORTABLE ME EQUIPMENT	95
4.2.201	Opposite polarity and philosophy of IEC 60601-1	96
4.2.202	Separation device	97
4.2.203	Consult ACCOMPANYING DOCUMENTS	98
4.2.204	AP-ENCLOSURE requirements	100
4.2.205	Guidewire	101
4.2.206	H or L mains fuses	102
4.2.207	APPLIED PART temperature	103
4.2.208	Cecon plug as permanently installed MEE	103
4.2.209	Biocompatibility for enclosures and other parts	104
4.2.210	Safety relevant LEDs	105
4.2.211	Lithium coin cells	105
4.2.212	Motor capacitors	106
4.2.213	Warning, caution, safety notice	106
4.2.214	ESSENTIAL PERFORMANCE related to RM (P1 and P2)	107
4.2.215	IEC 60601-1-8 symbol color	109
4.2.216	Indicator lights for standby switch	109
4.2.217	CLASS II symbol	110
4.2.218	Authorized SERVICE PERSONNEL	111
4.2.219	Scope of IEC 62133 and requirement in 15.4.3.4 related to PORTABLE batteries	112
4.2.220	IT-NETWORK requirements	112
4.2.221	Non-lithium batteries	113
4.2.222	AP and APG	114
4.2.223	Non-weighted 10 mA PATIENT AUXILIARY CURRENT	115
4.2.224	IPX test and test criteria	116
4.2.225	ALARM SETTINGS, alarm presets, default alarm presets	117
4.2.226	AUDIBLE ALARM SIGNALS	119
4.2.227	ISO 8820-3 fuses	120

4.2.228	Luminous colour of ambient light	121
4.2.229	WITHDRAWN	121
4.2.230	WITHDRAWN	121
4.2.231	Assumed typing errors in several clauses	122
4.2.232	Indicator lights	123
4.2.233	PEMS	124
4.2.234	PEMS validation	126
4.2.235	Instability excluding transport	127
4.2.236	Separating transformer output voltage accuracy	127
4.2.237	CLASS I ME EQUIPMENT in EMS environment	128
4.2.238	Fire ENCLOSURE top cover	129
4.2.239	Unacceptable RISK – Mechanical strength	130
4.2.240	PE plus 1 MOP for non-medical components	130
4.2.241	Resistance temperature method for non-copper windings	132
4.2.242	DUPLICATE / WITHDRAWN	132
4.2.243	Drop test during INTENDED USE	133
Annex A (informative) Overview of the recommendations developed by SC 62A		134
Bibliography		141
Figure 1 – WORKING VOLTAGE measurement		29
Figure 2 – Example of creepage measurement		92
Figure 3 – Same severity could result in an acceptable or unacceptable RISK, depending on the probability factor		108
Table A.1 – Cross-references to IEC 60601-1:2005 and IEC 60601:2005/AMD1:2012 in numerical order		134
Table A.2 – Cross-references to IEC 60601-1-8:2006 and IEC 60601-1- 8:2006/AMD1:2012 in numerical order		139
Table A.3 – Cross-references to IEC 60601-1-11:2010 and IEC 60601-1-11:2015 in numerical order		140
Table A.4 – Cross-references to IEC 60601-1-12:2014 in numerical order		140

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

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IEC TR 60601-4-3, which is a technical report, has been prepared by subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice.

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

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

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

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

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

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

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

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

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

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

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

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

INTRODUCTION

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

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

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

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

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

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

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

MEDICAL ELECTRICAL EQUIPMENT –

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

1 Scope

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

This document is primarily intended to be used by:

- MANUFACTURERS OF MEDICAL ELECTRICAL EQUIPMENT;
- test laboratories and others responsible for assessment of compliance with IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012, IEC 60601-1-11:2010, IEC 60601-1-11:2015 and IEC 60601-1-12:2014;
- those developing subsequent editions of IEC 60601-1.

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

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

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

2 Normative references

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

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

- a) Written IEC 60601-1:2005, meant only Edition 3.0 from 2005.
- b) Written IEC 60601-1:2005/AMD1:2012, meant only Amendment 1:2012.
- c) Written IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, meant Edition 3.0 and Amendment 1:2012 combined.
- d) Written IEC 60601-1 (in undated form), meant IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 (in the year 2018 the latest edition of IEC 60601-1).

