

INTERNATIONAL STANDARD



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



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**MEDICAL ELECTRICAL EQUIPMENT –
Part 1: General requirements for basic safety
and essential performance**

INTERPRETATION SHEET 1

This interpretation sheet has been prepared by SC 62A: Common aspects of electrical equipment used in medical practice

The text of this interpretation sheet is based on the following documents:

ISH	Report on voting
62A/599/ISH	62A/613/RVD

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

Subclause 1.1

This subclause is clarified by the following:

IEC 60601-1 does not apply to medical gas pipeline systems covered by ISO 7396-1, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum*.

NOTE Subclause 6.3 of ISO 7396-1 applies the requirement of IEC 60601-1-8 to certain monitoring and alarm signals.

This clarification will remain valid until a new version of IEC 60601-1 is published.

MEDICAL ELECTRICAL EQUIPMENT –

Part 1: General requirements for basic safety and essential performance

INTERPRETATION SHEET 2

This interpretation sheet has been prepared by subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this interpretation sheet is based on the following documents:

ISH	Report on voting
62A/634/ISH	62A/640/RVD

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Subclause 11.3

This subclause is clarified by the following:

As stated in the rationale for this subclause, fire ENCLOSURES are intended to be used only where there is a significant likelihood of fire due to the presence of a source of ignition (as described in the subclause) *and* a *significant* source of fuel. Most materials used in the construction of ME EQUIPMENT are not considered to be such a source of fuel unless they are in the presence of an OXYGEN RICH ENVIRONMENT. MANUFACTURERS should determine, through analyses documented in the RISK MANAGEMENT FILE, whether the ME EQUIPMENT contains combustible materials (fuel) in sufficient quantities to support combustion in conjunction with ignition sources (capable of releasing greater than 900 J).

Subclause 13.1.2

This subclause is clarified by the following:

As stated in subclause 4.7, it is the MANUFACTURER'S RISK ANALYSIS that determines which components are subject to failure testing based on the associated RISK. Where the associated RISK of fire exceeds the MANUFACTURER'S criteria for RISK acceptability, the MANUFACTURER'S simulation analysis (such as FMEAs) should be accepted in lieu of physical testing. As also stated in 4.7, component reliability and ratings are to be considered in such failure simulation analyses. Common electronic components that have a history of use without causing equipment fires should not be considered a likely source of ignition.

Where the subclause identifies "emission of flames, molten metal, poisonous or ignitable substance in hazardous quantities;" as a hazardous situation, this refers to emissions from *the ENCLOSURE* not from components themselves. Where it identifies "exceeding the allowable values for 'other components and materials' identified in Table 22 times 1,5 minus 12,5 °C", this applies only where doing so would result in an unacceptable RISK (as identified in the MANUFACTURER'S RISK ANALYSIS according to 4.7). Typically, this would be cases where

ESSENTIAL PERFORMANCE would not be maintained or where greater than 900 J of energy would be released in the presence of flammable materials that could sustain combustion.

The first exemption to fault analysis or testing identified in subclause 13.1.2 (“The construction or the supply circuit limits the power dissipation in SINGLE FAULT CONDITION to less than 15 W or the energy dissipation to less than 900 J.”) is intended to apply where the component design itself (“The construction”) or fusing (or other current limiting devices) in the supply circuit (“or the supply circuit”) assure the energy released during failures will not exceed the limits. For most common signal level components rated for operation below 5 Watts, the energy released by short-circuiting of outputs will not exceed the 900 J limit.

This clarification will remain valid until a new version of IEC 60601-1 is published.

