

Australian/New Zealand Standard™

Medical electrical equipment

**Part 1: General requirements for basic
safety and essential performance**



AS/NZS IEC 60601.1:2015

This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HE-003, Medical Electrical Equipment. It was approved on behalf of the Council of Standards Australia on 19 August 2015 and on behalf of the Council of Standards New Zealand on 21 August 2015.

This Standard was published on 23 September 2015.

The following are represented on Committee HE-003:

Australian and New Zealand College of Anaesthetists
Australian Dental Association
Australian Society of Anaesthetists
Canterbury District Health Board
College of Biomedical Engineering Engineers Australia
Department of Defence
Engineers Australia
Medical Technology Association of Australia
Ministry of Business, Innovation and Employment, New Zealand
New Zealand Institute of Healthcare Engineering
Testing Interests, Australia
Therapeutic Goods Administration
Wairarapa District Health Board
Waitemata District Health Board

Keeping Standards up-to-date

Standards are living documents which reflect progress in science, technology and systems. To maintain their currency, all Standards are periodically reviewed, and new editions are published. Between editions, amendments may be issued. Standards may also be withdrawn. It is important that readers assure themselves they are using a current Standard, which should include any amendments which may have been published since the Standard was purchased.

Detailed information about joint Australian/New Zealand Standards can be found by visiting the Standards Web Shop at www.saiglobal.com.au or Standards New Zealand web site at www.standards.co.nz and looking up the relevant Standard in the on-line catalogue.

For more frequent listings or notification of revisions, amendments and withdrawals, Standards Australia and Standards New Zealand offer a number of update options. For information about these services, users should contact their respective national Standards organization.

We also welcome suggestions for improvement in our Standards, and especially encourage readers to notify us immediately of any apparent inaccuracies or ambiguities. Please address your comments to the Chief Executive of either Standards Australia or Standards New Zealand at the address shown on the back cover.

This Standard was issued in draft form for comment as DR AS/NZS IEC 60601.1:2015.



Documents
Document Sharing Hub

Australian/New Zealand Standard™

Medical electrical equipment

Part 1: General requirements for basic safety and essential performance

Originated in Australia as AS C200—1970.
Originated in New Zealand as NZS 6150:1990.
Previous edition AS/NZS 3200.1.0:1998.
Jointly revised and redesignated as AS/NZS IEC 60601.1:2015.

COPYRIGHT

© Standards Australia Limited/Standards New Zealand

All rights are reserved. No part of this work may be reproduced or copied in any form or by any means, electronic or mechanical, including photocopying, without the written permission of the publisher, unless otherwise permitted under the Copyright Act 1968 (Australia) or the Copyright Act 1994 (New Zealand).

Jointly published by SAI Global Limited under licence from Standards Australia Limited, GPO Box 476, Sydney, NSW 2001 and by Standards New Zealand, Private Bag 2439, Wellington 6140.

ISBN 978 1 76035 244 8

PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee, HE-003 Medical Electrical Equipment, to supersede AS/NZS 3200.1.0:1998 *Medical electrical equipment, Part 1.0: General requirements for safety—Parent Standard*.

The objective of this Standard is to specify general requirements for basic safety and essential performance of medical electrical equipment and medical electrical systems. This is applicable to a subgroup of medical electrical equipment (e.g. radiological equipment) and a specific characteristic of all medical electrical equipment not fully addressed in this Standard.

This Standard is identical with, and has been reproduced from IEC 60601-1 Ed.3.1 (2012), *Medical electrical equipment, Part 1: General requirements for basic safety and essential performance*. This edition 3.1 incorporates the Corrigenda dated 2006 and 2007 and Amendment 1 (2012). The text affected by Amendment 1 is indicated in the text by marginal bars, redline and strikeout.

As this Standard is reproduced from an International Standard, the following applies:

- (a) In the source text ‘this International Standard’ should read ‘this Australian/New Zealand Standard’.
- (b) A full point substitutes for a comma when referring to a decimal marker.

References to International Standards should be replaced by references to Australian or Australian/New Zealand Standards, as follows:

<i>Reference to International Standard</i>		<i>Australian/New Zealand Standard</i>	
IEC		AS/NZS	
60079	Explosive atmospheres	60079	Explosive atmospheres
60079-0	Part 0: Equipment—General requirements	60079.0	Part 0: Equipment—General requirements
60335	Household and similar electrical appliances—Safety	60335	Household and similar electrical appliances—Safety
60335-1	Part 1: General requirements	60335.1	Part 1: General requirements (IEC 60335-1 Ed.5, MOD)
		AS	
60529	Degrees of protection provided by enclosures (IP Code)	60529	Degrees of protection provided by enclosures (IP Code)
		AS/NZS	
60601	Medical electrical equipment	3200	Medical electrical equipment
60601-1-8	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	3200.1.8	Part 1.8: General requirements for safety—Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
		AS/NZS IEC	
60825	Safety of laser products	60825	Safety of laser products
60825-1	Part 1: Equipment classification and requirements	60825.1	Part 1: Equipment classification and requirements

IEC		AS/NZS	
60884	Plugs and socket-outlets for household and similar purposes	60884	Plugs and socket-outlets for household and similar purposes
60884-1	Part 1: General requirements	60884.1	Part 1: General requirements (IEC 60884-1, Ed. 3.1 (2006) MOD)
60950	Information technology equipment—Safety	60950	Information technology equipment—Safety
60950-1	Part 1: General requirements	60950.1	Part 1: General requirements (IEC 60950-1, Ed. 2.0 (2005) MOD)
61058	Switches for appliances	61058	Switches for appliances
61058-1	Part 1: General requirements	61058.1	Part 1: General requirements (IEC 61058-1, Ed. 3.1 (2000) MOD)
ISO		AS	
780	Packaging—Pictorial marking for handling of goods	2852	Packaging—Pictorial marking for the handling of packages
		AS ISO	
5349	Mechanical vibration—Measurement and evaluation of human exposure to hand-transmitted vibration	5349	Mechanical vibration—Measurement and evaluation of human exposure to hand-transmitted vibration
5349-1	Part 1: General requirements	5349.1	Part 1: General requirements
10993	Biological evaluation of medical devices	10993	Biological evaluation of medical devices
10993-4	Part 4: Selection of tests for interactions with blood	10993.4	Part 4: Selection of tests for interactions with blood
10993-14	Part 14: Identification and quantification of degradation products from ceramics	10993.14	Part 14: Identification and quantification of degradation products from ceramics
10993-15	Part 15: Identification and quantification of degradation products from metals and alloys	10993.15	Part 15: Identification and quantification of degradation products from metals and alloys
10993-17	Part 17: Establishment of allowable limits for leachable substances	10993.17	Part 17: Establishment of allowable limits for leachable substances
		AS/NZS ISO	
11137	Sterilization of health care products—Radiation	11137	Sterilization of health care products—Radiation
11137-1	Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	11137.1	Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
		AS/NZS	
13857	Safety of machinery—Safety distances to prevent hazard zones being reached by upper and lower limbs	4024	Safety of machinery
		4024.1801	Part 1801: Safety distances to prevent danger zones being reached by upper and lower limbs

Only normative references that have been adopted as Australian or Australian/New Zealand Standards have been listed.

The terms ‘normative’ and ‘informative’ have been used in this Standard to define the application of the annex to which they apply. A ‘normative’ annex is an integral part of a Standard, whereas an ‘informative’ annex is only for information and guidance.

CONTENTS

1	Scope, object and related standards	17
1.1	* Scope	17
1.2	Object	17
1.3	* Collateral standards	17
1.4	* Particular standards	18
2	* Normative references	18
3	* Terminology and definitions	18
4	General requirements	42
4.1	* Conditions for application to ME EQUIPMENT or ME SYSTEMS	42
4.2	* RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS	43
4.3	* ESSENTIAL PERFORMANCE	43
4.4	* EXPECTED SERVICE LIFE	46
4.5	* Equivalent safety for ME EQUIPMENT or ME SYSTEMS * Alternative RISK CONTROL measures or test methods for ME EQUIPMENT or ME SYSTEMS	47
4.6	* ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT	47
4.7	* SINGLE FAULT CONDITION for ME EQUIPMENT	47
4.8	* Components of ME EQUIPMENT	48
4.9	* Use of COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS in ME EQUIPMENT	49
4.10	* Power supply	50
4.11	Power input	50
5	* General requirements for testing ME EQUIPMENT	51
5.1	* TYPE TESTS	51
5.2	* Number of samples	51
5.3	Ambient temperature, humidity, atmospheric pressure	51
5.4	Other conditions	51
5.5	Supply voltages, type of current, nature of supply, frequency	52
5.6	Repairs and modifications	52
5.7	* Humidity preconditioning treatment	53
5.8	Sequence of tests	53
5.9	* Determination of APPLIED PARTS and ACCESSIBLE PARTS	53
6	* Classification of ME EQUIPMENT and ME SYSTEMS	57
6.1	General	57
6.2	* Protection against electric shock	57
6.3	* Protection against harmful ingress of water or particulate matter	57
6.4	Method(s) of sterilization	57
6.5	Suitability for use in an OXYGEN RICH ENVIRONMENT	57
6.6	* Mode of operation	57

7	ME EQUIPMENT identification, marking and documents	58
7.1	General	58
7.2	Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts	59
7.3	Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts	64
7.4	Marking of controls and instruments	65
7.5	Safety signs	67
7.6	Symbols	67
7.7	Colours of the insulation of conductors	68
7.8	* Indicator lights and controls	68
7.9	ACCOMPANYING DOCUMENTS	69
8	* Protection against electrical HAZARDS from ME EQUIPMENT	75
8.1	Fundamental rule of protection against electric shock	75
8.2	Requirements related to power sources	76
8.3	Classification of APPLIED PARTS	77
8.4	Limitation of voltage, current or energy	77
8.5	Separation of parts	80
8.6	* Protective earthing, functional earthing and potential equalization of ME EQUIPMENT	90
8.7	LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS	93
8.8	Insulation	115
8.9	* CREEPAGE DISTANCES and AIR CLEARANCES	121
8.10	Components and wiring	138
8.11	MAINS PARTS, components and layout	140
9	* Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS	146
9.1	MECHANICAL HAZARDS of ME EQUIPMENT	146
9.2	* MECHANICAL HAZARDS associated with moving parts	146
9.3	* MECHANICAL HAZARD associated with surfaces, corners and edges	152
9.4	* Instability HAZARDS	152
9.5	* Expelled parts HAZARD	157
9.6	Acoustic energy (including infra- and ultrasound) and vibration	158
9.7	* Pressure vessels and parts subject to pneumatic and hydraulic pressure	159
9.8	* MECHANICAL HAZARDS associated with support systems	162
10	* Protection against unwanted and excessive radiation HAZARDS	168
10.1	X-Radiation	168
10.2	Alpha, beta, gamma, neutron and other particle radiation	169
10.3	Microwave radiation	169
10.4	* Lasers and light emitting diodes (LEDs)	169
10.5	Other visible electromagnetic radiation	170
10.6	Infrared radiation	170
10.7	Ultraviolet radiation	170
11	* Protection against excessive temperatures and other HAZARDS	170
11.1	* Excessive temperatures in ME EQUIPMENT	170
11.2	* Fire prevention	175
11.3	* Constructional requirements for fire ENCLOSURES of ME EQUIPMENT	180

11.4	* ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics	181
11.5	* ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents	182
11.6	Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT	182
11.7	Biocompatibility of ME EQUIPMENT and ME SYSTEMS	184
11.8	* Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT	184
12	* Accuracy of controls and instruments and protection against hazardous outputs	184
12.1	Accuracy of controls and instruments	184
12.2	USABILITY of ME EQUIPMENT	184
12.3	ALARM SYSTEMS	184
12.4	Protection against hazardous output.....	185
13	* HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT	186
13.1	Specific HAZARDOUS SITUATIONS	186
13.2	SINGLE FAULT CONDITIONS	187
14	* PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	192
14.1	* General.....	192
14.2	* Documentation	193
14.3	* RISK MANAGEMENT plan	193
14.4	* PEMS DEVELOPMENT LIFE-CYCLE	193
14.5	* Problem resolution	194
14.6	RISK MANAGEMENT PROCESS.....	194
14.7	* Requirement specification	195
14.8	* Architecture	195
14.9	* Design and implementation	195
14.10	* VERIFICATION	195
14.11	* PEMS VALIDATION	196
14.12	* Modification	196
14.13	* Connection of PEMS by NETWORK/DATA COUPLING to other equipment * PEMS intended to be incorporated into an IT-NETWORK	196
15	Construction of ME EQUIPMENT	197
15.1	* Arrangements of controls and indicators of ME EQUIPMENT	198
15.2	* Serviceability	198
15.3	Mechanical strength	198
15.4	ME EQUIPMENT components and general assembly.....	202
15.5	* MAINS SUPPLY TRANSFORMERS of ME EQUIPMENT and transformers providing separation in accordance with 8.5	207
16	* ME SYSTEMS	211
16.1	* General requirements for the ME SYSTEMS	211
16.2	* ACCOMPANYING DOCUMENTS of an ME SYSTEM	212
16.3	* Power supply	213
16.4	ENCLOSURES	213
16.5	* SEPARATION DEVICES.....	213
16.6	* LEAKAGE CURRENTS.....	214
16.7	* Protection against MECHANICAL HAZARDS.....	215

16.8	Interruption of the power supply to parts of an ME SYSTEM	215
16.9	ME SYSTEM connections and wiring	215
17	* Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	217
Annex A (informative)	General guidance and rationale.....	218
Annex B (informative)	Sequence of testing	331
Annex C (informative)	Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS	335
Annex D (informative)	Symbols on marking.....	338
Annex E (informative)	Examples of the connection of the measuring device (MD) for measurement of the PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT	347
Annex F (informative)	Suitable measuring supply circuits.....	349
Annex G (normative)	Protection against HAZARDS of ignition of flammable anaesthetic mixtures.....	352
Annex H (informative)	PEMS structure, PEMS DEVELOPMENT LIFE-CYCLE and documentation	367
Annex I (informative)	ME SYSTEMS aspects.....	380
Annex J (informative)	Survey of insulation paths.....	386
Annex K (informative)	Simplified PATIENT LEAKAGE CURRENT diagrams	389
Annex L (normative)	Insulated winding wires for use without interleaved insulation.....	392
Annex M (normative)	Reduction of pollution degrees	395
Bibliography.....		396
INDEX OF ABBREVIATIONS AND ACRONYMS		400
INDEX		402
Figure 1 – Detachable mains connection.....		23
Figure 2 – Example of the defined terminals and conductors.....		25
Figure 3 – Example of a CLASS I ME EQUIPMENT		26
Figure 4 – Example of a metal-enclosed CLASS II ME EQUIPMENT		26
Figure 5 – Schematic flow chart for component qualification		49
Figure 6 – Standard test finger.....		55
Figure 7 – Test hook.....		56
Figure 8 – Test pin.....		79
Figure 9 – Application of test voltage to bridged PATIENT CONNECTIONS for DEFIBRILLATION-PROOF APPLIED PARTS.....		86
Figure 10 – Application of test voltage to individual PATIENT CONNECTIONS for DEFIBRILLATION-PROOF APPLIED PARTS.....		88
Figure 11 – Application of test voltage to test the delivered defibrillation energy		90
Figure 12 – Example of a measuring device and its frequency characteristics.....		95
Figure 13 – Measuring circuit for the EARTH LEAKAGE CURRENT of CLASS I ME equipment, with or without APPLIED PART		98

