

TECHNICAL REPORT



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

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

ICS 11.040.01

ISBN 978-2-8322-6278-8

Warning! Make sure that you obtained this publication from an authorized distributor.

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

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

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

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

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