**MEDICAL ELECTRICAL EQUIPMENT –
Part 1: General requirements for basic safety and essential performance**

INTERPRETATION SHEET 3

This interpretation sheet has been prepared by subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this interpretation sheet is based on the following documents:

ISH	Report on voting
62A/858/ISH	62A/875/RVD

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Subclause 13.1.2 fourth dash (Emissions, deformation of ENCLOSURE or exceeding maximum temperature)


This subclause states the following:

The following HAZARDOUS SITUATIONS shall not occur:

-
- temperatures of ME EQUIPMENT parts that are not APPLIED PARTS but are likely to be touched, exceeding the allowable values in Table 23 when measured and adjusted as described in 11.1.3;

This is clarified by the following:

The above requirement is regarded as fulfilled in accordance with Subclause 4.5 for temperatures at the surfaces of the enclosure, if the following conditions are fulfilled:

- The maximum allowed temperature on OPERATOR accessible surfaces in SINGLE FAULT CONDITION is 105 °C; and
- the instructions for use contain a warning that, under some SINGLE FAULT CONDITIONS, the temperature of: (*indicate the surface of concern*) could get hot and there is a possible RISK of a burn if touched, and
- if the RISK ANALYSIS demonstrates a need for a warning symbol on the ENCLOSURE, safety sign ISO 7010-W018 () shall be used on or adjacent to the hot spot on the ENCLOSURE; and
- the RISK ASSESSMENT demonstrates that the temperature attained in the SINGLE FAULT CONDITION is acceptable, and
- the RISK ASSESSMENT demonstrates that applying the alternative RISK CONTROL measures in this Interpretation Sheet results in a RESIDUAL RISK that is comparable to the RESIDUAL RISK resulting from applying the requirement of the standard.

NOTE 1 This Interpretation Sheet is intended to be used with both Edition 3.0 and Edition 3.1 of IEC 60601-1.

NOTE 2 An example of an analysis that demonstrates an adequately low probability of occurrence of HARM is shown below.

Example RISK ASSESSMENT:

The sum failure rate for parts that could increase the surface temperature of parts of the enclosure of XYZ device touchable only by the OPERATOR to values above those of Table 23 calculates to be 60 FIT (1 FIT = $1\text{E-}9/\text{h}$) according to the standard MIL-HDBK-217F where FIT stands for "failure in time". In case of such failures, the device would emit an odour and would no longer function properly. It is estimated, that only in one of 3 cases the device would not be switched off immediately and the hot surface would be resulting in a burn.

The resulting overall probability of such HARM where adequate warning is provided in the instructions for use in combination with warning sign ISO 7010 W018 would be: probability = $1/3 * 60 \text{ FIT} = 2 \text{ E-}8/\text{h} \approx \text{approx. } 0,0002 \text{ per year.}$

In this example, the WXW Company's RISK acceptance criteria require that a HARM of that severity must have a probability of less than 0,0003 per year for the associated RISK to be considered acceptable. Based on that RISK acceptance criterion, the RISK associated with overtemperature of the ENCLOSURE caused by single faults in the circuitry is acceptable.

CONTENTS

FOREWORD	11
INTRODUCTION	14
INTRODUCTION TO AMENDMENT 1	16
INTRODUCTION TO AMENDMENT 2	16
1 Scope, object and related standards	18
1.1 * Scope	18
1.2 Object	18
1.3 * Collateral standards	18
1.4 * Particular standards	19
2 * Normative references	19
3 * Terminology and definitions	24
4 General requirements	45
4.1 * Conditions for application to ME EQUIPMENT or ME SYSTEMS	45
4.2 * RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS	45
4.3 * ESSENTIAL PERFORMANCE	48
4.4 * EXPECTED SERVICE LIFE	49
4.5 * Equivalent safety for ME EQUIPMENT or ME SYSTEMS * Alternative RISK CONTROL measures or test methods for ME EQUIPMENT or ME SYSTEMS	50
4.6 * ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT	50
4.7 * SINGLE FAULT CONDITION for ME EQUIPMENT	50
4.8 * Components of ME EQUIPMENT	51
4.9 * Use of COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS in ME EQUIPMENT	52
4.10 * Power supply	53
4.11 Power input	53
5 * General requirements for testing ME EQUIPMENT	54
5.1 * TYPE TESTS	54
5.2 * Number of samples	54
5.3 Ambient temperature, humidity, atmospheric pressure	54
5.4 Other conditions	54
5.5 Supply voltages, type of current, nature of supply, frequency	55
5.6 Repairs and modifications	55
5.7 * Humidity preconditioning treatment	55
5.8 Sequence of tests	56
5.9 * Determination of APPLIED PARTS and ACCESSIBLE PARTS	56
6 * Classification of ME EQUIPMENT and ME SYSTEMS	59
6.1 General	59
6.2 * Protection against electric shock	59
6.3 Protection against harmful ingress of water or particulate matter	59
6.4 Method(s) of sterilization	59
6.5 Suitability for use in an OXYGEN RICH ENVIRONMENT	59
6.6 * Mode of operation	59
7 ME EQUIPMENT identification, marking and documents	60
7.1 General	60