Figure 14 – Measuring circuit for the TOUCH CURRENT	100
Figure 15 – Measuring circuit for the PATIENT LEAKAGE CURRENT from the PATIENT CONNECTION to earth.....	102
Figure 16 – Measuring circuit for the PATIENT LEAKAGE CURRENT via the PATIENT CONNECTION(S) of an F-TYPE APPLIED PART to earth caused by an external voltage on the PATIENT CONNECTION(S)	104
Figure 17 – Measuring circuit for the PATIENT LEAKAGE CURRENT from PATIENT CONNECTION(S) to earth caused by an external voltage on a SIGNAL INPUT/OUTPUT PART	106
Figure 18 – Measuring circuit for the PATIENT LEAKAGE CURRENT from PATIENT CONNECTION(S) to earth caused by an external voltage on a metal ACCESSIBLE PART that is not PROTECTIVELY EARTHED	108
Figure 19 – Measuring circuit for the PATIENT AUXILIARY CURRENT	109
Figure 20 – Measuring circuit for the total PATIENT LEAKAGE CURRENT with all PATIENT CONNECTIONS of all APPLIED PARTS of the same type (TYPE B APPLIED PARTS, TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS) connected together.....	110
Figure 21 – Ball-pressure test apparatus	121
Figure 22 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 1	134
Figure 23 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 2	134
Figure 24 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 3	134
Figure 25 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 4	135
Figure 26 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 5	135
Figure 27 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 6	135
Figure 28 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 7	136
Figure 29 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 8	136
Figure 30 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 9	137
Figure 31 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 10	138
Figure 32 – Ratio between HYDRAULIC TEST PRESSURE and MAXIMUM PERMISSIBLE WORKING PRESSURE	161
Figure 33 – Human body test mass Body upper-carriage module	167
Figure 34 – Spark ignition test apparatus.....	176
Figure 35 – Maximum allowable current I as a function of the maximum allowable voltage U measured in a purely resistive circuit in an OXYGEN RICH ENVIRONMENT	177
Figure 36 – Maximum allowable voltage U as a function of the capacitance C measured in a capacitive circuit used in an OXYGEN RICH ENVIRONMENT	177
Figure 37 – Maximum allowable current I as a function of the inductance L measured in an inductive circuit in an OXYGEN RICH ENVIRONMENT	178
Figure 38 – Baffle	181
Figure 39 – Area of the bottom of an ENCLOSURE as specified in 11.3 b) 1)	181
Figure A.1 – Identification of ME EQUIPMENT, APPLIED PARTS and PATIENT CONNECTIONS in an ECG monitor	224
Figure A.2 – Example of the insulation of an F-TYPE APPLIED PART with the insulation incorporated in the ME EQUIPMENT	224
Figure A.3 – Identification of ME EQUIPMENT, APPLIED PARTS and PATIENT CONNECTIONS in a PATIENT monitor with invasive pressure monitoring facility	225
Figure A.4 – Identification of ME EQUIPMENT, APPLIED PARTS and PATIENT CONNECTIONS in a multifunction PATIENT monitor with invasive pressure monitoring facilities.....	226

Figure A.5 – Identification of APPLIED PARTS and PATIENT CONNECTIONS in an X-ray ME SYSTEM	227
Figure A.6 – Identification of ME EQUIPMENT, APPLIED PARTS and PATIENT CONNECTIONS in a transcutaneous electronic nerve stimulator (TENS) intended to be worn on the PATIENT'S belt and connected to electrodes applied to the PATIENT'S upper arm.....	227
Figure A.7 – Identification of ME EQUIPMENT or ME SYSTEM, APPLIED PARTS and PATIENT CONNECTIONS in a personal computer with an ECG module	228
Figure A.8 – Pictorial representation of the relationship of HAZARD, sequence of events, HAZARDOUS SITUATION and HARM	231
Figure A.9 – Example of PATIENT ENVIRONMENT.....	237
Figure A.10 – Floating circuit	256
Figure A.11 – Interruption of a power-carrying conductor between ME EQUIPMENT parts in separate ENCLOSURES.....	258
Figure A.12 – Identification of MEANS OF PATIENT PROTECTION and MEANS OF OPERATOR PROTECTION.....	263
Figure A.13 – Allowable protective earth impedance where the fault current is limited	270
Figure A.14 – Probability of ventricular fibrillation	276
Figure A.15 – Example of a measuring circuit for the PATIENT LEAKAGE CURRENT from a PATIENT CONNECTION to earth for ME EQUIPMENT with multiple PATIENT CONNECTIONS	281
Figure A.16 – Instability test conditions.....	292
Figure A.17 – Example of determining TENSILE SAFETY FACTOR using Table 21	299
Figure A.18 – Example of determining design and test loads	300
Figure A.19 – Example of human body mass distribution	300
Figure A.20 – Relationship of the terms used to describe equipment, ACCESSORIES or equipment parts.....	234
Figure A.21 – Example of ME EQUIPMENT having two different functions on one common APPLIED PART circuit.....	268
Figure A.22 – Maximum allowable temperature for surfaces and APPLIED PARTS at higher altitudes	305
Figure A.23 – Example of the needed MEANS OF OPERATOR PROTECTION between the terminals of an INTERNAL ELECTRICAL POWER SOURCE and a subsequent protective device.....	323
Figure E.1 – TYPE B APPLIED PART.....	347
Figure E.2 – TYPE BF APPLIED PART	347
Figure E.3 – TYPE CF APPLIED PART	348
Figure E.4 – PATIENT AUXILIARY CURRENT	348
Figure E.5 – Loading of the PATIENT CONNECTIONS if specified by the MANUFACTURER	348
Figure F.1 – Measuring supply circuit with one side of the SUPPLY MAINS at approximately earth potential	349
Figure F.2 – Measuring supply circuit with SUPPLY MAINS approximately symmetrical to earth potential.....	349
Figure F.3 – Measuring supply circuit for polyphase ME EQUIPMENT specified for connection to a polyphase SUPPLY MAINS	350
Figure F.4 – Measuring supply circuit for single-phase ME EQUIPMENT specified for connection to a polyphase SUPPLY MAINS	350
Figure F.5 – Measuring supply circuit for ME EQUIPMENT having a separate power supply unit or intended to receive its power from another equipment in an ME SYSTEM.....	351

Figure G.1– Maximum allowable current I_{ZR} as a function of the maximum allowable voltage U_{ZR} measured in a purely resistive circuit with the most flammable mixture of ether vapour with air	358
Figure G.2 – Maximum allowable voltage U_{ZC} as a function of the capacitance C_{max} measured in a capacitive circuit with the most flammable mixture of ether vapour with air	359
Figure G.3 – Maximum allowable current I_{ZL} as a function of the inductance L_{max} measured in an inductive circuit with the most flammable mixture of ether vapour with air ..	359
Figure G.4 – Maximum allowable current I_{ZR} as a function of the maximum allowable voltage U_{ZR} measured in a purely resistive circuit with the most flammable mixture of ether vapour with oxygen	363
Figure G.5 – Maximum allowable voltage U_{ZC} as a function of the capacitance C_{max} measured in a capacitive circuit with the most flammable mixture of ether vapour with oxygen.....	364
Figure G.6 – Maximum allowable current I_{ZL} as a function of the inductance L_{max} measured in an inductive circuit with the most flammable mixture of ether vapour with oxygen.....	364
Figure G.7 – Test apparatus	364
Figure H.1 – Examples of PEMS/ PESS structures	368
Figure H.2 – A PEMS DEVELOPMENT LIFE-CYCLE model	369
Figure H.3 – PEMS documentation requirements from Clause 14 and ISO 14971:2000 Not used	373
Figure H.4 – Example of potential parameters required to be specified for NETWORK/DATA COUPLING an IT-NETWORK	379
Figure I.1 – Example of the construction of a MULTIPLE SOCKET-OUTLET (MSO)	384
Figure I.2 – Examples of application of MULTIPLE SOCKET-OUTLETS (MSO)	385
Figure J.1 – Insulation example 1	386
Figure J.2 – Insulation example 2	386
Figure J.3 – Insulation example 3	386
Figure J.4 – Insulation example 4	387
Figure J.5 – Insulation example 5	387
Figure J.6 – Insulation example 6	388
Figure J.7 – Insulation example 7	388
Figure K.1 – ME EQUIPMENT with an ENCLOSURE made of insulating material.....	389
Figure K.2 – ME EQUIPMENT with an F-TYPE APPLIED PART.....	389
Figure K.3 – ME EQUIPMENT with an APPLIED PART and a SIGNAL INPUT/OUTPUT PART	390
Figure K.4 – ME EQUIPMENT with a PATIENT CONNECTION of a TYPE B APPLIED PART that is not PROTECTIVELY EARTHED	390
Figure K.5 – ME EQUIPMENT with a PATIENT CONNECTION of a TYPE BF APPLIED PART that is not PROTECTIVELY EARTHED	391
Table 1 – Units outside the SI units system that may be used on me equipment	66
Table 2 – Colours of indicator lights and their meaning for me equipment	69
Table 3 – * Allowable values of patient leakage currents and patient auxiliary currents under normal condition and single fault condition	96
Table 4 – * Allowable values of patient leakage currents under the special test conditions identified in 8.7.4.7	97

Table 5 – Legends of symbols for Figure 9 to Figure 11, Figure 13 to Figure 20, Figure A.15, Annex E and Annex F	111
Table 6 – Test voltages for solid insulation forming a means of protection	118
Table 7 – Test voltages for means of operator protection	119
Table 8 – Multiplication factors for air clearances for altitudes up to 5 000 m	122
Table 9 – Material group classification	122
Table 10 – Mains transient voltage	124
Table 11 – Minimum creepage distances and air clearances between parts of opposite polarity of the mains part Not used	125
Table 12 – Minimum creepage distances and air clearances providing means of patient protection	126
Table 13 – Minimum air clearances providing means of operator protection from the mains part	127
Table 14 – Additional air clearances for insulation in mains parts with peak working voltages exceeding the peak value of the nominal mains voltage a	128
Table 15 – Minimum air clearances for means of operator protection in secondary circuits	129
Table 16 – Minimum Creepage distances providing means of operator protection	130
Table 17 – Nominal cross-sectional area of conductors of a power supply cord	142
Table 18 – Testing of cord anchorages	143
Table 19 – Mechanical hazards covered by this clause	146
Table 20 – Acceptable gaps	148
Table 21 – Determination of tensile safety factor	163
Table 22 – Allowable maximum temperatures of parts	171
Table 23 – Allowable maximum temperatures for me equipment parts that are likely to be touched	171
Table 24 – Allowable maximum temperatures for skin contact with me equipment applied parts	172
Table 25 – Acceptable perforation of the bottom of an enclosure	180
Table 26 – * Temperature limits of motor windings	190
Table 27 – Maximum motor winding steady-state temperature	192
Table 28 – Mechanical strength test applicability	199
Table 29 – Drop height	200
Table 30 – Test torques for rotating controls	206
Table 31 – Maximum allowable temperatures of transformer windings under overload and short-circuit conditions at 25 °C (± 5 °C) ambient temperature	208
Table 32 – Test current for transformers	209
Table 33 – Test conditions for overtravel end stop test	151
Table A.1 – Values of air clearance and creepage distance derived from Table 7 of IEC 61010-1:2001 and Table 12	284
Table A.2 – Creepage distances to avoid failure due to tracking from IEC 60664-1	285
Table A.3 – Instability test conditions	292
Table A.4 – Allowable time exposure for level of acceleration	295

Table A.5 – Guidance on surface temperatures for me equipment that creates low temperatures (cools) for therapeutic purposes or as part of its operation	304
Table C.1– Marking on the outside of me equipment, me systems or their parts	335
Table C.2 – Marking on the inside of me equipment, me systems or their parts.....	336
Table C.3 – Marking of controls and instruments.....	336
Table C.4 – Accompanying documents, general.....	336
Table C.5 – Accompanying documents, instructions for use	337
Table D.1 – General symbols	339
Table D.2 – Safety signs	344
Table D.3 – General codes	346
Table G.1 – Gas-tightness of cord inlets	361
Table H.1 – Network/data-coupling-classification Not used	377
Table I.1 – Some examples of me systems for illustration	382
Table L.1– Mandrel diameter	393
Table L.2 – Oven temperature	393
Table M.1 – Reduction of the pollution degree of internal environment through the use of additional protection	395

IEC FOREWORD

In this standard the following print types are used:

- Requirements and definitions: in roman type.
- *Test specifications: in italic type.*
- Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
- TERMS USED THROUGHOUT THIS STANDARD THAT HAVE BEEN DEFINED IN CLAUSE 3 AND ALSO GIVEN IN THE INDEX: IN SMALL CAPITALS.

In referring to the structure of this standard, the term

- “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
- “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex G of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex A.

INTRODUCTION

In 1976, IEC subcommittee 62A published the first edition of IEC/TR 60513, *Basic aspects of the safety philosophy for electrical equipment used in medical practice*. The first edition of IEC/TR 60513 provided the basis for developing:

- the first edition of IEC 60601-1 (the parent safety standard for MEDICAL ELECTRICAL EQUIPMENT);
- the IEC 60601-1-xx series of collateral standards for MEDICAL ELECTRICAL EQUIPMENT;
- the IEC 60601-2-xx series of particular standards for particular types of MEDICAL ELECTRICAL EQUIPMENT; and
- the IEC 60601-3-xx series of performance standards for particular types of MEDICAL ELECTRICAL EQUIPMENT.

Aware of the need and the urgency for a standard covering electrical equipment used in medical practice, the majority of National Committees voted in 1977 in favour of the first edition of IEC 60601-1, based on a draft that at the time represented a first approach to the problem. The extent of the scope, the complexity of the equipment concerned, and the specific nature of some of the protective measures and the corresponding tests for verifying them, required years of effort in order to prepare this first standard, which can now be said to have served as a universal reference since its publication.

However, the frequent application of the first edition revealed room for improvement. These improvements were all the more desirable in view of the considerable success that this standard has enjoyed since its publication.

The careful work of revision subsequently undertaken and continued over a number of years resulted in the publication of the second edition in 1988. This edition incorporated all the improvements that could be reasonably expected up to that time. Further developments remained under constant study. The second edition was amended in 1991 and then again in 1995.

