



IEC 60601-1

Edition 3.1 2012-08

INTERNATIONAL STANDARD



Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

PRICE CODE **CW**

ICS 11.040

ISBN 978-2-8322-0331-6

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

CONTENTS

FOREWORD.....	11
INTRODUCTION.....	14
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

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 1: General requirements for basic safety and essential performance

FOREWORD

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

This consolidated version of IEC 60601-1 consists of the third edition (2005) [documents 62A/505A/FDIS and 62A/512/RVD], its amendment 1 (2012) [documents 62A/805/FDIS and 62A/820/RVD] and its corrigenda of December 2006 and 2007. It bears the edition number 3.1.

The technical content is therefore identical to the base edition and its amendment and has been prepared for user convenience. A vertical line in the margin shows where the base publication has been modified by amendment 1. Additions and deletions are displayed in red, with deletions being struck through.

International Standard IEC 60601-1 has been prepared by subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice.

This third edition cancels and replaces the second edition published in 1988, its Amendment 1 (1991) and Amendment 2 (1995), **the second edition of IEC 60601-1-1 published in 2000 and the first edition of IEC 60601-1-4 published in 1996 and its Amendment 1 (1999)**. This edition constitutes a technical revision. This edition has been significantly restructured. Requirements in the electrical section have been further aligned with those for information technology equipment covered by IEC 60950-1 and a requirement for including a RISK MANAGEMENT PROCESS has been added. For an expanded description of this revision, see Annex A.3.

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

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.

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

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

NOTE The attention of National Committees is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC or ISO publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for mandatory implementation nationally not earlier than 3 years from the date of publication.

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

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.

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 series²⁾. This standard does not apply to the implantable parts of active implantable medical devices covered by ISO 14708-1³⁾.~~

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 3.4 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 tests ¹⁵⁾~~
~~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 2882 ¹⁶⁾, *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:2004 ¹⁷⁾, *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*