7.2	Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts (see also Table C.1)	61
7.3	Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts (see also Table C.2)	66
7.4	Marking of controls and instruments (see also Table C.3)	67
7.5	Safety signs SAFETY SIGNS	69
7.6	Symbols	70
7.7	Colours of the insulation of conductors	70
7.8	* Indicator lights and controls	71
7.9	ACCOMPANYING DOCUMENTS	72
8	* Protection against electrical HAZARDS from ME EQUIPMENT	79
8.1	Fundamental rule of protection against electric shock	79
8.2	Requirements related to power sources	80
8.3	Classification of APPLIED PARTS	80
8.4	Limitation of voltage, current or energy	81
8.5	Separation of parts	84
8.6	* Protective earthing, functional earthing and potential equalization of ME EQUIPMENT	97
8.7	LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS	100
8.8	Insulation	122
8.9	* CREEPAGE DISTANCES and AIR CLEARANCES	129
8.10	Components and wiring	147
8.11	MAINS PARTS, components and layout	149
9	* Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS	155
9.1	MECHANICAL HAZARDS of ME EQUIPMENT	155
9.2	* MECHANICAL HAZARDS associated with moving parts	155
9.3	* MECHANICAL HAZARD associated with surfaces, corners and edges	161
9.4	* Instability HAZARDS	161
9.5	* Expelled parts HAZARD	166
9.6	Acoustic energy (including infra- and ultrasound) and vibration	167
9.7	* Pressure vessels and parts subject to pneumatic and hydraulic pressure	168
9.8	* MECHANICAL HAZARDS associated with support systems	171
10	* Protection against unwanted and excessive radiation HAZARDS	177
10.1	X-Radiation	177
10.2	Alpha, beta, gamma, neutron and other particle radiation	178
10.3	Microwave radiation	178
10.4	* Lasers and light emitting diodes (LEDs)	179
10.5	* Other visible electromagnetic radiation	179
10.6	* Infrared radiation	179
10.7	* Ultraviolet radiation	179
11	Protection against excessive temperatures and other HAZARDS	179
11.1	* Excessive temperatures in ME EQUIPMENT	179
11.2	* Fire prevention	184
11.3	* Constructional requirements for fire ENCLOSURES of ME EQUIPMENT	188
11.4	* ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics	191
11.5	* ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents	191

11.6	Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT	191
11.7	Biocompatibility of ME EQUIPMENT and ME SYSTEMS	194
11.8	* Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT	194
12	* Accuracy of controls and instruments and protection against hazardous outputs	194
12.1	Accuracy of controls and instruments	194
12.2	USABILITY of ME EQUIPMENT	194
12.3	ALARM SYSTEMS	194
12.4	Protection against hazardous output.....	194
13	* HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT	196
13.1	Specific HAZARDOUS SITUATIONS	196
13.2	SINGLE FAULT CONDITIONS	198
14	* PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	203
14.1	* General.....	203
14.2	* Documentation.....	204
14.3	* RISK MANAGEMENT plan	204
14.4	* PEMS DEVELOPMENT LIFE-CYCLE	204
14.5	* Problem resolution	204
14.6	RISK MANAGEMENT PROCESS.....	205
14.7	* Requirement specification	205
14.8	* Architecture	205
14.9	* Design and implementation	206
14.10	* VERIFICATION	206
14.11	* PEMS VALIDATION	206
14.12	* Modification	207
14.13	* Connection of PEMS by NETWORK/DATA COUPLING to other equipment * PEMS intended to be incorporated into an IT-NETWORK	207
15	Construction of ME EQUIPMENT	208
15.1	* Arrangements of controls and indicators of ME EQUIPMENT.....	208
15.2	* Serviceability	208
15.3	Mechanical strength	209
15.4	ME EQUIPMENT components and general assembly.....	212
15.5	* MAINS SUPPLY TRANSFORMERS of ME EQUIPMENT and transformers providing separation in accordance with 8.5	218
16	* ME SYSTEMS	222
16.1	* General requirements for the ME SYSTEMS	222
16.2	* ACCOMPANYING DOCUMENTS of an ME SYSTEM	223
16.3	* Power supply	224
16.4	ENCLOSURES	224
16.5	* SEPARATION DEVICES	224
16.6	* LEAKAGE CURRENTS	224
16.7	* Protection against MECHANICAL HAZARDS	225
16.8	Interruption of the power supply to parts of an ME SYSTEM	226
16.9	ME SYSTEM connections and wiring	226
17	* Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	228
Annex A	(informative) General guidance and rationale.....	229
Annex B	(informative) Sequence of testing	351