The original IEC approach was to prepare separate BASIC SAFETY and performance standards for MEDICAL ELECTRICAL EQUIPMENT. This was a natural extension of the historical approach taken at the national and international level with other electrical equipment standards (e.g. those for domestic equipment), where BASIC SAFETY is regulated through mandatory standards but other performance specifications are regulated by market pressure. In this context, it has been said that, “The ability of an electric kettle to boil water is not critical to its safe use!”

It is now recognized that this is not the situation with many items of MEDICAL ELECTRICAL EQUIPMENT, and RESPONSIBLE ORGANIZATIONS have to depend on standards to ensure ESSENTIAL PERFORMANCE as well as BASIC SAFETY. Such areas include the accuracy with which the equipment controls the delivery of energy or therapeutic substances to the PATIENT, or processes and displays physiological data that will affect PATIENT management.

This recognition means that separating BASIC SAFETY and performance is somewhat inappropriate in addressing the HAZARDS that result from inadequate design of MEDICAL ELECTRICAL EQUIPMENT. Many particular standards in the IEC 60601-2-xx series address a range of ESSENTIAL PERFORMANCE requirements that cannot be directly evaluated by the RESPONSIBLE ORGANIZATION without applying such standards. (However, the current IEC 60601 series includes fewer requirements for ESSENTIAL PERFORMANCE than for BASIC SAFETY).

In anticipation of a third edition of IEC 60601-1, IEC subcommittee 62A prepared a second edition of IEC/TR 60513 [12]¹⁾ in 1994. It was intended that the second edition of IEC/TR 60513 would provide guidance for developing this edition of IEC 60601-1, and for the further development of the IEC 60601-1-xx and IEC 60601-2-xx series.

In order to achieve consistency in international standards, address present expectations in the health care community and align with developments in IEC 60601-2-xx, the second edition of IEC/TR 60513 includes two major new principles:

- the first change is that the concept of “SAFETY” has been broadened from the BASIC SAFETY considerations in the first and second editions of IEC 60601-1 to include ESSENTIAL PERFORMANCE matters, (e.g. the accuracy of physiological monitoring equipment). Application of this principle leads to the change of the title of this publication from “Medical electrical equipment, Part 1: General requirements for safety” in the second edition, to “Medical electrical equipment, Part 1: General requirements for basic safety and essential performance”;
- the second change is that, in specifying minimum safety requirements, provision is made for assessing the adequacy of the design PROCESS when this is the only practical method of assessing the safety of certain technologies such as programmable electronic systems. Application of this principle is one of the factors leading to introduction of a general requirement to carry out a RISK MANAGEMENT PROCESS. In parallel with the development of the third edition of IEC 60601-1, a joint project with ISO/TC 210 resulted in the publication of a general standard for RISK MANAGEMENT of medical devices. Compliance with this edition of IEC 60601-1 requires that the MANUFACTURER have in place a RISK MANAGEMENT PROCESS complying with parts of ISO 14971 (see 4.2).

This standard contains requirements concerning BASIC SAFETY and ESSENTIAL PERFORMANCE that are generally applicable to MEDICAL ELECTRICAL EQUIPMENT. For certain types of MEDICAL ELECTRICAL EQUIPMENT, these requirements are either supplemented or modified by the special requirements of a collateral or particular standard. Where particular standards exist, this standard should not be used alone.

Amendment 1 to this standard is intended to address:

- issues identified by National Committees and other interested parties since the publication of IEC 60601-1:2005;
- the way in which RISK MANAGEMENT has been introduced into IEC 60601-1:2005; and
- the way the concept of ESSENTIAL PERFORMANCE is used in IEC 60601-1:2005.

1) Figures in square brackets refer to the Bibliography.

INTRODUCTION TO THE AMENDMENT

The third edition of IEC 60601-1 was published in 2005. At the time of publication, there were 94 National Committee comments on the 2nd CDV and the FDIS that were deferred to a future amendment/revision. Each of their deferred comments was captured in an Issue Sheet by the SC 62A secretariat. By the time of the Auckland meeting in April 2008, the Subcommittees had developed two Interpretation Sheets and the SC 62A secretariat has received an additional 15 issues from National Committees and other interested parties.

At the Auckland meeting, IEC/TC 62 approved a project to develop the 1st amendment to IEC 60601-1:2005 based on the issues outstanding at the time. The TC approved developing the 1st amendment with a view to addressing outstanding issues, including but not limited to:

- those listed in 62A/593/DC and 62A/602/INF;
- the way in which risk management has been introduced into IEC 60601-1:2005; and
- the way the concept of essential performance is used in IEC 60601-1:2005.

Since the Auckland meeting, the secretariat has received 73 additional issues from National Committees or other interested parties for a total of 182 Issues Sheets. This amendment is intended to address those issues.

AUSTRALIAN/NEW ZEALAND STANDARD

Medical electrical equipment**Part 1:****General requirements for basic safety and essential performance****1 Scope, object and related standards****1.1 * Scope**

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS, hereafter referred to as ME EQUIPMENT and ME SYSTEMS.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1.

NOTE 1 See also 4.2.

~~This standard can also be applied to equipment used for compensation or alleviation of disease, injury or disability.~~

~~In vitro diagnostic equipment that does not fall within the definition of ME EQUIPMENT is covered by the IEC 61010 series ²⁾. This standard does not apply to the implantable parts of active implantable medical devices covered by ISO 14708-1 ³⁾.~~

The IEC 60601 series does not apply to:

- in vitro diagnostic equipment that does not fall within the definition of ME EQUIPMENT, which is covered by the IEC 61010 series [61];
- implantable parts of active implantable medical devices covered by the ISO 14708 series [69]; or
- medical gas pipeline systems covered by ISO 7396-1 [68].

NOTE 2 ISO 7396-1 applies the requirement of IEC 60601-1-8 to certain monitoring and ALARM SIGNALS.

1.2 Object

The object of this standard is to specify general requirements and to serve as the basis for particular standards.

1.3 * Collateral standards

In the IEC 60601 series, collateral standards specify general requirements for BASIC SAFETY and ESSENTIAL PERFORMANCE applicable to:

- a subgroup of ME EQUIPMENT (e.g. radiological equipment);
- a specific characteristic of all ME EQUIPMENT not fully addressed in this standard.

Applicable collateral standards become normative at the date of their publication and shall apply together with this standard.

²⁾ ~~IEC 61010 (all parts), Safety requirements for electrical equipment for measurement, control, and laboratory use~~

³⁾ ~~ISO 14708-1, Implants for surgery – Active implantable medical devices – Part 1: General requirements for safety, marking and for information to be provided by the manufacturer~~

NOTE 1 When evaluating compliance with IEC 60601-1, it is permissible to independently assess compliance with the collateral standards.

NOTE 2 When declaring compliance with IEC 60601-1, the declarer should specifically list the collateral standards that have been applied. This allows the reader of the declaration to understand which collateral standards were part of the evaluation.

NOTE 3 Collateral standards in the IEC 60601 family are numbered IEC 60601-1-xx. Members of The IEC maintains a ~~register catalogue~~ of valid International Standards. Users of this standard should consult this ~~register catalogue~~ at "<http://webstore.iec.ch>" to determine which collateral standards have been published.

If a collateral standard applies to ME EQUIPMENT for which a particular standard exists, then the particular standard takes priority over the collateral standard.

1.4 * Particular standards

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in this standard as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

NOTE ~~Members of IEC and ISO maintain registers of valid International Standards. Users of this standard should consult these registers to determine which particular standards have been published.~~ Particular standards in the IEC 60601 family that are developed by IEC committees are numbered IEC 60601-2-xx. In addition, particular standards developed by joint projects between ISO and IEC can be numbered either IEC 80601-2-xx or ISO 80601-2-xx depending on which committee administered the project. IEC and ISO maintain catalogues of valid International Standards. Users of this standard should consult these catalogues at "<http://webstore.iec.ch>" and "<http://www.iso.org/iso/store.htm>" to determine which particular standards have been published.

A requirement of a particular standard takes priority over this standard.

2 * Normative references

The following referenced documents are indispensable for the application 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.

ATTENTION: Additional collateral standards of the IEC 60601 series, which are issued subsequent to publication of this standard, become normative at the date of their publication and shall be considered as being included among the normative references below. See 1.3.

NOTE Informative references are listed in the Bibliography on page 396.

IEC 60065:2001, *Audio, video and similar electronic apparatus – Safety requirements* ⁴⁾
 Amendment 1:2005
 Amendment 2:2010

IEC 60068-2-2:1974 2007, *Environmental testing – Part 2-2: Tests – Test B: Dry heat*
~~Amendment 1 (1993)~~
~~Amendment 2 (1994)~~

IEC 60079-0, *Electrical apparatus for explosive gas atmospheres – Part 0: General requirements*

IEC 60079-2, *Electrical apparatus for explosive gas atmospheres – Part 2: Pressurized enclosures “p”*

IEC 60079-5, *Electrical apparatus for explosive gas atmospheres – Part 5: Powder filling “q”*

IEC 60079-6, *Electrical apparatus for explosive gas atmospheres – Part 6: Oil-immersion “o”*

IEC 60083, *Plugs and socket-outlets for domestic and similar general use standardized in member countries of IEC*

⁴⁾ There exists a consolidated edition 7.2 including IEC 60065:2001 and its Amendment 1 (2005) and Amendment 2 (2010).

IEC 60085, *Electrical insulation – Thermal classification*

IEC 60086-4, *Primary batteries – Part 4: Safety of lithium batteries*

IEC 60112, *Method for the determination of the proof and the comparative tracking indices of solid insulating materials*

IEC 60127-1, *Miniature fuses – Part 1: Definitions for miniature fuses and general requirements for miniature fuse-links*

IEC 60227-1:1993 2007, *Polyvinyl chloride insulated cables of rated voltages up to and including 450/750 V – Part 1: General requirements*⁵⁾

~~Amendment 1 (1995)~~

~~Amendment 2 (1998)~~

IEC 60245-1:2003, *Rubber insulated cables – Rated voltages up to and including 450/750 V – Part 1: General requirements*⁶⁾

~~Amendment 1:2007~~

IEC 60252-1, *AC motor capacitors – Part 1: General – Performance, testing and rating – Safety requirements – Guide for installation and operation*

IEC 60320-1, *Appliance couplers for household and similar general purposes – Part 1: General requirements*

IEC 60335-1:2004 2010, *Household and similar electrical appliances – Safety – Part 1: General requirements*

IEC 60364-4-41, *Electrical installations of buildings – Part 4-41: Protection for safety – Protection against electric shock*

IEC 60384-14:2005, *Fixed capacitors for use in electronic equipment – Part 14: Sectional specification: Fixed capacitors for electromagnetic interference suppression and connection to the supply mains*

~~IEC 60417 DB:2002, Graphical symbols for use on equipment~~⁷⁾

IEC 60417, *Graphical symbols for use on equipment*. Available from: <<http://www.graphical-symbols.info/equipment>>

IEC 60445, *Basic and safety principles for man-machine interface, marking and identification – Identification of equipment terminals and of terminations of certain designated conductors, including general rules for an alphanumeric system*

IEC 60447, *Basic and safety principles for man-machine interface, marking and identification – Actuating principles*

IEC 60529:1989, *Degrees of protection provided by enclosures (IP Code)*⁸⁾
Amendment 1 (1999)

IEC 60601-1-2, *Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests*

⁵⁾ ~~There exists a consolidated edition 2.2 including IEC 60227-1:1993 and its Amendment 1 (1995) and Amendment 2 (1998).~~

⁶⁾ There exists a consolidated edition 4.1 including IEC 60245-1:2003 and its Amendment 1 (2007).

⁷⁾ "DB" refers to the joint ISO-IEC on-line database.

⁸⁾ There exists a consolidated version 2.1, including IEC 60529:1989 and its Amendment 1 (1999).

IEC 60601-1-3, *Medical electrical equipment – Part 1-3: General requirements for **basic safety and essential performance***. Collateral standard: ~~General requirements for~~ Radiation protection in diagnostic X-ray equipment

IEC 60601-1-6, *Medical electrical equipment – Part 1-6: General requirements for safety – Collateral standard: Usability*

IEC 60601-1-8, *Medical electrical equipment – Part 1-8: General requirements for safety – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

IEC 60664-1: ~~1992~~ 2007, *Insulation coordination for equipment within low-voltage systems – Part 1: Principles, requirements and tests* ⁹⁾

~~Amendment 1 (2000)~~

~~Amendment 2 (2002)~~

IEC 60695-11-10, *Fire hazard testing – Part 11-10: Test flames – 50 W horizontal and vertical flame test methods*

IEC 60730-1: ~~1999~~ 2010, *Automatic electrical controls for household and similar use – Part 1: General requirements* ¹⁰⁾

~~Amendment 1 (2003)~~

IEC 60825-1: ~~1993~~ 2007, *Safety of laser products – Part 1: Equipment classification **and requirements** ~~and user's guide~~* ¹¹⁾

~~Amendment 1 (1997)~~

~~Amendment 2 (2001)~~

IEC 60851-3: ~~1996~~ 2009, *Winding wires – Test methods – Part 3: Mechanical properties* ¹²⁾

~~Amendment 1 (1997)~~

~~Amendment 2 (2003)~~

IEC 60851-5: ~~1996~~ 2008, *Winding wires – Test methods – Part 5: Electrical properties* ¹³⁾

~~Amendment 1 (1997)~~

~~Amendment 2 (2004)~~

IEC 60851-6: 1996, *Winding wires – Test methods – Part 6: Thermal properties*
Amendment 1 (1997)

~~IEC 60878: 2003, *Graphical symbols for electrical equipment in medical practice*~~

IEC 60884-1, *Plugs and socket-outlets for household and similar purposes - Part 1: General requirements*

IEC 60950-1: 2001, *Information technology equipment – Safety – Part 1: General requirements*

IEC 61058-1: 2000, *Switches for appliances – Part 1: General requirements* ¹⁴⁾

Amendment 1: 2001

~~Amendment 2: 2007~~

⁹⁾ ~~There exists a consolidated edition 1.2, including IEC 60664-1:1992 and its Amendment 1 (2000) and Amendment 2 (2002).~~

¹⁰⁾ ~~There exists a consolidated edition 3.1, including IEC 60730-1:1999 and its Amendment 1 (2003).~~

¹¹⁾ ~~There exists a consolidated edition 1.2, including IEC 60825-1:1993 and its Amendment 1 (1997) and Amendment 2 (2001).~~

¹²⁾ ~~There exists a consolidated edition 2.1, including IEC 60851-3:1996 and its Amendment 1 (1997).~~

¹³⁾ ~~There exists a consolidated edition 3.2, including IEC 60851-5:1996 and its Amendment 1 (1997) and Amendment 2 (2004).~~