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

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

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

IEC 60529:1989, *Degrees of protection provided by enclosures (IP Code)*

IEC 60529:1989/AMD1:1999

IEC 60529:1989/AMD2:2013

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

IEC 60601-1:2005/AMD1:2012

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

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

IEC 60601-1-11:2010, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment¹*

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

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

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

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

IEC 62133, *Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications²*

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

IEC 62304:2006/AMD1:2015

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

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

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

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

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

UL 1642:2012, *Standard for lithium batteries*

3 Terms and definitions

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

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

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

4 Recommendations

4.1 Template used for recommendations prepared by SC 62A

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

Recommendation number	NNN ^a
Clause(s) number (only) ^b	
Source/problem ^c	
Discussion/comment ^d	
Submitter proposed recommendation ^e	
Recommendation ^f	
^a The numbering of the recommendations in the Technical Report starts with 101 instead of just 1 to ensure that these recommendations will not accidentally be confused with previously issued recommendations 1 to 63, which are based on the second edition of IEC 60601-1.	
^b The clause, subclause or requirement to which the question is related. If no standard is listed, the reference is to IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012. In case of a collateral standard, please specify: IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012, IEC 60601-1-11:2010, IEC 60601-1-11:2015 and IEC 60601-1-12:2014.	
^c A description of the problem as submitted to SC 62A.	
^d Additional discussion or commentary provided by the submitter.	
^e The submitter's proposed resolution to the problem, if one exists.	
^f The final recommendation developed by SC 62A.	

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

4.2 Recommendation sheets

4.2.101 Total PATIENT LEAKAGE CURRENT of a ME SYSTEM

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

4.2.102 Pollution degree for MOPP

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

4.2.103 Transients on DC mains

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

4.2.104 Altitude factor for DEFIBRILLATION-PROOF APPLIED PARTS

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

4.2.105 Defibrillation energy protection for MOOP/MOPP

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

4.2.106 Overvoltage categories III and IV

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

4.2.107 Pollution degree related to different micro/macro environments

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

4.2.108 Warnings versus ALARM SIGNALS

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

4.2.109 Single Y1 capacitor for MOPP

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

4.2.110 WORKING VOLTAGE > 14 140 V peak

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

4.2.111 CREEPAGE DISTANCE and AIR CLEARANCE for dental equipment

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

4.2.112 Short-circuiting of one constituent part of DOUBLE INSULATION

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

4.2.113 Instability in transport position

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

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

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

4.2.115 DEFIBRILLATION-PROOF TYPE B APPLIED PARTS

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

4.2.116 Instability excluding transport position

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

4.2.117 DIELECTRIC STRENGTH of two serial MOPP barrier parts

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

4.2.118 Overheating transformer

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

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

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

Recommendation 119 (continued)

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

4.2.120 Tolerances of apparatus

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

4.2.121 FUNCTIONAL EARTH CONDUCTOR and ESSENTIAL PERFORMANCE

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

4.2.122 AC motors

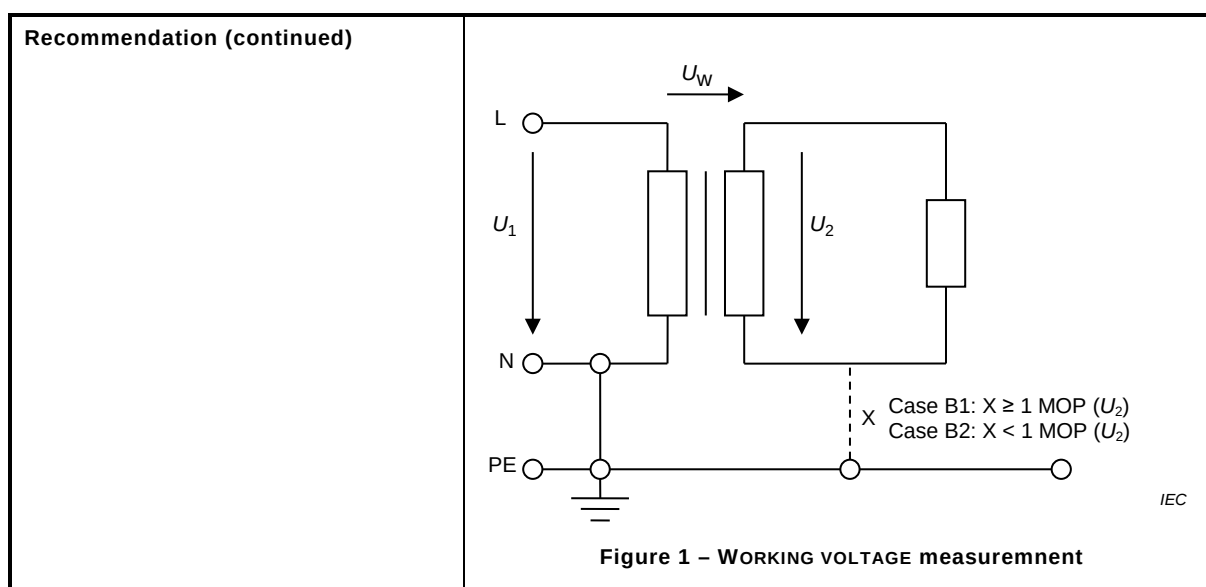
Recommendation number	122
Clause(s) number (only)	8.5.4
Source/problem	Resonance voltage on start capacitors on motors subclause 8.5.4 and CREEPAGE DISTANCE and AIR CLEARANCE values related to slot insulations in motors. From 8.5.4, it is clear that the measured U_c (voltage at cap) shall be used as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