Annex C (informative) Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS.....	355
Annex D (informative) Symbols on marking (see Clause 7).....	358
Annex E (informative) Examples of the connection of the measuring device (MD) for measurement of the PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT (see 8.7).....	367
Annex F (informative) Suitable measuring supply circuits.....	369
Annex G (normative) Protection against HAZARDS of ignition of flammable anaesthetic mixtures.....	372
Annex H (informative) PEMS structure, PEMS DEVELOPMENT LIFE-CYCLE and documentation.....	388
Annex I (informative) ME SYSTEMS aspects.....	401
Annex J (informative) Survey of insulation paths.....	407
Annex K (informative) Simplified PATIENT LEAKAGE CURRENT diagrams.....	410
Annex L (normative) Insulated winding wires for use without interleaved insulation.....	413
Annex M (normative) Reduction of pollution degrees.....	416
Bibliography.....	417
INDEX OF ABBREVIATIONS AND ACRONYMS.....	422
INDEX.....	424
Figure 1 – Detachable mains connection.....	25
Figure 2 – Example of the defined terminals and conductors.....	26
Figure 3 – Example of a CLASS I ME EQUIPMENT.....	27
Figure 4 – Example of a metal-enclosed CLASS II ME EQUIPMENT.....	27
Figure 5 – Schematic flow chart for component qualification (see 4.8).....	52
Figure 6 – Standard test finger (see 5.9.2.1).....	57
Figure 7 – Test hook (see 5.9.2.2).....	58
Figure 8 – Test pin (see 8.4.2 d).....	83
Figure 9 – Application of test voltage to bridged PATIENT CONNECTIONS for DEFIBRILLATION-PROOF APPLIED PARTS (see 8.5.5.1).....	93
Figure 10 – Application of test voltage to individual PATIENT CONNECTIONS for DEFIBRILLATION-PROOF APPLIED PARTS (see 8.5.5.1).....	95
Figure 11 – Application of test voltage to test the delivered defibrillation energy.....	97
Figure 12 – Example of a measuring device and its frequency characteristics.....	102
Figure 13 – Measuring circuit for the EARTH LEAKAGE CURRENT of CLASS I ME EQUIPMENT, with or without APPLIED PART.....	105
Figure 14 – Measuring circuit for the TOUCH CURRENT.....	107
Figure 15 – Measuring circuit for the PATIENT LEAKAGE CURRENT from the PATIENT CONNECTION to earth.....	109
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).....	111
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.....	113
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.....	115