¹⁴⁾ There exists a consolidated edition ~~3.1~~ 3.2, including IEC 61058-1:2000 and its Amendment 1 (2001) **and** Amendment 2 (2007)

~~IEC 61558-1:1997, Safety of power transformers, power supply units and similar – Part 1: General requirements and tests¹⁵⁾~~
~~Amendment 1 (1998)~~

IEC 61558-2-1, *Safety transformers, power supply units and similar – Part 2: Particular requirements for separating transformers for general use*

IEC 61672-1, *Electroacoustics – Sound level meters – Part 1: Specifications*

IEC 61672-2, *Electroacoustics – Sound level meters – Part 2: Pattern evaluation tests*

IEC 61965, *Mechanical safety of cathode ray tubes*

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

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

~~ISO 31 (all parts), Quantities and units~~

ISO 780, *Packaging – Pictorial marking for handling of goods*

~~ISO 1000, SI units and recommendations for the use of their multiples and of certain other units~~

ISO 1853, *Conducting and dissipative rubbers, vulcanized or thermoplastic – Measurement of resistivity*

ISO 2878, *Rubber, vulcanized – Antistatic and conductive products – Determination of electrical resistance*

ISO 2882¹⁶⁾, *Rubber, vulcanized – Antistatic and conductive products for hospital use – Electrical resistance limits*

ISO 3746, *Acoustics – Determination of sound power levels of noise sources using sound pressure – Survey method using an enveloping measurement surface over a reflecting plane*

ISO 3864-1:2002, *Graphical symbols – Safety colours and safety signs – Part 1: Design principles for safety signs in workplaces and public areas*

ISO 5349-1, *Mechanical vibration – Measurement and evaluation of human exposure to hand-transmitted vibration – Part 1: General requirements*

ISO 7000-DB:2004¹⁷⁾, *Graphical symbols for use on equipment – Collection of symbols*

ISO 7010:2003 2011, *Graphical symbols – Safety colours and safety signs – Registered safety signs* ~~used in workplaces and public areas~~

ISO 9614-1, *Acoustics – Determination of sound power levels of noise sources using sound intensity – Measurement at discrete points*

ISO 10993 (all parts), *Biological evaluation of medical devices*

~~ISO 11134, Sterilization of health care products – Requirements for validation and routine control – Industrial moist heat sterilization~~

~~ISO 11135, Medical devices – Validation and routine control of ethylene oxide sterilization~~

¹⁵⁾ ~~There exists a consolidated edition 1.1, including IEC 61558-1:1997 and its Amendment 1 (1998).~~

¹⁶⁾ ISO 2882 was withdrawn on 1 February 2005 and no replacement standard has been identified.

¹⁷⁾ "DB" refers to the joint ISO-IEC on-line database.

ISO 11135-1:2007, Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

~~*ISO 11137, Sterilization of health care products – Requirements for validation and routine control – Radiation sterilization*~~

ISO 11137-1:2006, Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

~~*ISO 13852, Safety of machinery – Safety distances to prevent danger zones being reached by the upper limbs*~~

ISO 13857:2008, Safety of machinery – Safety distances to prevent hazard zones being reached by the upper and lower limbs

ISO 14971:2000 2007, Medical devices – Application of risk management to medical devices

~~*ISO 15223, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied*~~

ISO 15223-1:2012, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements

ISO 17665-1:2006, Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices

ISO 23529, Rubber – General procedures for preparing and conditioning test pieces for physical test methods

ISO 80000-1:2009, Quantities and units – Part 1: General

3 * Terminology and definitions

For the purposes of this document, the following terms and definitions apply.

NOTE 1 Where the terms “voltage” and “current” are used in this document, they mean the r.m.s. values of an alternating, direct or composite voltage or current unless stated otherwise.

NOTE 2 The term “electrical equipment” is used to mean ME EQUIPMENT (see 3.63) or other electrical equipment. This standard also uses the term “equipment” to mean ME EQUIPMENT or other electrical or non-electrical equipment in the context of an ME SYSTEM (see 3.64).

NOTE 3 When the term “safety” is used in this document in roman or italic type, it does not mean “safety” as defined in ISO 14971, but rather is used to mean “the state of being protected from or guarded against hurt or injury; freedom from danger”.

NOTE 3.4 An index is found beginning on page 402.

3.1

ACCESS COVER

part of an ENCLOSURE or GUARD providing the possibility of access to electrical equipment parts for the purpose of adjustment, inspection, replacement or repair

3.2

ACCESSIBLE PART

part of electrical equipment other than an APPLIED PART that can be touched by means of the standard test finger

NOTE See also 5.9.2.1.

3.3**ACCESSORY**

additional part for use with equipment in order to:

- achieve the INTENDED USE,
- adapt it to some special use,
- facilitate its use,
- enhance its performance, or
- enable its functions to be integrated with those of other equipment

[IEC 60788:2004, rm-83-06 modified]

3.4**ACCOMPANYING DOCUMENT**

document accompanying ME EQUIPMENT, an ME SYSTEM, equipment or an ACCESSORY and containing information for the RESPONSIBLE ORGANIZATION or OPERATOR, particularly regarding BASIC SAFETY and ESSENTIAL PERFORMANCE

3.5**AIR CLEARANCE**

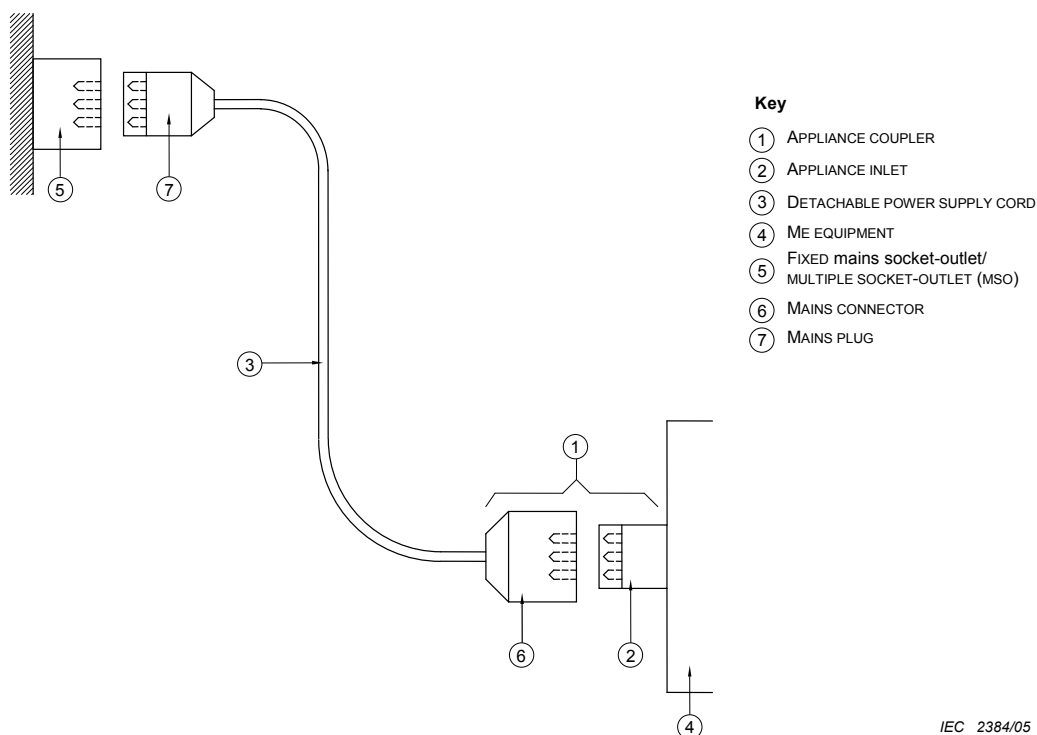
shortest path in air between two conductive parts

NOTE Adapted from IEC 60664-1:2007, definition 1.3.2.

3.6**APPLIANCE COUPLER**

means enabling the connection of a flexible cord to electrical equipment without the use of a TOOL, consisting of two parts: a MAINS CONNECTOR and an APPLIANCE INLET

NOTE See Figure 1.



IEC 2384/05

Figure 1 – Detachable mains connection
(see definitions)

3.7**APPLIANCE INLET**

part of an APPLIANCE COUPLER either integrated in or FIXED to electrical equipment

NOTE See Figure 1 and Figure 2.

3.8*** APPLIED PART**

part of ME EQUIPMENT that in NORMAL USE necessarily comes into physical contact with the PATIENT for ME EQUIPMENT or an ME SYSTEM to perform its function

NOTE 1 See Figure 3, Figure 4 and Figure A.1 to Figure A.7 (inclusive).

NOTE 2 See also 4.6 regarding the treatment of parts that do not fall within the definition of APPLIED PARTS but need to be treated as APPLIED PARTS as a result of applying the RISK MANAGEMENT PROCESS.

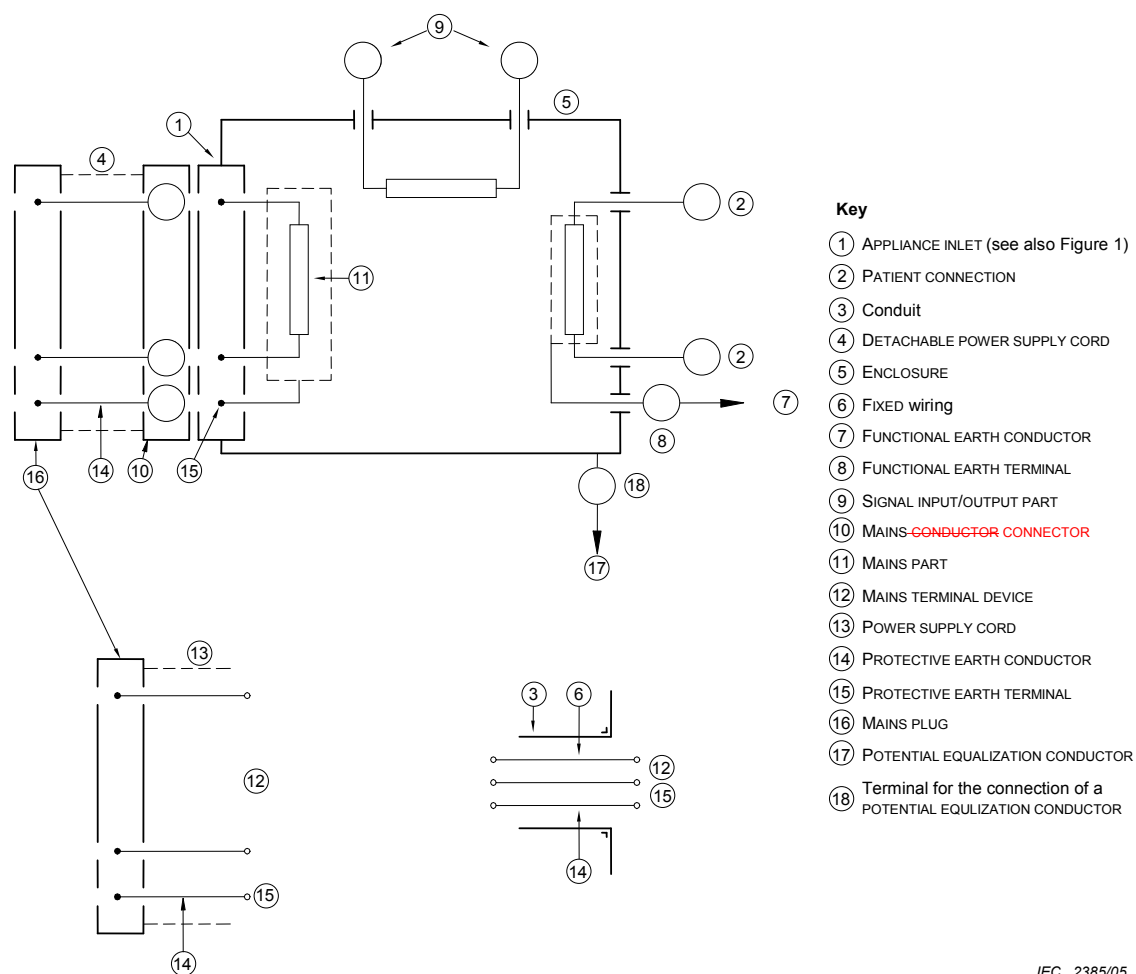
NOTE 3 See also 3.78 for the definition of the associated term PATIENT CONNECTION.

3.9*** BASIC INSULATION**

insulation providing basic protection against electric shock

[IEV 826-12-14, modified]

NOTE BASIC INSULATION provides one MEANS OF PROTECTION.



IEC 2385/05

Figure 2 – Example of the defined terminals and conductors
(see definitions)

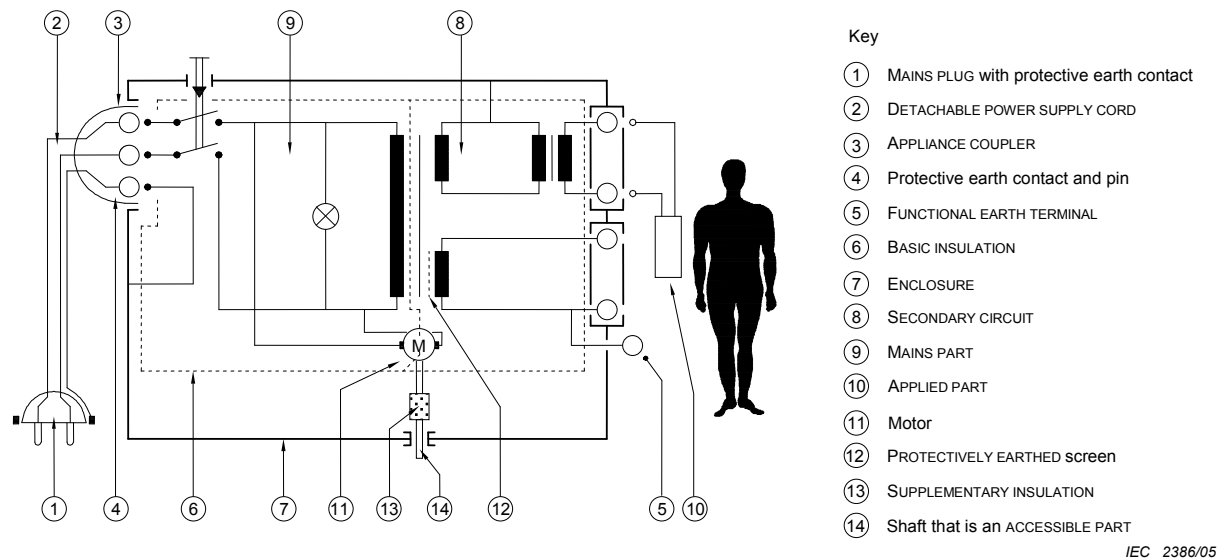


Figure 3 – Example of a CLASS I ME EQUIPMENT
(see definitions)