4.2.123 Operational insulation

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

4.2.124 WORKING VOLTAGE measurement

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

Recommendation 124 (continued)**4.2.125 Defibrillation test**

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

4.2.126 Oil containers for moving parts

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

4.2.127 PERMANENTLY INSTALLED ME EQUIPMENT in the HOME HEALTHCARE ENVIRONMENT

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

Recommendation 127 (continued)

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

Recommendation 127 (continued)

SC 62A recommendation (continued)	SC 62A additional information: <u>To fix a mains plug with screws to the wall is against the national electrical code in some countries.</u> <u>Separation from mains shall be ensured by suitable mains switches OR DETACHABLE POWER SUPPLY CORD.</u>
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4.2.128 Polystyrene plate for LEAKAGE CURRENT tests

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

Recommendation 128 (continued)

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

4.2.129 Push buttons

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

4.2.130 Temperature limit at the ENCLOSURE in SINGLE FAULT CONDITION

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

4.2.131 Optic coupler requirements

Recommendation number	131														
Clause(s) number (only)	4.8, 8.5, 8.8.2, 8.8.3, 8.9.1, 8.9.3														
Source/problem	Optic couplers: Do the ME EQUIPMENT end-product standard's insulation requirements apply?														
Discussion/comment	According to 4.8 a), an optic coupler providing at least 1 MOP would need to comply with applicable optic coupler standard, IEC 60747-5-5:2007 (replaces optic clauses from IEC 60747-1, -2, -3). This standard has appropriate insulation requirements for MOOP, however it does not include the 0,4 mm single layer thickness requirement in 8.8.2 of IEC 60601-1:2005, nor does it require the 30 day cemented joint requirement in 8.9.3. It does require a partial discharge test for solid insulation, including cemented joints, and presumably there is aging/conditioning done prior to partial discharge. Presumably is not appropriate for the CR, CL, DS requirements considered necessary for MOPP. According to Figure 5, which is associated with 4.8 a), there is a decision box at end that says after complying with component standard, "are additional end product requirements necessary?" I am not sure how the flow chart matches with the wording of 4.8, but it would seem it is always appropriate to consider any ME EQUIPMENT end-product requirements that might be appropriate for a general component used with ME EQUIPMENT. Questions: Assuming optic coupler provides at least 1 MOP, complies with IEC 60747-5-5:2007 and is being used within its ratings (as required by 4.8.a)), 1) for optic couplers providing at least 1 MOP (MOOP or MOPP), do we need to require the 30-day thermal cycling test in 8.9.3? 2) if optic coupler insulation is supplementary or reinforced (MOOP or MOPP) for > 71 V peak, is it necessary to verify the 0,4 mm thickness in 8.8.2? 3) if optic coupler is being used as MOOP, is it necessary to verify CR, CL, and DS? 4) if optic coupler is being used as MOPP, is it necessary to verify CR, CL, and DS? For review, here is a comparison of the ME EQUIPMENT insulation requirements for an optic coupler providing 2 MOOP for mains voltage, versus 2 MOPP for mains voltage: <table><tr><th>Insulation</th><th>2 MOPP</th><th>2 MOOP</th></tr><tr><td rowspan="5">RI (240 V RMS)</td><td>8 mm CR,</td><td>5 mm CR,</td></tr><tr><td>5 mm CL,</td><td>4 mm CL,</td></tr><tr><td>4 kV RMS DS,</td><td>3 kV RMS DS,</td></tr><tr><td>0,4 mm DTI^a,</td><td>0,4 mm DTI^a,</td></tr><tr><td>30 d thermal cycling for cemented joint</td><td>30 d thermal cycling for cemented joint</td></tr></table> ^a Perhaps represented by IEC 60747-5-5:2007 partial discharge testing with pre-conditioning.	Insulation	2 MOPP	2 MOOP	RI (240 V RMS)	8 mm CR,	5 mm CR,	5 mm CL,	4 mm CL,	4 kV RMS DS,	3 kV RMS DS,	0,4 mm DTI ^a ,	0,4 mm DTI ^a ,	30 d thermal cycling for cemented joint	30 d thermal cycling for cemented joint
Insulation	2 MOPP	2 MOOP													
RI (240 V RMS)	8 mm CR,	5 mm CR,													
	5 mm CL,	4 mm CL,													
	4 kV RMS DS,	3 kV RMS DS,													
	0,4 mm DTI ^a ,	0,4 mm DTI ^a ,													
	30 d thermal cycling for cemented joint	30 d thermal cycling for cemented joint													