Figure 19 – Measuring circuit for the PATIENT AUXILIARY CURRENT	116
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.....	117
Figure 21 – Ball-pressure test apparatus	129
Figure 22 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 1	142
Figure 23 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 2	142
Figure 24 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 3	142
Figure 25 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 4	143
Figure 26 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 5	143
Figure 27 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 6	144
Figure 28 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 7	144
Figure 29 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 8	145
Figure 30 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 9	146
Figure 31 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 10	147
Figure 32 – Ratio between HYDRAULIC TEST PRESSURE and MAXIMUM- PERMISSIBLE WORKING EQUIPMENT PRESSURE	170
Figure 33 – Human body test mass (see 9.8.3.3) Body upper-carriage module	176
Figure 34 – Spark ignition test apparatus	185
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	186
Figure 36 – Maximum allowable voltage U as a function of the capacitance C measured in a capacitive circuit used in an OXYGEN RICH ENVIRONMENT	186
Figure 37 – Maximum allowable current I as a function of the inductance L measured in an inductive circuit in an OXYGEN RICH ENVIRONMENT	187
Figure 38 – Baffle	190
Figure 39 – Area of the bottom of an ENCLOSURE as specified in 11.3 b) 1)	191
Figure 40 – Identification of MEANS OF PATIENT PROTECTION and MEANS OF OPERATOR PROTECTION.....	85
Figure 41 – WORKING VOLTAGE measurement	90
Figure A.1 – Identification of ME EQUIPMENT, APPLIED PARTS and PATIENT CONNECTIONS in an ECG monitor	235
Figure A.2 – Example of the insulation of an F-TYPE APPLIED PART with the insulation incorporated in the ME EQUIPMENT	235
Figure A.3 – Identification of ME EQUIPMENT, APPLIED PARTS and PATIENT CONNECTIONS in a PATIENT monitor with invasive pressure monitoring facility	236
Figure A.4 – Identification of ME EQUIPMENT, APPLIED PARTS and PATIENT CONNECTIONS in a multifunction PATIENT monitor with invasive pressure monitoring facilities.....	237
Figure A.5 – Identification of APPLIED PARTS and PATIENT CONNECTIONS in an X-ray ME SYSTEM	238
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.....	239
Figure A.7 – Identification of ME EQUIPMENT or ME SYSTEM, APPLIED PARTS and PATIENT CONNECTIONS in a personal computer with an ECG module	240
Figure A.8 – Pictorial representation Illustration of the relationship of HAZARD, sequence of events, HAZARDOUS SITUATION and HARM	244
Figure A.9 – Example of PATIENT ENVIRONMENT.....	250

Figure A.10 – Floating circuit	271
Figure A.11 – Interruption of a power-carrying conductor between ME EQUIPMENT parts in separate ENCLOSURES.....	272
Figure A.12 – Identification of MEANS OF PATIENT PROTECTION and MEANS OF OPERATOR PROTECTION.....	272
Figure A.13 – Allowable protective earth impedance where the fault current is limited	289
Figure A.14 – Probability of ventricular fibrillation	295
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	300
Figure A.16 – Instability test conditions.....	313
Figure A.17 – Example of determining TENSILE SAFETY FACTOR using Table 21	319
Figure A.18 – Example of determining design and test loads	320
Figure A.19 – Example of human body mass distribution	320
Figure A.20 – Relationship of the terms used to describe equipment, ACCESSORIES or equipment parts	246
Figure A.21 – Example of ME EQUIPMENT having two different functions on one common APPLIED PART circuit.....	287
Figure A.22 – Maximum allowable temperature for surfaces and APPLIED PARTS at higher altitudes	325
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.....	343
Figure A.24 – Example of Scenario 1	276
Figure A.25 – Example of Scenario 2	277
Figure A.26 – Procedure for determination of AIR CLEARANCE requirements IEC TR 62368-2:2019 [77], 5.4.2.1 (modified).....	281
Figure E.1 – TYPE B APPLIED PART.....	367
Figure E.2 – TYPE BF APPLIED PART	367
Figure E.3 – TYPE CF APPLIED PART	368
Figure E.4 – PATIENT AUXILIARY CURRENT	368
Figure E.5 – Loading of the PATIENT CONNECTIONS if specified by the MANUFACTURER	368
Figure F.1 – Measuring supply circuit with one side of the SUPPLY MAINS at approximately earth potential.....	369
Figure F.2 – Measuring supply circuit with SUPPLY MAINS approximately symmetrical to earth potential.....	369
Figure F.3 – Measuring supply circuit for polyphase ME EQUIPMENT specified for connection to a polyphase SUPPLY MAINS.....	370
Figure F.4 – Measuring supply circuit for single-phase ME EQUIPMENT specified for connection to a polyphase SUPPLY MAINS.....	370
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.....	371
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	378
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.....	379