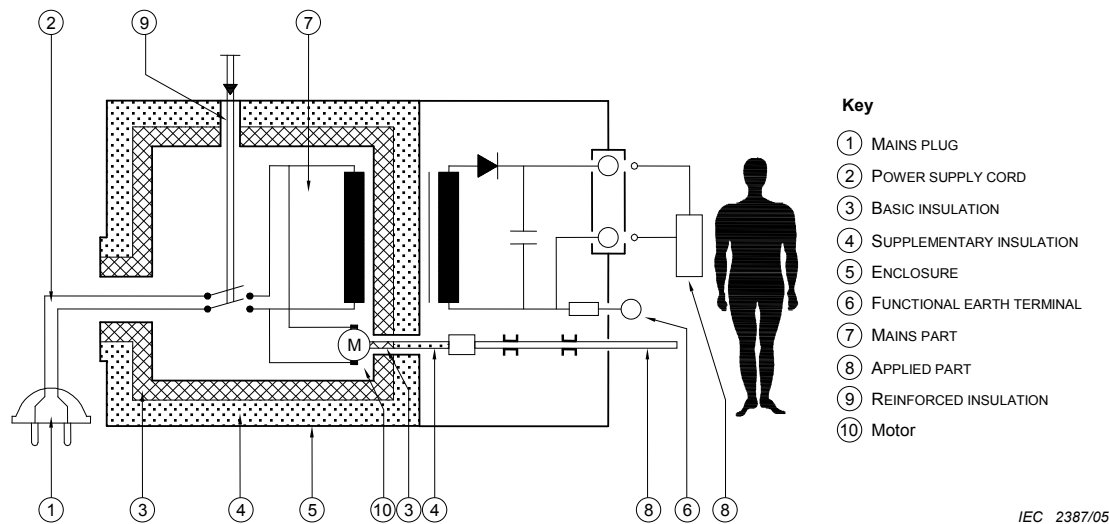


Figure 4 – Example of a metal-enclosed CLASS II ME EQUIPMENT
(see definitions)

3.10*** BASIC SAFETY**

freedom from unacceptable RISK directly caused by physical HAZARDS when ME EQUIPMENT is used under NORMAL CONDITION and SINGLE FAULT CONDITION

3.11**CATEGORY AP**

rating for ME EQUIPMENT or an ME EQUIPMENT part complying with specified requirements on construction, marking and documentation in order to avoid sources of ignition in a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR

3.12**CATEGORY APG**

rating for ME EQUIPMENT or an ME EQUIPMENT part complying with specified requirements on construction, marking and documentation in order to avoid sources of ignition in a FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE

3.13**CLASS I**

term referring to electrical equipment in which protection against electric shock does not rely on BASIC INSULATION only, but which includes an additional safety precaution in that means are provided for ACCESSIBLE PARTS of metal or internal parts of metal to be PROTECTIVELY EARTHED

NOTE See Figure 3.

3.14**CLASS II**

term referring to electrical equipment in which protection against electric shock does not rely on BASIC INSULATION only, but in which additional safety precautions such as DOUBLE INSULATION or REINFORCED INSULATION are provided, there being no provision for protective earthing or reliance upon installation conditions

NOTE 1 See Figure 4.

NOTE 2 CLASS II equipment can be provided with a FUNCTIONAL EARTH TERMINAL or a FUNCTIONAL EARTH CONDUCTOR. See also 8.6.8 and 8.6.9.

3.15*** CLEARLY LEGIBLE**

capable of being read by a person with normal vision

NOTE See ~~also~~ the test in 7.1.2.

3.16**COLD CONDITION**

condition obtained if electrical equipment is de-energized for a sufficiently long time to attain the ambient temperature

3.17*** COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS**

component where one or more characteristics ensure that its function is fault-free in relation to the safety requirements of this standard during the EXPECTED SERVICE LIFE of the ME EQUIPMENT in NORMAL USE and reasonably foreseeable misuse

3.18*** CONTINUOUS OPERATION**

operation in NORMAL USE for an unlimited period of time without the specified limits of temperature being exceeded

3.19**CREEPAGE DISTANCE**

shortest distance along the surface of the insulating material between two conductive parts

[IEV 151-15-50, modified]

3.20*** DEFIBRILLATION-PROOF APPLIED PART**

APPLIED PART that is protected against the effects of a discharge of a cardiac defibrillator to the PATIENT

3.21*** DETACHABLE POWER SUPPLY CORD**

flexible cord intended to be connected to electrical equipment by means of a suitable APPLIANCE COUPLER for mains supply purposes

NOTE See Figure 1, Figure 2 and Figure 3.

3.22*** DIRECT CARDIAC APPLICATION**

use of APPLIED PART that can come in direct contact with the PATIENT'S heart

3.23*** DOUBLE INSULATION**

insulation comprising both BASIC INSULATION and SUPPLEMENTARY INSULATION

[IEV 195-06-08]

NOTE DOUBLE INSULATION provides two MEANS OF PROTECTION.

3.24*** DUTY CYCLE**

maximum activation (on) time followed by minimum deactivation (off) time necessary for the safe operation of the ME EQUIPMENT

3.25**EARTH LEAKAGE CURRENT**

current flowing from the MAINS PART through or across the insulation into the PROTECTIVE EARTH CONDUCTOR **or a functional earthed connection according to 8.6.9**

3.26*** ENCLOSURE**

exterior surface of electrical equipment or parts thereof

NOTE For the purpose of testing to this standard, metal foil, with specified dimensions, applied in contact with parts of the exterior surface made of material with low conductivity or made of insulating material is considered a part of the ENCLOSURE (see Figure 2, Figure 3 and Figure 4).

3.27*** ESSENTIAL PERFORMANCE**

~~performance necessary to achieve freedom from unacceptable risk~~
performance of a clinical function, other than that related to BASIC SAFETY, where loss or degradation beyond the limits specified by the MANUFACTURER results in an unacceptable RISK

NOTE ESSENTIAL PERFORMANCE is most easily understood by considering whether its absence or degradation would result in an unacceptable RISK.

3.28**EXPECTED SERVICE LIFE**

~~maximum period of useful life as defined by the MANUFACTURER~~ time period specified by the MANUFACTURER during which the ME EQUIPMENT or ME SYSTEM is expected to remain safe for use (i.e. maintain BASIC SAFETY and ESSENTIAL PERFORMANCE)

NOTE Maintenance can be necessary during the EXPECTED SERVICE LIFE.

3.29**F-TYPE ISOLATED (FLOATING) APPLIED PART** (herein F-TYPE APPLIED PART)

APPLIED PART in which the PATIENT CONNECTIONS are isolated from other parts of the ME EQUIPMENT to such a degree that no current higher than the allowable PATIENT LEAKAGE CURRENT flows if an unintended voltage originating from an external source is connected to the PATIENT, and thereby applied between the PATIENT CONNECTION and earth

NOTE F-TYPE APPLIED PARTS are either TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS.

3.30**FIXED**

term meaning fastened or otherwise secured at a specific location either permanently or so that it can only be detached by means of a TOOL

EXAMPLE 1 Permanently affixed by welding, etc.

EXAMPLE 2 Affixed by means of fasteners (screws, nuts, etc.) making removal/opening impossible without using a TOOL.

NOTE See the taxonomy in the rationale for definition 3.63.

3.31**FLAMMABLE ANAESTHETIC MIXTURE WITH AIR**

mixture of a flammable anaesthetic vapour with air in such a concentration that ignition can occur under specified conditions

3.32**FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE**

mixture of a flammable anaesthetic vapour with oxygen or with nitrous oxide in such a concentration that ignition can occur under specified conditions

3.33*** FUNCTIONAL CONNECTION**

connection, electrical or otherwise, including those intended to transfer signals, data, power or substances

NOTE Connection to a FIXED SUPPLY MAINS socket-outlet, whether single or multiple, is not considered to result in a FUNCTIONAL CONNECTION.

3.34**FUNCTIONAL EARTH CONDUCTOR**

conductor to be connected to a FUNCTIONAL EARTH TERMINAL

NOTE See Figure 2.

3.35*** FUNCTIONAL EARTH TERMINAL**

terminal, directly connected to a circuit or to a screening part, that is intended to be earthed for functional purposes

NOTE See Figure 2, Figure 3 and Figure 4.

3.36**GUARD**

part of equipment specifically used to provide protection by means of a physical barrier

NOTE Depending on its construction, a GUARD can be called a casing, cover, screen, door, enclosing guard, etc. A GUARD can act:

- alone; it is then only effective when it is in place;
- in conjunction with an interlocking device with or without guard locking; in this case, protection is ensured whatever the position of the GUARD.

3.37**HAND-HELD**

~~term referring to electrical equipment intended to be supported by the hand during NORMAL USE~~
 term referring to equipment that, once installed and placed into service, is intended to be supported by the hand

NOTE 1 Equipment can refer to ACCESSORIES or equipment parts.

NOTE 2 See the taxonomy in the rationale for definition 3.63.

3.38*** HARM**

physical injury or damage to the health of people or animals, or damage to property or the environment

[ISO 14971:20002007, definition 2.2, modified]

3.39**HAZARD**

potential source of HARM

[ISO 14971:20002007, definition 2.3]

3.40*** HAZARDOUS SITUATION**

circumstance in which people, property, or the environment are exposed to one or more HAZARD(S)

~~[ISO/IEC Guide 51:1999, definition 3.6]~~ ISO 14971:2007, definition 2.4]

3.41**HIGH VOLTAGE**

voltage over 1 000 V a.c. or over 1 500 V d.c. or over 1 500 V peak value

3.42**HYDRAULIC TEST PRESSURE**

pressure applied to test a vessel or part of it

NOTE See 9.7.5.

3.43**INSULATION CO-ORDINATION**

mutual correlation of insulation characteristics of electrical equipment taking into account the expected micro-environment and other influencing stresses

NOTE This includes insulation types, CREEPAGE DISTANCES, AIR CLEARANCES, distance through insulation, coatings, encapsulation, environmental aspects, etc.

3.44*** INTENDED USE****INTENDED PURPOSE**

~~use-of for which~~ a product, PROCESS or service ~~in accordance with~~ is intended according to the specifications, instructions and information provided by the MANUFACTURER

[ISO 14971:20002007, definition 2.5]

NOTE INTENDED USE should not be confused with NORMAL USE. While both include the concept of use as intended by the MANUFACTURER, INTENDED USE focuses on the medical purpose while NORMAL USE incorporates not only the medical purpose, but maintenance, ~~service~~, transport, etc. as well.

3.45**INTERNAL ELECTRICAL POWER SOURCE**

electrical power source for operating equipment that is a part of the equipment and which produces electrical current from some other form of energy

EXAMPLE Chemical, mechanical, solar, or nuclear

NOTE An INTERNAL ELECTRICAL POWER SOURCE can be inside the principal part of equipment, attached to the outside, or contained in a separate ENCLOSURE.

3.46**INTERNALLY POWERED**

term referring to electrical equipment that is able to operate from an INTERNAL ELECTRICAL POWER SOURCE

3.47**LEAKAGE CURRENT**

current that is not functional

NOTE The following LEAKAGE CURRENTS are defined: EARTH LEAKAGE CURRENT, TOUCH CURRENT and PATIENT LEAKAGE CURRENT.

3.48**MAINS CONNECTOR**

part of an APPLIANCE COUPLER integral with or intended to be attached to a flexible cord that is intended to be connected to the SUPPLY MAINS

NOTE A MAINS CONNECTOR is intended to be inserted into the APPLIANCE INLET of electrical equipment (see Figure 1 and Figure 2).

3.49*** MAINS PART**

~~electrical circuit~~ part of electrical equipment forming a circuit that is intended to be connected to the SUPPLY MAINS

NOTE 1 The MAINS PART includes all conductive parts that are not separated from the SUPPLY MAINS by at least one MEANS OF PROTECTION.

NOTE 2 For the purpose of this definition, the PROTECTIVE EARTH CONDUCTOR is not regarded as a part of the MAINS PART (see Figure 2 and Figure 3).

3.50*** MAINS PLUG**

part, integral with or intended to be attached to a POWER SUPPLY CORD of electrical equipment, to be inserted into a mains socket-outlet

NOTE 1 See Figure 1.

NOTE 2 See also IEC 60083 and IEC 60309-1 [8].

3.51**MAINS SUPPLY TRANSFORMER**

static piece of equipment with two or more windings which, by electro-magnetic induction, transforms an alternating voltage and current from a SUPPLY MAINS into a voltage and current usually of different values at the same frequency

3.52**MAINS TERMINAL DEVICE**

TERMINAL DEVICE by which the electrical connection to the SUPPLY MAINS is made

NOTE See Figure 2.

3.53**MAINS TRANSIENT VOLTAGE**

highest peak voltage expected at the power input to the electrical equipment, arising from external transients on the SUPPLY MAINS

3.54**MAINS VOLTAGE**

voltage of a SUPPLY MAINS between two line conductors of a polyphase system or voltage between the line conductor and the neutral conductor of a single-phase system

3.55**MANUFACTURER**

natural or legal person with responsibility for the design, manufacture, packaging, or labelling of ME EQUIPMENT, assembling an ME SYSTEM, or adapting ME EQUIPMENT or an ME SYSTEM, regardless of whether these operations are performed by that person or on that person's behalf by a third party

NOTE 1 ISO 13485 [30] defines "labelling" as written, printed or graphic matter

- affixed to a medical device or any of its containers or wrappers, or
- accompanying a medical device,

related to identification, technical description, and use of the medical device, but excluding shipping documents. In this standard, that material is described as markings and ACCOMPANYING DOCUMENTS.

NOTE 2 "Adapting" includes making substantial modifications to ME EQUIPMENT or an ME SYSTEM already in use.

NOTE 3 In some jurisdictions, the RESPONSIBLE ORGANIZATION can be considered a MANUFACTURER when involved in the activities described.

NOTE 4 Adapted from ISO 14971:2000 2007, definition 2-6 2.8.

3.56*** MAXIMUM MAINS VOLTAGE**

voltage used for test purposes related to the voltage of the SUPPLY MAINS and connected to certain ME EQUIPMENT parts

NOTE The value for MAXIMUM MAINS VOLTAGE is determined according to 8.5.3.

3.57*** MAXIMUM PERMISSIBLE WORKING PRESSURE**

maximum pressure permitted on a component according to a declaration of the manufacturer of such component

3.58*** MEANS OF OPERATOR PROTECTION****MOOP**

MEANS OF PROTECTION for reducing the RISK due to electric shock to persons other than the PATIENT

3.59*** MEANS OF PATIENT PROTECTION****MOPP**

MEANS OF PROTECTION for reducing the RISK due to electric shock to the PATIENT

3.60*** MEANS OF PROTECTION****MOP**

means for reducing the RISK due to electric shock in accordance with the requirements of this standard

NOTE MEANS OF PROTECTION include insulation, AIR CLEARANCES, CREEPAGE DISTANCES, impedances, and PROTECTIVE EARTH CONNECTIONS.