Recommendation 131 (continued)

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

4.2.132 Eye-verification of tester before legibility test

Recommendation number	132
Clause(s) number (only)	7.1.2
Source/problem	IEC 60601-1 has special requirements for tester's eyes. Why was Jaeger card (N6) added with an "and" conjunction (in IEC 60050-1:2005/AMD1:2012)? How shall it be proved that the tester is able to read N6 of Jaeger test card, i.e. visit a doctor? Shall it be done before every test?
Discussion/comment	The 2nd Edition of IEC 60601-1 uses the term "normal vision". Because "normal vision" is an undefined term, the 3rd Edition tried to set up reproducible test requirements, which has consequently led to compliance criteria related to the tester's eyes. The compliance criteria in the 3.1 edition says: <i>The ME EQUIPMENT or its part is positioned so that the viewpoint is the intended position of the OPERATOR. If the intended position of the OPERATOR is not specified and the position is not obvious, the viewpoint is at any point within the base of a cone subtended by an angle of 30° to the axis normal to the centre of the plane of the marking and at a distance of 1 m. The ambient illumination is the least favourable level in the range of 100 lx to 1 500 lx.</i> <i>The observer has a visual acuity, corrected if necessary, of:</i> – 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; <i>in normal room lighting conditions (approximately 500 lx).</i> The following aspects are still not defined in the compliance criteria and remain unclear: 1) What does "The observer has a visual acuity, corrected if necessary, of: 0 on the log Minimum Angle of Resolution (log MAR) scale or 6/6 (20/20)" mean? 2) How should compliance be proven in practice? 3) Is it sufficient if the tester visits an eye-physician in his medical office before each test, under the condition that the lighting in the medical office is checked with a calibrated test equipment to be approximately 500 lx? 4) What does "approximately" mean? Does it mean for example 450 lx is not adequate? What about 475 lx? Where is the limit for acceptance? 5) The normal vision of humans changes during a normal work day. It has been proven in the standard committee that members confirmed that early in the morning they were able to read the screen whereas in the evening they were not, even though nothing had changed with the projector. Is it therefore required that test laboratories hire eye-physicians to verify exactly, before each hour the tester conducts the test, that the normal vision (acuity) is still given? Consequently, testing without having an eye-physician and the 500 lx room available shall be forbidden. 6) Because the colour of the light during test at the ME EQUIPMENT and during verification of the tester's eyes is not defined, should we wait with further testing until Amendment 2 fills the gap? 7) Is it allowed to print out a Jaeger card from the Internet and use this to prove the tester's eyes acuity? If yes, which printer is defined and which paper size is defined, and which Internet Jaeger card shall be downloaded? 8) Are there any suggestions based on equivalent safety to show compliance with this still unclear subclause?

Recommendation 132 (continued)

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

4.2.133 End stops to prevent overtravel

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

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

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

Recommendation 134 (continued)

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

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

Recommendation 135 (continued)

Source/problem (continued)	Where no marking of the ACCESSORIES is practicable, these markings may be affixed to the individual packaging. 3.3 ACCESSORY <u>additional</u> part for use with equipment in order to: – achieve the INTENDED USE, – adapt it to some special use, – facilitate its use, – enhance its performance, or – enable its functions to be integrated with those of other equipment ➔ Problem: The above IEC 60601-1 subclauses address requirements for: a) detachable components (not a defined term); b) ACCESSORIES (defined term). When applying these IEC 60601-1 requirements <u>literally</u>, 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 <u>ENTIRE</u> medical industry will fail the requirements.
Discussion/comment	At the moment ALL stakeholders (all MANUFACTURERS, test laboratories, Notified Bodies, ministries of health) do not apply IEC 60601-1 so restrictively and literally as reflected by the submitter above.
Submitter proposed recommendation	–
SC 62A recommendation	7.2.2 and 7.2.4 should be read by considering defined terms and notes in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012. 1. Detachable parts: It is recommended to interpret the undefined term "detachable component" as follows: Is an <u>external</u> component (single item or subassembly) which could be detached from the ME EQUIPMENT or ME SYSTEM <u>without using a tool</u>. NOTE 1 Components <u>inside</u> 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 <u>outside</u> of the ME EQUIPMENT are not considered as detachable parts, because only an authorized expert is allowed to change these parts by using a TOOL. 2. ACCESSORIES: It is recommended to read 7.2.2 and 7.2.4 in the context of IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 as a whole, as follows:

Recommendation 135 (continued)

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