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	379
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	383
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	384
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	385
Figure G.7 – Test apparatus	387
Figure H.1 – Examples of PEMS/ PESS structures	389
Figure H.2 – A PEMS DEVELOPMENT LIFE-CYCLE model	390
Figure H.3 – PEMS documentation requirements from Clause 14 and ISO 14971:2000 Not used	394
Figure H.4 – Example of potential parameters required to be specified for NETWORK/DATA COUPLING an IT-NETWORK	400
Figure I.1 – Example of the construction of a MULTIPLE SOCKET-OUTLET (MSO)	405
Figure I.2 – Examples of application of MULTIPLE SOCKET-OUTLETS (MSO)	406
Figure J.1 – Insulation example 1	407
Figure J.2 – Insulation example 2	407
Figure J.3 – Insulation example 3	407
Figure J.4 – Insulation example 4	408
Figure J.5 – Insulation example 5	408
Figure J.6 – Insulation example 6	409
Figure J.7 – Insulation example 7	409
Figure K.1 – ME EQUIPMENT with an ENCLOSURE made of insulating material	410
Figure K.2 – ME EQUIPMENT with an F-TYPE APPLIED PART	410
Figure K.3 – ME EQUIPMENT with an APPLIED PART and a SIGNAL INPUT/OUTPUT PART	411
Figure K.4 – ME EQUIPMENT with a PATIENT CONNECTION of a TYPE B APPLIED PART that is not PROTECTIVELY EARTHED	411
Figure K.5 – ME EQUIPMENT with a PATIENT CONNECTION of a TYPE BF APPLIED PART that is not PROTECTIVELY EARTHED	412
Table 1 – Units outside the SI units system that may be used on ME EQUIPMENT	69
Table 2 – Colours of indicator lights and their meanings of indicator lights and alarm indicator lights for ME EQUIPMENT	72
Table 3 – * Allowable values of PATIENT LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS under NORMAL CONDITION and SINGLE FAULT CONDITION	103
Table 4 – * Allowable values of PATIENT LEAKAGE CURRENTS under the special test conditions identified in 8.7.4.7	104
Table 5 – Legends of symbols for Figure 9 to Figure 11, Figure 13 to Figure 20, Figure A.15, Annexes E and F	118
Table 6 – Test voltages for solid insulation forming a MEANS OF PROTECTION	126
Table 7 – Test voltages for MEANS OF OPERATOR PROTECTION	127
Table 8 – Multiplication factors for AIR CLEARANCES for altitudes up to 5 000 m	130