3.61**MECHANICAL HAZARD**

HAZARD connected with or produced by physical force

3.62**MECHANICAL PROTECTIVE DEVICE**

device that eliminates or reduces mechanical RISK to an acceptable level and which operates in the case of SINGLE FAULT CONDITION

3.63*** MEDICAL ELECTRICAL EQUIPMENT****ME EQUIPMENT**

electrical equipment having an APPLIED PART or transferring energy to or from the PATIENT or detecting such energy transfer to or from the PATIENT and which is:

- a) provided with not more than one connection to a particular SUPPLY MAINS; and
- b) intended by its MANUFACTURER to be used:
 - 1) in the diagnosis, treatment, or monitoring of a PATIENT; or
 - 2) for compensation or alleviation of disease, injury or disability

NOTE 1 ME EQUIPMENT includes those ACCESSORIES as defined by the MANUFACTURER that are necessary to enable the NORMAL USE of the ME EQUIPMENT.

NOTE 2 Not all electrical equipment used in medical practice falls within this definition (e.g. some in vitro diagnostic equipment).

NOTE 3 The implantable parts of active implantable medical devices can fall within this definition, but they are excluded from the scope of this standard by appropriate wording in Clause 1.

NOTE 4 This standard uses the term "electrical equipment" to mean ME EQUIPMENT or other electrical equipment.

NOTE 5 See also 4.10.1, 8.2.1 and 16.3.

3.64*** MEDICAL ELECTRICAL SYSTEM****ME SYSTEM**

combination, as specified by its MANUFACTURER, of items of equipment, at least one of which is ME EQUIPMENT to be inter-connected by FUNCTIONAL CONNECTION or by use of a MULTIPLE SOCKET-OUTLET

NOTE Equipment, when mentioned in this standard, should be taken to include ME EQUIPMENT.

3.65**MOBILE**

term referring to TRANSPORTABLE equipment that, once installed and placed into service, is intended to be moved from one location to another while supported by its own wheels or equivalent means

NOTE See the taxonomy in the rationale for definition 3.63.

3.66*** MODEL OR TYPE REFERENCE**

combination of figures, letters or both used to identify a particular model of equipment or ACCESSORY

3.67*** MULTIPLE SOCKET-OUTLET****MSO**

one or more socket-outlets intended to be connected to, or integral with, flexible cables, ~~or~~ cords or ME EQUIPMENT ~~for~~ providing SUPPLY MAINS or equivalent voltage

NOTE A MULTIPLE SOCKET-OUTLET can be a separate item or an integral part of equipment.

3.68*** NETWORK/DATA COUPLING**

any means to transmit or receive information to or from other equipment in accordance with the MANUFACTURER'S specifications

3.69**NOMINAL (value)**

value quoted for reference purposes that is subject to agreed tolerances

EXAMPLE NOMINAL MAINS VOLTAGE or NOMINAL diameter of a screw

3.70**NORMAL CONDITION**

condition in which all means provided for protection against HAZARDS are intact

3.71**NORMAL USE**

operation, including routine inspection and adjustments by any OPERATOR, and stand-by, according to the instructions for use

NOTE NORMAL USE should not be confused with INTENDED USE. While both include the concept of use as intended by the MANUFACTURER, INTENDED USE focuses on the medical purpose while NORMAL USE incorporates not only the medical purpose, but maintenance, ~~service~~, transport, etc. as well.

3.72**OBJECTIVE EVIDENCE**

~~information which can be proven true, based on facts obtained through observation, measurement, test or other means~~ data supporting the existence or verity of something

NOTE Objective evidence can be obtained through observation, measurement, testing or other means.

[ISO 14971:2000 2007, definition ~~2-8~~ 2.10]

3.73*** OPERATOR**

person handling equipment

NOTE See also 3.101.

3.74**OVER-CURRENT RELEASE**

protective device that causes a circuit to open, with or without time-delay, when the current in the device exceeds a predetermined value

[IEV 441-16-33, modified]

3.75*** OXYGEN RICH ENVIRONMENT**

environment in which the concentration of oxygen is:

- a) greater than 25 % for ambient pressures up to 110 kPa; or
- b) the partial pressure of oxygen is greater than 27,5 kPa at ambient pressures exceeding 110 kPa

3.76**PATIENT**

living being (person or animal) undergoing a medical, surgical or dental procedure

NOTE A PATIENT can be an OPERATOR.

3.77*** PATIENT AUXILIARY CURRENT**

current flowing in the PATIENT in NORMAL USE between any PATIENT CONNECTION and all other PATIENT CONNECTIONS and not intended to produce a physiological effect

3.78*** PATIENT CONNECTION**

individual point on the APPLIED PART through which current can flow between the PATIENT and the ME EQUIPMENT in NORMAL CONDITION or SINGLE FAULT CONDITION

3.79*** PATIENT ENVIRONMENT**

any volume in which intentional or unintentional contact can occur between a PATIENT and parts of the ME EQUIPMENT or ME SYSTEM or between a PATIENT and other persons touching parts of the ME EQUIPMENT or ME SYSTEM

3.80**PATIENT LEAKAGE CURRENT**

current:

- flowing from the PATIENT CONNECTIONS via the PATIENT to earth; or
- originating from the unintended appearance of a voltage from an external source on the PATIENT and flowing from the PATIENT via the PATIENT CONNECTIONS of an F-TYPE APPLIED PART to earth

3.81*** PEAK WORKING VOLTAGE**

highest peak or d.c. value of a WORKING VOLTAGE, including repetitive peak impulses generated in the electrical equipment, but not including external transients

[IEC 60950-1:2004 2005, definition 1.2.9.7 1.2.9.8, modified]

3.82**PEMS DEVELOPMENT LIFE-CYCLE**

necessary activities occurring during a period of time that starts at the concept phase of a project and finishes when the PEMS VALIDATION is complete

NOTE See also 3.90.

3.83**PEMS VALIDATION**

PROCESS of evaluating a PEMS or a component of a PEMS during or at the end of the development PROCESS, to determine whether it satisfies the requirements for its INTENDED USE

NOTE See also 3.90.

3.84**PERMANENTLY INSTALLED**

term meaning electrically connected to the SUPPLY MAINS by means of a permanent connection that can only be detached by the use of a TOOL

3.85**PORTABLE**

term referring to TRANSPORTABLE equipment that, once installed and placed into service, is intended to be moved from one location to another while being carried by one or more persons

NOTE 1 Equipment can refer to ACCESSORIES or equipment parts.

NOTE 2 See the taxonomy in the rationale for definition 3.63.

3.86**POTENTIAL EQUALIZATION CONDUCTOR**

conductor other than a PROTECTIVE EARTH CONDUCTOR or a neutral conductor, providing a direct connection between electrical equipment and the potential equalization busbar of the electrical installation

NOTE See Figure 2.

3.87**POWER SUPPLY CORD**

flexible cord, FIXED to or assembled with electrical equipment for connection to SUPPLY MAINS

NOTE See Figure 1 to Figure 4 (inclusive).

3.88**PROCEDURE**

specified way to ~~perform~~ carry out an activity or a PROCESS

[ISO 14971:2000 2007, definition 2.9 2.12]

3.89**PROCESS**

set of inter-related ~~or interacting resources and~~ activities which transforms inputs into outputs
[ISO 14971:2000 2007, definition 2.10 2.13]

3.90**PROGRAMMABLE ELECTRICAL MEDICAL SYSTEM****PEMS**

ME EQUIPMENT or an ME SYSTEM containing one or more PROGRAMMABLE ELECTRONIC SUBSYSTEMS (PESS)

3.91**PROGRAMMABLE ELECTRONIC SUBSYSTEM****PESS**

system based on one or more central processing units, including their software and interfaces

3.92**PROPERLY INSTALLED**

installed in accordance with the ACCOMPANYING DOCUMENTS

3.93**PROTECTIVE EARTH CONDUCTOR**

conductor to be connected between the PROTECTIVE EARTH TERMINAL and an external protective earthing system

NOTE See Figure 2.

3.94**PROTECTIVE EARTH CONNECTION**

connection to the PROTECTIVE EARTH TERMINAL provided for protective purposes and complying with the requirements of this standard

3.95**PROTECTIVE EARTH TERMINAL**

terminal connected to conductive parts of CLASS I equipment for safety purposes. This terminal is intended to be connected to an external protective earthing system by a PROTECTIVE EARTH CONDUCTOR

NOTE See Figure 2.

3.96**PROTECTIVELY EARTHED**

connected to the PROTECTIVE EARTH TERMINAL for protective purposes by means complying with the requirements of this standard

3.97**RATED (value)**

term referring to a value assigned by the MANUFACTURER for a specified operating condition

3.98**RECORD**

~~document which furnishes OBJECTIVE EVIDENCE of activities performed or results achieved~~
document stating results achieved or providing evidence of activities performed

[ISO 14971:2000 2007, definition 2.14 2.14]

3.99*** REINFORCED INSULATION**

single insulation system that provides two MEANS OF PROTECTION

3.100**RESIDUAL RISK**

RISK remaining after ~~protective~~ RISK CONTROL measures have been taken

[ISO 14971:2000 2007, definition 2-12 2.15]

3.101**RESPONSIBLE ORGANIZATION**

entity accountable for the use and maintenance of an ME EQUIPMENT or an ME SYSTEM

NOTE 1 The accountable entity can be, for example, a hospital, an individual clinician or a layperson. In home use applications, the PATIENT, OPERATOR and RESPONSIBLE ORGANIZATION can be one and the same person.

NOTE 2 Education and training is included in "use."

3.102**RISK**

combination of the probability of occurrence of HARM and the SEVERITY of that HARM

[ISO 14971:2000 2007, definition 2-13 2.16]

3.103**RISK ANALYSIS**

systematic use of available information to identify HAZARDS and to estimate the RISK

[ISO 14971:2000 2007, definition 2-14 2.17]

3.104**RISK ASSESSMENT**

overall PROCESS comprising a RISK ANALYSIS and a RISK EVALUATION

[ISO 14971:2000 2007, definition 2-15 2.18]

3.105**RISK CONTROL**

~~PROCESS through which decisions are reached and protective measures are implemented for reducing risks to, or maintaining risks within, specified levels~~ PROCESS in which decisions are made and measures implemented by which RISKS are reduced to, or maintained within, specified levels

[ISO 14971:2000 2007, definition 2-16 2.19]

3.106**RISK EVALUATION**

~~judgement, on the basis of RISK ANALYSIS, of whether a RISK which is acceptable has been achieved in a given context based on the current values of society~~ PROCESS of comparing the estimated RISK against given RISK criteria to determine the acceptability of the RISK

[ISO 14971:2000 2007, definition 2-17 2.21]

3.107**RISK MANAGEMENT**

systematic application of management policies, PROCEDURES and practices to the tasks of analyzing, evaluating and controlling RISK

[ISO 14971:2000 2007, definition 2-18 2.22]

NOTE For the purposes of this standard, RISK MANAGEMENT does not include planning for or monitoring of production and post-production information; whereas this is required for compliance with ISO 14971 (see 4.2.2).

3.108**RISK MANAGEMENT FILE**

set of RECORDS and other documents, ~~not necessarily contiguous~~, that are produced by a RISK MANAGEMENT ~~PROCESS~~

[ISO 14971:2000 2007, definition 2-19 2.23]

NOTE All safety related information including MANUFACTURER'S calculations, test results, etc. is considered to be part of the RISK MANAGEMENT FILE. See also 4.2.

3.109

SAFE WORKING LOAD

maximum external mechanical load (mass) on equipment or an equipment part that is permitted in NORMAL USE

3.110

* SECONDARY CIRCUIT

circuit which is separated from the MAINS PART by at least one MEANS OF PROTECTION and derives its power from a transformer, converter or equivalent isolation device, or from an INTERNAL ELECTRICAL POWER SOURCE

NOTE See also 8.9.1.12.

3.111

SELF-RESETTING THERMAL CUT-OUT

THERMAL CUT-OUT that automatically restores the current after the relevant part of electrical equipment has cooled

3.112

* SEPARATION DEVICE

component or arrangement of components with input parts and output parts that, for safety reasons, prevents a transfer of unwanted voltage or current between parts of an ME SYSTEM

3.113

SERVICE PERSONNEL

individuals or entity accountable to the RESPONSIBLE ORGANIZATION that install, assemble, maintain or repair ME EQUIPMENT, ME SYSTEMS or equipment

3.114

SEVERITY

measure of the possible consequences of a HAZARD

[ISO 14971:2000 2007, definition 2-24 2.25]

3.115

* SIGNAL INPUT/OUTPUT PART

SIP/SOP

part of ME EQUIPMENT, not being an APPLIED PART, intended to deliver or receive signals to or from other electrical equipment, for example, for display, recording or data processing

NOTE See Figure 2.

3.116

SINGLE FAULT CONDITION

condition of ME EQUIPMENT in which a single means for reducing a RISK is defective or a single abnormal condition is present

NOTE See 4.7 and 13.2.

3.117

SINGLE FAULT SAFE

characteristic of ME EQUIPMENT or its parts whereby it remains free of unacceptable RISK during its EXPECTED SERVICE LIFE under SINGLE FAULT CONDITIONS

NOTE See 4.7.

3.118**STATIONARY**

term referring to equipment that, **once installed and placed into service**, is not intended to be moved from one place to another

NOTE See the taxonomy in the rationale for definition 3.63.

3.119**SUPPLEMENTARY INSULATION**

independent insulation applied in addition to BASIC INSULATION in order to provide protection against electric shock in the event of a failure of BASIC INSULATION

[IEV 826-12-15, modified]

NOTE SUPPLEMENTARY INSULATION provides one MEANS OF PROTECTION.

3.120*** SUPPLY MAINS**

source of electrical energy not forming part of ME EQUIPMENT or ME SYSTEM

NOTE This also includes battery systems and converter systems in ambulances and the like.

3.121**TENSILE SAFETY FACTOR**

ratio between TENSILE STRENGTH and the stress corresponding to the TOTAL LOAD

3.122**TENSILE STRENGTH**

maximum tensile stress a test piece will withstand before rupturing

3.123**TERMINAL DEVICE**

part of electrical equipment by which electrical connection is made

NOTE A TERMINAL DEVICE can contain several individual contacts.

3.124**THERMAL CUT-OUT**

device that, during an abnormal condition, limits the temperature of electrical equipment or of part of it, by automatically opening the circuit or by reducing the current, and that is so constructed that its setting cannot be altered except by qualified SERVICE PERSONNEL

3.125**THERMAL STABILITY**

condition under which the temperature of an object does not increase by more than 2 °C over a period of 1 h

3.126**THERMOSTAT**

temperature sensing control that is intended to keep a temperature within a specific range or above/below a preset value

3.127**TOOL**

extra-corporeal object that can be used to secure or release fasteners or to make adjustments

NOTE Coins and keys are considered TOOLS within the context of this standard.