Table 9 – Material group classification	131
Table 10 – MAINS TRANSIENT VOLTAGE	132
Table 11 – Minimum CREEPAGE DISTANCES and AIR CLEARANCES between parts of opposite polarity of the MAINS PART Not used.....	133
Table 12 – Minimum CREEPAGE DISTANCES and AIR CLEARANCES providing MEANS OF PATIENT PROTECTION	134
Table 13 – Minimum AIR CLEARANCES providing MEANS OF OPERATOR PROTECTION from the MAINS PART	135
Table 14 – Additional AIR CLEARANCES for insulation in MAINS PARTS with PEAK WORKING VOLTAGES exceeding the peak value of the NOMINAL MAINS VOLTAGE ^a	136
Table 15 – Minimum AIR CLEARANCES for MEANS OF OPERATOR PROTECTION in SECONDARY CIRCUITS.....	137
Table 16 – Minimum CREEPAGE DISTANCES providing MEANS OF OPERATOR PROTECTION ^a	138
Table 17 – NOMINAL cross-sectional area of conductors of a POWER SUPPLY CORD	151
Table 18 – Testing of cord anchorages	152
Table 19 – MECHANICAL HAZARDS covered by this clause	155
Table 20 – Acceptable gaps ^a	157
Table 21 – Determination of TENSILE SAFETY FACTOR	172
Table 22 – Allowable maximum temperatures of parts.....	180
Table 23 – Allowable maximum temperatures for ME EQUIPMENT parts ACCESSIBLE PARTS that are likely to be touched	180
Table 24 – Allowable maximum temperatures for skin contact with ME EQUIPMENT APPLIED PARTS	181
Table 25 – Acceptable perforation of the bottom of an ENCLOSURE	190
Table 26 – * Temperature limits of motor windings.....	200
Table 27 – Maximum motor winding steady-state temperature	202
Table 28 – Mechanical strength test applicability	209
Table 29 – Drop height	211
Table 30 – Test torques for rotating controls.....	216
Table 31 – Maximum allowable temperatures of transformer windings under overload and short-circuit conditions at 25 °C (± 5 °C) ambient temperature	219
Table 32 – Test current for transformers	220
Table 33 – Test conditions for overtravel end stop test	160
Table 34 – Allowable maximum temperatures for ACCESSIBLE PARTS that are likely to be touched, but not intended to be touched to operate the ME EQUIPMENT	197
Table A.1 – Values of AIR CLEARANCE and CREEPAGE DISTANCE derived from Table 7 of IEC 61010-1:2001 and Table 12	304
Table A.2 – CREEPAGE DISTANCES to avoid failure due to tracking from IEC 60664-1	305
Table A.3 – Instability test conditions.....	312
Table A.4 – Allowable time exposure for level of acceleration	315
Table A.5 – Guidance on surface temperatures for ME EQUIPMENT that creates low temperatures (cools) for therapeutic purposes or as part of its operation	324
Table A.6 – Typical scenarios for the use of equipment complying with IEC 62368-1:2018 in ME EQUIPMENT	276
Table C.1– Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts	355
Table C.2 – Marking on the inside of ME EQUIPMENT, ME SYSTEMS or their parts	356

Table C.3 – Marking of controls and instruments.....	356
Table C.4 – ACCOMPANYING DOCUMENTS, general.....	356
Table C.5 – ACCOMPANYING DOCUMENTS, instructions for use.....	357
Table D.1 – General symbols.....	359
Table D.2 – Safety signs SAFETY SIGNS	364
Table D.3 – General codes	366
Table G.1 – Gas-tightness of cord inlets	381
Table H.1 – NETWORK/DATA COUPLING classification Not used	398
Table I.1 – Some examples of ME SYSTEMS for illustration	403
Table L.1– Mandrel diameter	414
Table L.2 – Oven temperature	414
Table M.1 – Reduction of the pollution degree of internal environment through the use of additional protection	416

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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.
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- 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 the official IEC Standard and its amendments has been prepared for user convenience.

IEC 60601-1 edition 3.2 contains the third edition (2005-12) [documents 62A/505A/FDIS and 62A/512/RVD], its amendment 1 (2012-07) [documents 62A/805/FDIS and 62A/820/RVD] and its amendment 2 (2020-08) [documents 62A/1389/FDIS and 62A/1404/RVD].

This Consolidated version includes the contents of the corrigenda 1 (2006-12) and 2 (2007-12), the contents of the corrigendum to Amendment 1 (2014-07), as well as the interpretation sheets 1 (2008-04), 2 (2009-01) and 3 (2013-05).

In this Redline version, a vertical line in the margin shows where the technical content is modified by amendments 1 and 2. Additions are in green text, deletions are in strikethrough red text. A separate Final version with all changes accepted is available in this publication.

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.

Throughout this document, there are many references to, and requirements incorporated from IEC 60950-1. Some of these requirements are derived from IEC 60950-1. For example, the requirements for spaces filled by insulating compound in 8.9.3. In other cases, the requirements are incorporated by a normative reference to IEC 60950-1:2005. For example, the requirements for solid insulation forming a MEANS OF OPERATOR PROTECTION in 8.5.1.3. The requirements incorporated by reference are primarily found in Clause 8 of this document, including many of the tables used to determine the requirements for MEANS OF PROTECTION, primarily MEANS OF OPERATOR PROTECTION and INSULATION CO-ORDINATION. The requirements incorporated by reference are addressed in Amendment 2. The derived requirements will be addressed during the development of the fourth edition of this document.

1) Figures in square brackets refer to the Bibliography.

INTRODUCTION TO AMENDMENT 1

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.

INTRODUCTION TO AMENDMENT 2

The third edition of IEC 60601-1 was published in 2005 and amended in 2012. Since the publication of IEC 60601-1:2005/AMD1:2012, the IEC Subcommittee (SC) 62A Secretariat has been collecting issues from a variety of sources including comments from National Committees and questions submitted to IEC/SC 62A/Working Group (WG) 14. At the November 2015 meeting of IEC/SC 62A in Kobe, Japan, the subcommittee initiated a process to identify high-priority issues that need to be considered in Amendment 2 and should not wait until the fourth edition of IEC 60601-1, which is presently targeted for publication sometime after 2024.

Those issues selected for inclusion on the final "short list" to be addressed in Amendment 2 were those approved by a 2/3 majority of the National Committees present and voting at the Frankfurt meeting of SC 62A. At the meeting held on 10 October 2016, 109 items were presented to the National Committees present. A total of 78 items received the required 2/3 majority of the National Committees present and voting and were included in the "short list" for consideration in preparing Amendment 2. All remaining issues have been placed on a "long list" for consideration in the fourth edition of IEC 60601-1.

The "short list" of issues was documented in the design specification for Amendment 2. The responsible expert groups were directed to consider each issue assigned to it in Clause 6 of the design specification and develop an appropriate solution for the identified problem. That final solution in this amendment can encompass any technical solution proposed by the author of the issue or it can involve a different solution developed by the expert group. The expert group can also have recommended that no change to the standard was justified by the problem statement.

Because this is an amendment to the 2005 edition of IEC 60601-1, the style in force at the time of publication of IEC 60601-1 has been applied to this amendment. The style specified in ISO/IEC Directives, Part 2:2018 has only been applied when implementing the new style guidance would not result in additional editorial changes. For example, notes to definitions are designated as "NOTE" rather than "Note to entry" in Clause 3.

Users of this document should note that when constructing the dated references to specific elements in a standard, such as definitions, amendments are only referenced if they modified

the text being cited. For example, if a reference is made to a definition that has not been modified by an amendment, then the reference to the amendment is not included in the dated reference.

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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 specify BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for the particular ME EQUIPMENT and ME SYSTEMS. Particular standards may modify, replace or delete requirements contained in this standard and applicable collateral standards as appropriate for the particular ME EQUIPMENT and ME SYSTEMS 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 and applicable collateral standards.

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 apply together with this standard when applicable. They 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 60068-2-2:19742007, *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"*

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

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*

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*

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.~~

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

IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance* – Collateral standard: *Electromagnetic compatibility disturbances – Requirements and tests*
Amendment 1:2020

IEC 60601-1-3:2008, *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*
Amendment 1:2013

IEC 60601-1-6:2010, *Medical electrical equipment – Part 1-6: General requirements for safety basic and essential performance* – Collateral standard: *Usability*
Amendment 1:2013
Amendment 2:2020

IEC 60601-1-8:2006, *Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance* – Collateral standard: *General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*
Amendment 1:2012
Amendment 2:2020

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

IEC 60825-1:1993/2014, *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)~~

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

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).~~

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 60950-1:2004/2005, *Information technology equipment – Safety – Part 1: General requirements*
Amendment 1:2009
Amendment 2:2013

IEC 61058-1:2000, *Switches for appliances – Part 1: General requirements* ¹⁴⁾
Amendment 1:2001
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 62133-2, *Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications – Part 2: Lithium systems*

IEC 62304:2006, *Medical device software – Software life cycle processes*
Amendment 1:2015

IEC 62368-1:2018, *Audio/video, information and communication technology equipment – Part 1: Safety requirements*

~~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*~~

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)

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

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~~2019, *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~~

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:~~2007~~2019, *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 15223-1:2016, *Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements*

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 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 4-3.2.