3.128**TOTAL LOAD**

maximum total loading of a part including the maximum SAFE WORKING LOAD, where applicable, and the static and dynamic forces occurring in NORMAL USE

NOTE 1 Examples of dynamic forces include forces caused by acceleration or deceleration of masses.

NOTE 2 Where a load is divided over several parallel supporting parts and the distribution over these parts is not determined unequivocally, the least favourable possibility is to be considered.

3.129

TOUCH CURRENT

LEAKAGE CURRENT flowing from the ENCLOSURE or from parts thereof, excluding PATIENT CONNECTIONS, accessible to any OPERATOR or PATIENT in NORMAL USE, through an external path other than the PROTECTIVE EARTH CONDUCTOR, to earth or to another part of the ENCLOSURE

NOTE The meaning of this term is the same as that of "enclosure leakage current" in the first and second editions of this standard. The term has been changed to align with IEC 60950-1 and to reflect the fact that the measurement now applies also to parts that are normally PROTECTIVELY EARTHED.

3.130

TRANSPORTABLE

term referring to equipment that, **once installed and placed into service**, is intended to be moved from one place to another whether or not connected to a supply and without an appreciable restriction of range

EXAMPLE MOBILE equipment, ~~and~~ PORTABLE equipment. **and BODY-WORN equipment**

NOTE See the taxonomy in the rationale for definition 3.63.

3.131

TRAPPING ZONE

accessible location on or within the ME EQUIPMENT, ME SYSTEM or in the equipment environment where a human body or a part of the human body is exposed to a trapping, crushing, shearing, impact, cutting, entanglement, drawing in, stabbing or abrasion HAZARD

3.132

* TYPE B APPLIED PART

APPLIED PART complying with the specified requirements of this standard to provide protection against electric shock, particularly regarding allowable PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT

NOTE 1 A TYPE B APPLIED PART is marked with symbol IEC 60417-5840 (~~DB~~:2002-10) (see Table D.1, symbol 19) or, when applicable, with symbol IEC 60417-5841 (~~DB~~:2002-10) (see Table D.1, symbol 25). See also 3.20.

NOTE 2 TYPE B APPLIED PARTS are not suitable for DIRECT CARDIAC APPLICATION.

NOTE 3 See also 4.6 regarding the treatment of parts that do not fall within the definition of APPLIED PARTS but need to be considered as APPLIED PARTS as a result of applying the RISK MANAGEMENT PROCESS.

3.133

* TYPE BF APPLIED PART

F-TYPE APPLIED PART complying with the specified requirements of this standard to provide a higher degree of protection against electric shock than that provided by TYPE B APPLIED PARTS

NOTE 1 A TYPE BF APPLIED PART is marked with symbol IEC 60417-5333 (~~DB~~:2002-10) (see Table D.1, symbol 20) or, when applicable, with symbol 60417-5334 (~~DB~~:2002-10) (see Table D.1, symbol 26). See also 3.20.

NOTE 2 TYPE BF APPLIED PARTS are not suitable for DIRECT CARDIAC APPLICATION.

NOTE 3 See also 4.6 regarding the treatment of parts that do not fall within the definition of APPLIED PARTS but need to be considered as APPLIED PARTS as a result of applying the RISK MANAGEMENT PROCESS.

3.134

* TYPE CF APPLIED PART

F-TYPE APPLIED PART complying with the specified requirements of this standard to provide a higher degree of protection against electric shock than that provided by TYPE BF APPLIED PARTS

NOTE 1 A TYPE CF APPLIED PART is marked with symbol IEC 60417-5335 (~~DB~~:2002-10) (see Table D.1, symbol 21) or, when applicable, with symbol 60417-5336 (~~DB~~:2002-10) (see Table D.1, symbol 27). See also 3.20.

NOTE 2 See also 4.6 regarding the treatment of parts that do not fall within the definition of APPLIED PARTS but need to be considered as APPLIED PARTS as a result of applying the RISK MANAGEMENT PROCESS.

NOTE 3 See the rationale for the definition of DIRECT CARDIAC APPLICATION (3.22) concerning the applied parts that need to be TYPE CF APPLIED PARTS.

3.135**TYPE TEST**

test on a representative sample of the equipment with the objective of determining if the equipment, as designed and manufactured, can meet the requirements of this standard

3.136**USABILITY**

characteristic of the OPERATOR interface that establishes effectiveness, efficiency, ease of OPERATOR learning and OPERATOR learnability and satisfaction

[~~IEC 60601-1-6:2004, definition 2.211~~ IEC 62366:2007, definition 3.17, modified]

3.137**USABILITY ENGINEERING**

application of knowledge about human behaviour, abilities, limitations, and other characteristics to the design of tools, ~~machines, equipment~~, devices, systems, tasks, jobs, and environments to achieve adequate USABILITY

[~~IEC 60601-1-6:2004, definition 2.212~~ IEC 62366:2007, definition 3.18]

3.138**VERIFICATION**

confirmation ~~by examination and, through the~~ provision of OBJECTIVE EVIDENCE that specified requirements have been fulfilled

NOTE—In design and development, VERIFICATION concerns the PROCESS of examining the result of a given activity to determine conformity with the stated requirements for that activity.

NOTE 1 The term "verified" is used to designate the corresponding status.

NOTE 2 Confirmation can comprise activities such as:

- performing alternative calculations;
- comparing a new design specification with a similar proven design specification;
- undertaking tests and demonstrations;
- reviewing documents prior to issue.

[ISO 14971:2000 2007, definition 2.22 2.28]

3.139*** WORKING VOLTAGE**

highest voltage to which the insulation or the component under consideration is, or can be, subjected when the electrical equipment is operating under conditions of NORMAL USE

[IEC 60950-1:2004 2005, definition 1.2.9.6]

3.140**AIR KERMA**

K

quotient of dE_{tr} by dm , where dE_{tr} is the sum of the initial kinetic energies of all the charged particles liberated by uncharged particles in a mass dm of air, thus

$$K = \frac{dE_{tr}}{dm}$$

Unit: J kg⁻¹

The special name for the unit of AIR KERMA is gray (Gy) (ICRU 60)

[IEC 60601-1-3:2008, definition 3.4]

3.141**ALARM CONDITION**

state of the ALARM SYSTEM when it has determined that a potential or actual HAZARDOUS SITUATION exists for which OPERATOR awareness or response is required

NOTE 1 An ALARM CONDITION can be invalid, i.e. a false positive ALARM CONDITION.

NOTE 2 An ALARM CONDITION can be missed, i.e. a false negative ALARM CONDITION.

[IEC 60601-1-8:2006 / Amendment 1 (2012), definition 3.1]

3.142

ALARM SIGNAL

type of signal generated by the ALARM SYSTEM to indicate the presence (or occurrence) of an ALARM CONDITION

[IEC 60601-1-8:2006, definition 3.9]

3.143

ALARM SYSTEM

parts of ME EQUIPMENT or a ME SYSTEM that detect ALARM CONDITIONS and, as appropriate, generate ALARM SIGNALS

[IEC 60601-1-8:2006, definition 3.11]

3.144

BODY-WORN

term referring to TRANSPORTABLE equipment whose INTENDED USE includes operation while being worn by a PATIENT or attached to a PATIENT'S clothing

NOTE 1 TRANSPORTABLE equipment can be both BODY-WORN and HAND-HELD.

[IEC 60601-1-11:2010, definition 3.1]

NOTE 2 See the taxonomy in the rationale for definition 3.63.

3.145

IT-NETWORK

INFORMATION TECHNOLOGY NETWORK

a system or systems composed of communicating nodes and transmission links to provide physically linked or wireless transmission between two or more specified communication nodes

[IEC 80001-1:2010, definition 2.12]

3.146

PRIMARY OPERATING FUNCTION

function that involves OPERATOR interaction that is frequently used or related to the safety of the ME EQUIPMENT

[IEC 62366:2007, definition 3.14, modified]

3.147

USABILITY ENGINEERING FILE

set of RECORDS and other documents that are produced by the USABILITY ENGINEERING PROCESS

[IEC 62366:2007, definition 3.19]

4 General requirements

4.1 * Conditions for application to ME EQUIPMENT or ME SYSTEMS

Unless otherwise specified, the requirements of this standard shall apply in NORMAL USE and reasonably foreseeable misuse.

When applying this standard to ME EQUIPMENT or ME SYSTEMS intended for the compensation or alleviation of disease, injury or disability, the definitions and requirements that use the term

PATIENT shall be considered as applying to the person for whom the ME EQUIPMENT or ME SYSTEM is intended.

4.2 * RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS

~~A RISK MANAGEMENT PROCESS complying with ISO 14971 shall be performed.~~

~~In applying ISO 14971:~~

- ~~— The term “medical device” shall assume the same meaning as ME EQUIPMENT or ME SYSTEM.~~
- ~~— The term “fault conditions” referred to in ISO 14971 shall include, but shall not be limited to, SINGLE FAULT CONDITIONS identified in this standard.~~
- ~~— The policy for determining acceptable RISK and the acceptability of the RESIDUAL RISK(S) shall be established by the MANUFACTURER.~~
- ~~— Where this standard or any of its collateral or particular standards specify verifiable requirements addressing particular RISKS, and these requirements are complied with, the RESIDUAL RISKS addressed by these requirements shall be presumed to be acceptable unless there is OBJECTIVE EVIDENCE to the contrary.~~

~~NOTE 1 This standard specifies requirements that are generally applicable to RISKS associated with ME EQUIPMENT or ME SYSTEMS, and is intended to serve as a tool during the RISK MANAGEMENT PROCESS. The RISK MANAGEMENT PROCESS should identify not only those HAZARDS addressed by this standard, but all HAZARDS, their associated RISKS and RISK CONTROL measures.~~

~~NOTE 2 Conditions or faults that can give rise to HAZARDS are identified in the clauses of this standard. In these cases, it will often be necessary to carry out a RISK MANAGEMENT PROCESS to determine what the actual HAZARDS are and the tests that need to be done to show that the identified HAZARDS do not arise in the specified circumstances.~~

~~NOTE 3 It is recognized that the MANUFACTURER might not be able to follow all the PROCESSES identified in this standard for each constituent component of the ME EQUIPMENT or ME SYSTEM, such as proprietary components, subsystems of non-medical origin, and legacy devices. In this case, the MANUFACTURER should take special account of the need for additional RISK CONTROL measures.~~

~~NOTE 4 Where requirements of this standard refer to freedom from unacceptable RISK, acceptability or unacceptability of this RISK is determined by the MANUFACTURER in accordance with the MANUFACTURER'S policy for determining acceptable RISK.~~

~~NOTE 5 Not all the RISKS associated with ME EQUIPMENT and ME SYSTEMS are subject to specific requirements of this standard (see 1.1).~~

~~Compliance is checked by inspection of the RISK MANAGEMENT FILE. The requirements of this clause and all requirements of this standard referring to inspection of the RISK MANAGEMENT FILE are considered to be satisfied if the MANUFACTURER has:~~

- ~~— established a RISK MANAGEMENT PROCESS;~~
- ~~— established acceptable levels of RISK; and~~
- ~~— demonstrated that the RESIDUAL RISK(S) is acceptable (in accordance with the policy for determining acceptable RISK).~~

4.2.1 Introduction to RISK MANAGEMENT

Subclause 4.2 specifies the RISK MANAGEMENT PROCESS that is required for compliance with this standard. This RISK MANAGEMENT PROCESS is intended to serve the following purposes:

- a) To identify whether the normative requirements specified in Clauses 5 to 17 of this standard, together with the requirements of applicable collateral and particular standards, address all the HAZARDS associated with the particular ME EQUIPMENT or ME SYSTEM under consideration.
- b) To identify the way in which some particular tests specified in this standard should be applied to a particular ME EQUIPMENT or ME SYSTEM.
- c) To identify whether particular HAZARDS or HAZARDOUS SITUATIONS for which this standard does not provide specific acceptance criteria result in any RISKS for a particular ME EQUIPMENT or ME SYSTEM, and, if so, to establish acceptable RISK levels and evaluate the RESIDUAL RISKS.

- d) To evaluate the acceptability of alternative RISK CONTROL strategies by comparing RESIDUAL RISK with that achieved by applying the full requirements of this standard.

Although the RISK MANAGEMENT PROCESS specified in this standard is required to comply with the relevant requirements of ISO 14971, it is not as extensive as and does not include all of the elements required for compliance with ISO 14971. For example, the RISK MANAGEMENT PROCESS required for compliance with this standard does not include the production and post-production monitoring required in ISO 14971. Furthermore, verification of compliance with the RISK MANAGEMENT requirements of this standard can be accomplished by examination of the RECORDS and other documentation required by this standard and assessment of the processes cited in this standard and does not require auditing of the RISK MANAGEMENT PROCESS.

4.2.2 General requirement for RISK MANAGEMENT

A RISK MANAGEMENT PROCESS complying with ISO 14971 shall be performed. For compliance with this standard, all elements of the ISO 14971:2007 RISK MANAGEMENT PROCESS shall be applied except:

- the planning for and execution of production and post-production monitoring (subclause 3.1, fourth dash, subclause 3.4, item f), and Clause 9 of ISO 14971:2007), and
- periodic reviews of the suitability of the RISK MANAGEMENT PROCESS (subclause 3.2, fourth dash, of ISO 14971:2007).

When applying any of the requirements of ISO 14971:

- the term “medical device” shall assume the same meaning as ME EQUIPMENT or ME SYSTEM; and
- the term “fault conditions” referred to in ISO 14971 shall include, but shall not be limited to, SINGLE FAULT CONDITIONS identified in this standard.

NOTE 1 This standard specifies requirements that are generally applicable to RISKS associated with the ME EQUIPMENT or ME SYSTEMS. Those requirements are intended to facilitate the RISK MANAGEMENT PROCESS. The RISK MANAGEMENT PROCESS is aimed at identifying not only those HAZARDS addressed by this standard, but all HAZARDS, their associated RISKS and RISK CONTROL measures.

NOTE 2 Conditions or faults that can give rise to HAZARDOUS SITUATIONS are identified in the clauses of this standard. In these cases, it will often be necessary to carry out a RISK MANAGEMENT PROCESS to determine what the actual HAZARDOUS SITUATIONS are and the tests that need to be done to show that the identified HAZARDOUS SITUATIONS do not arise in the specified circumstances.

NOTE 3 It is recognized that the MANUFACTURER might not be able to follow all the PROCESSES identified in this standard for each constituent component of the ME EQUIPMENT or ME SYSTEM, such as proprietary components, subsystems of non-medical origin, and legacy devices. In this case, the MANUFACTURER would need to take special account of the need for additional RISK CONTROL measures.

NOTE 4 Where requirements of this standard refer to freedom from unacceptable RISK, acceptability or unacceptability of this RISK is determined by the MANUFACTURER in accordance with the MANUFACTURER'S policy for determining acceptable RISK.

NOTE 5 Not all the RISKS associated with the ME EQUIPMENT or ME SYSTEM are subject to specific requirements of this standard (see 1.1).

Compliance is checked by:

- *inspection of the MANUFACTURER'S policy for determining criteria for RISK acceptability;*
- *inspection of the RISK MANAGEMENT plan for the particular ME EQUIPMENT or ME SYSTEM under consideration; and*
- *confirming the MANUFACTURER has prepared a RISK MANAGEMENT FILE containing the RISK MANAGEMENT RECORDS and other documentation required by this standard for the particular ME EQUIPMENT or ME SYSTEM under consideration.*

NOTE 6 It is helpful to keep an index containing references or pointers to the RISK MANAGEMENT RECORDS and other documentation required by this standard.

4.2.3 Evaluating RISK

4.2.3.1 HAZARDS identified in the IEC 60601-series

The requirements of this standard shall be applied in the following way when evaluating RISK:

- a) Where this standard or its collateral or particular standards specify requirements addressing particular HAZARDS or HAZARDOUS SITUATIONS, together with specific acceptance criteria, compliance with these requirements is presumed to establish that the RESIDUAL RISKS have been reduced to acceptable levels unless there is OBJECTIVE EVIDENCE to the contrary.

EXAMPLE 1 Subclause 8.5.1.2, MEANS OF PATIENT PROTECTION (MOPP)

EXAMPLE 2 Subclause 9.4.2.1, Instability in transport position

Compliance is checked by satisfying the relevant requirements of this standard and its collateral and particular standards.

- b) Where this standard or its collateral or particular standards specify requirements addressing particular HAZARDS or HAZARDOUS SITUATIONS but do not provide specific acceptance criteria, the MANUFACTURER shall provide the acceptance criteria defined in the RISK MANAGEMENT plan. These acceptance criteria shall ensure that the RESIDUAL RISK is acceptable according to the criteria for RISK acceptability recorded in the RISK MANAGEMENT plan.

EXAMPLE 3 Subclause 9.8.3.3, Dynamic forces due to loading from persons

EXAMPLE 4 Subclause 11.6.3, Spillage on ME EQUIPMENT and ME SYSTEMS

Compliance is checked by confirming that the RECORDS in the RISK MANAGEMENT FILE demonstrate that, after applying the specific requirements of this standard, the acceptance criteria determined by the MANUFACTURER are satisfied. Only the relevant parts of the RISK MANAGEMENT FILE need to be reviewed, e.g. the MANUFACTURER'S calculations or test results, or the determination of RISK acceptability.

- c) Where this standard or its collateral or particular standards identify particular HAZARDS or HAZARDOUS SITUATIONS that have to be investigated without providing specific technical requirements:

- the MANUFACTURER shall determine whether such HAZARDS or HAZARDOUS SITUATIONS exist for the particular ME EQUIPMENT or ME SYSTEM, and
- where such HAZARDS or HAZARDOUS SITUATIONS exist for the particular ME EQUIPMENT or ME SYSTEM, the MANUFACTURER shall evaluate and (if necessary) control these RISKS following the RISK MANAGEMENT PROCESS specified in 4.2.2.

EXAMPLE 5 Subclause 10.2, Alpha, beta, gamma, neutron and other particle radiation

Compliance is checked by confirming that the RECORDS in the RISK MANAGEMENT FILE demonstrate that the RESIDUAL RISK is acceptable using the criteria for RISK acceptability recorded in the RISK MANAGEMENT plan, i.e. no unacceptable RISK remains. Only the relevant parts of the RISK MANAGEMENT FILE need to be reviewed, e.g. the MANUFACTURER'S calculations or test results, or the determination of RISK acceptability.

NOTE When ME EQUIPMENT or an ME SYSTEM has been designed in such way that for a certain type of HAZARDS or HAZARDOUS SITUATION exists, no further RISK ASSESSMENT for that HAZARD is necessary. This can be verified by tests or inspections.

4.2.3.2 HAZARDS not identified in the IEC 60601 series

For HAZARDS or HAZARDOUS SITUATIONS that are identified for the particular ME EQUIPMENT or ME SYSTEM but are not specifically addressed in this standard or its collateral or particular standards, the MANUFACTURER shall address those HAZARDS in the RISK MANAGEMENT PROCESS as specified in 4.2.2.

EXAMPLE ME EQUIPMENT or an ME SYSTEM for which there are particular RISKS but no particular standard.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

4.3 * ESSENTIAL PERFORMANCE

~~The MANUFACTURER shall identify which functions of the ME EQUIPMENT and ME SYSTEMS are ESSENTIAL PERFORMANCE. Where this standard specifies that ESSENTIAL PERFORMANCE is to be maintained following a particular test, these functions shall be used and compliance shall be checked by inspection, and if necessary, by functional test.~~

~~NOTE — Where requirements of this standard refer to ESSENTIAL PERFORMANCE, that ESSENTIAL PERFORMANCE is determined by the MANUFACTURER in accordance with the MANUFACTURER'S policy for RISK acceptability.~~

~~Compliance is checked by inspection of the RISK MANAGEMENT FILE.~~

During RISK ANALYSIS, the MANUFACTURER shall identify the performance of the clinical function(s) of the ME EQUIPMENT or ME SYSTEM, other than that related to BASIC SAFETY, that is necessary to achieve its INTENDED USE or that could affect the safety of the ME EQUIPMENT or ME SYSTEM.

The MANUFACTURER shall then specify performance limits between fully functional and total loss of the identified performance in both NORMAL CONDITION and SINGLE FAULT CONDITION.

The MANUFACTURER shall then evaluate the RISK from the loss or degradation of the identified performance beyond the limits specified by the MANUFACTURER. If the resulting RISK is unacceptable, then the identified performance constitutes an ESSENTIAL PERFORMANCE of the ME EQUIPMENT or ME SYSTEM.

The MANUFACTURER shall implement RISK CONTROL measures to reduce the RISK from the loss or degradation of the identified performance to an acceptable level.

NOTE 1 The performance of the RISK CONTROL measure might well become an aspect of the ESSENTIAL PERFORMANCE of the ME EQUIPMENT or ME SYSTEM. For example, the generation of the ALARM SIGNAL to indicate the interruption of the SUPPLY MAINS could be "essential" if an interruption of the SUPPLY MAINS could result in an unacceptable RISK if it went unattended.

The MANUFACTURER shall specify the methods used to verify the effectiveness of the RISK CONTROL measures. This shall include any assessment made to determine whether verification is needed.

NOTE 2 Following the principles of RISK MANAGEMENT, the MANUFACTURER is required to verify the effectiveness of each RISK CONTROL measure. This can involve demonstrating that the RISK CONTROL measure will operate in the presence of the conditions that result in the loss or degradation of the identified performance.

EXAMPLE 1 If ESSENTIAL PERFORMANCE is lost because of an interruption of the SUPPLY MAINS, an ALARM SYSTEM intended to notify the OPERATOR that the SUPPLY MAINS has been interrupted would need to have a backup power source so that the generation of the ALARM SIGNAL would not depend on the SUPPLY MAINS.

EXAMPLE 2 If the failure of a component results in the loss of ESSENTIAL PERFORMANCE, the design of the ME EQUIPMENT or ME SYSTEM would need to be such that the component failure does not compromise the effectiveness of any RISK CONTROL measures put in place to mitigate the RISK from the loss of the ESSENTIAL PERFORMANCE.

NOTE 3 Each collateral standard or particular standard in the IEC 60601 or the IEC/ISO 80601 series can list potential ESSENTIAL PERFORMANCES to guide the MANUFACTURER to identify particular ESSENTIAL PERFORMANCE in accordance with 4.3.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

Where this standard requires that ESSENTIAL PERFORMANCE is to be maintained following a particular test, compliance is checked by inspection and, if necessary, by functional test(s) that demonstrate the MANUFACTURER'S specified limits are maintained or the ME EQUIPMENT or ME SYSTEM transitions to a safe state as defined by the MANUFACTURER.

4.4 * EXPECTED SERVICE LIFE

The MANUFACTURER shall state the EXPECTED SERVICE LIFE of the ME EQUIPMENT or ME SYSTEM in the RISK MANAGEMENT FILE.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

4.5 ~~* Equivalent safety for ME EQUIPMENT or ME SYSTEMS~~ * Alternative RISK CONTROL measures or test methods for ME EQUIPMENT or ME SYSTEMS

~~Where this standard specifies requirements addressing particular RISKS, alternative means of addressing these RISKS are acceptable provided that the MANUFACTURER can justify that the RESIDUAL RISKS that result from applying the alternative means are equal to or less than the RESIDUAL RISKS that result from applying the requirements of this standard.~~

~~Compliance is checked by inspection of the RISK MANAGEMENT FILE.~~

Where this standard specifies a particular RISK CONTROL measure or test method, an alternative RISK CONTROL measure or test method is acceptable, provided that the MANUFACTURER can demonstrate through scientific data or clinical opinion or comparative studies that the RESIDUAL RISK that results from applying the alternative RISK CONTROL measure or test method remains acceptable and is comparable to the RESIDUAL RISK that results from applying the requirements of this standard.

Comparative studies in this context mean studies comparing the effect of the alternative RISK CONTROL measure or test method with the RISK CONTROL measure or test method specified in this standard.

NOTE Alternative RISK CONTROL measures can allow for exceeding limits specified in this standard or in its collateral or particular standards if additional measures for compensation are provided.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

4.6 * ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT

~~The RISK MANAGEMENT PROCESS shall include an assessment of whether parts that can come into contact with the PATIENT but fall outside of the definition of APPLIED PARTS shall be subject to the requirements for APPLIED PARTS. If the RISK MANAGEMENT PROCESS determines that such parts are subject to the requirements for APPLIED PARTS, then all the relevant requirements and tests of this standard shall apply, except that 7.2.10 does not apply to such parts.~~

~~Compliance is checked by inspection of the RISK MANAGEMENT FILE.~~

The RISK MANAGEMENT PROCESS shall include an assessment of whether parts that can come into contact with the PATIENT but fall outside of the definition of APPLIED PARTS need to be subject to the requirements for APPLIED PARTS. For the parts concerned, the requirements for TYPE B APPLIED PART shall be applied unless the assessment identifies a need for the requirements for a TYPE BF APPLIED PART or TYPE CF APPLIED PART to apply.

If the RISK MANAGEMENT PROCESS determines that such parts are subject to the requirements for APPLIED PARTS, then all the relevant requirements and tests of this standard and of relevant collateral and particular standards shall apply, except that 7.2.10 does not apply to such parts.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

4.7 * SINGLE FAULT CONDITION for ME EQUIPMENT

ME EQUIPMENT shall be so designed and manufactured that it remains SINGLE FAULT SAFE, or the RISK remains acceptable as determined through application of 4.2.

NOTE 1 The NORMAL CONDITIONS identified in 8.1 a) are taken into consideration during evaluation of compliance with any requirement of this standard that they might affect.

ME EQUIPMENT is considered SINGLE FAULT SAFE if:

- a) it employs a single means for reducing a RISK that has a negligible probability of failure (e.g. REINFORCED INSULATION, suspended masses without MECHANICAL PROTECTIVE DEVICES)

employing a TENSILE SAFETY FACTOR of 8X, COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS), or

b) a SINGLE FAULT CONDITION occurs, but:

- the initial fault will be detected during the EXPECTED SERVICE LIFE of the ME EQUIPMENT and before a second means for reducing a RISK fails (e.g. suspended masses with MECHANICAL PROTECTIVE DEVICES); or
- the probability that the second means of reducing the RISK will fail during the EXPECTED SERVICE LIFE of the ME EQUIPMENT is negligible.

Where a SINGLE FAULT CONDITION causes another SINGLE FAULT CONDITION, the two failures are considered as one SINGLE FAULT CONDITION.

During any test under SINGLE FAULT CONDITION, only one fault at a time shall be applied.

NOTE 2 Faults are generally divided into 3 probability categories:

- a) so remote that they can be ignored. The RISKS arising from these faults are considered acceptable;
- b) probable enough that they need to be considered, but improbable enough that they need only be considered one at a time (single fault). Faults of this category include all those identified as SINGLE FAULT CONDITIONS in this standard, and any other faults identified in applying ISO 14971 that meet the SINGLE FAULT CONDITION criteria;
- c) so likely, so unpredictable or undetectable that they are considered to be a NORMAL CONDITION and need to be considered individually and collectively.

The results of the RISK ANALYSIS shall be used to determine which failures shall be tested. The failure of any one component at a time that could result in a HAZARDOUS SITUATION, including those mentioned in 13.1, shall be simulated, physically or theoretically. The evaluation of whether a component is subject to failure simulation shall take into account the RISK associated with the failure of the component during the EXPECTED SERVICE LIFE of the ME EQUIPMENT. This evaluation shall be accomplished by applying the principles of RISK MANAGEMENT. The evaluation shall take into account issues such as reliability, TENSILE SAFETY FACTORS and rating of components. Additionally, during the simulation of SINGLE FAULT CONDITIONS, component failures that are highly probable or undetectable shall be simulated.

NOTE 3 See also Note 2 in 4.2.

This requirement and relevant tests shall not be applied to failures of DOUBLE or REINFORCED INSULATION or COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS.

Compliance is determined by applying the specific requirements and tests associated with the SINGLE FAULT CONDITIONS identified in 13.2, and tests for the failures identified from evaluation of the results of the RISK ANALYSIS. Compliance is confirmed if the introduction of any of the SINGLE FAULT CONDITIONS described in 13.2, one at a time, does not lead directly to the HAZARDOUS SITUATIONS described in 13.1, or any other outcome that results in an unacceptable RISK.

4.8 * Components of ME EQUIPMENT

All components, including wiring, the failure of which could result in a HAZARDOUS SITUATION shall be used in accordance with their specified ratings unless a specific exception is made in this standard or through the RISK MANAGEMENT PROCESS. The reliability of components that are used as MEANS OF PROTECTION shall be assessed for the conditions of use in the ME EQUIPMENT. They shall comply with one of the following (see also 4.5):

a) the applicable safety requirements of a relevant IEC or ISO standard;

NOTE 1 For the components, it is not necessary to carry out identical or equivalent tests already performed to check compliance with the component standard.

b) where there is no relevant IEC or ISO standard, the requirements of this standard have to be applied.

NOTE 2 If there are neither requirements in this standard nor in an IEC or ISO standard, any other applicable source (e.g. standards for other types of devices, national standards) could be used to demonstrate compliance with the RISK MANAGEMENT PROCESS.