

FINAL VERSION

VERSION FINALE



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

**Appareils électromédicaux –
Partie 1: Exigences générales pour la sécurité de base et les performances
essentiels**

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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.

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**MEDICAL ELECTRICAL EQUIPMENT –
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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 or 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 = 1E-9/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 = $1/3 * 60 \text{ FIT} = 2 \text{ E-8/h} \approx 0,0002 \text{ per year}$.

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.....	10
INTRODUCTION.....	13
INTRODUCTION TO THE AMENDMENT	15
1 Scope, object and related standards.....	16
1.1 * Scope	16
1.2 Object	16
1.3 * Collateral standards.....	16
1.4 * Particular standards.....	17
2 * Normative references.....	17
3 * Terminology and definitions	20
4 General requirements.....	40
4.1 * Conditions for application to ME EQUIPMENT or ME SYSTEMS.....	40
4.2 * RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS	41
4.3 * ESSENTIAL PERFORMANCE	43
4.4 * EXPECTED SERVICE LIFE	44
4.5 * Alternative RISK CONTROL measures or test methods for ME EQUIPMENT or ME SYSTEMS	44
4.6 * ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT	44
4.7 * SINGLE FAULT CONDITION for ME EQUIPMENT.....	44
4.8 * Components of ME EQUIPMENT	45
4.9 * Use of COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS in ME EQUIPMENT	46
4.10 * Power supply	46
4.11 Power input.....	47
5 * General requirements for testing ME EQUIPMENT	48
5.1 * TYPE TESTS.....	48
5.2 * Number of samples.....	48
5.3 Ambient temperature, humidity, atmospheric pressure.....	48
5.4 Other conditions	48
5.5 Supply voltage, amount of current, nature of supply, frequency	48
5.6 Repairs and modifications	49
5.7 * Humidity preconditioning treatment.....	49
5.8 Sequence of tests	50
5.9 * Determination of APPLIED PARTS and ACCESSIBLE PARTS	50
6 * Classification of ME EQUIPMENT and ME SYSTEMS.....	52
6.1 General.....	52
6.2 * Protection against electric shock.....	52
6.3 * Protection against harmful ingress of water or particulate matter	53
6.4 Method(s) of sterilization	53
6.5 Suitability for use in an OXYGEN RICH ENVIRONMENT	53
6.6 * Mode of operation.....	53
7 ME EQUIPMENT identification, marking and documents.....	53
7.1 General.....	53
7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts (see also Table C.1).....	54
7.3 Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts (see also Table C.2).....	59

7.4	Marking of controls and instruments (see also Table C.3)	60
7.5	Safety signs	62
7.6	Symbols	62
7.7	Colours of the insulation of conductors	63
7.8	* Indicator lights and controls	63
7.9	ACCOMPANYING DOCUMENTS	64
8	* Protection against electrical HAZARDS from ME EQUIPMENT	70
8.1	Fundamental rule of protection against electric shock	70
8.2	Requirements related to power sources	71
8.3	Classification of APPLIED PARTS	71
8.4	Limitation of voltage, current or energy	72
8.5	Separation of parts	74
8.6	* Protective earthing, functional earthing and potential equalization of ME EQUIPMENT	82
8.7	LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS	85
8.8	Insulation	101
8.9	* CREEPAGE DISTANCES and AIR CLEARANCES	107
8.10	Components and wiring	122
8.11	MAINS PARTS, components and layout	124
9	* Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS	129
9.1	MECHANICAL HAZARDS of ME EQUIPMENT	129
9.2	* MECHANICAL HAZARDS associated with moving parts	130
9.3	* MECHANICAL HAZARD associated with surfaces, corners and edges	136
9.4	* Instability HAZARDS	136
9.5	* Expelled parts HAZARD	141
9.6	Acoustic energy (including infra- and ultrasound) and vibration	141
9.7	* Pressure vessels and parts subject to pneumatic and hydraulic pressure	142
9.8	* MECHANICAL HAZARDS associated with support systems	145
10	* Protection against unwanted and excessive radiation HAZARDS	151
10.1	X-Radiation	151
10.2	Alpha, beta, gamma, neutron and other particle radiation	152
10.3	Microwave radiation	152
10.4	* Lasers	152
10.5	Other visible electromagnetic radiation	153
10.6	Infrared radiation	153
10.7	Ultraviolet radiation	153
11	Protection against excessive temperatures and other HAZARDS	153
11.1	* Excessive temperatures in ME EQUIPMENT	153
11.2	* Fire prevention	157
11.3	Constructional requirements for fire ENCLOSURES of ME EQUIPMENT	162
11.4	* ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics	164
11.5	* ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents	165
11.6	Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT	165
11.7	Biocompatibility of ME EQUIPMENT and ME SYSTEMS	167
11.8	* Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT	167

12	* Accuracy of controls and instruments and protection against hazardous outputs	167
12.1	Accuracy of controls and instruments	167
12.2	USABILITY of ME EQUIPMENT	167
12.3	ALARM SYSTEMS	167
12.4	Protection against hazardous output.....	167
13	* HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT	169
13.1	Specific HAZARDOUS SITUATIONS	169
13.2	SINGLE FAULT CONDITIONS	170
14	* PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	175
14.1	* General.....	175
14.2	* Documentation.....	177
14.3	* RISK MANAGEMENT plan	176
14.4	* PEMS DEVELOPMENT LIFE-CYCLE	176
14.5	* Problem resolution.....	176
14.6	RISK MANAGEMENT PROCESS.....	176
14.7	* Requirement specification.....	177
14.8	* Architecture	177
14.9	* Design and implementation.....	178
14.10	* VERIFICATION	178
14.11	* PEMS VALIDATION	178
14.12	* Modification	179
14.13	* PEMS intended to be incorporated into a IT NETWORK	179
15	Construction of ME EQUIPMENT	180
15.1	* Arrangements of controls and indicators of ME EQUIPMENT.....	180
15.2	* Serviceability	180
15.3	Mechanical strength	180
15.4	ME EQUIPMENT components and general assembly.....	184
15.5	* MAINS SUPPLY TRANSFORMERS of ME EQUIPMENT and transformers providing separation in accordance with 8.5	189
16	* ME SYSTEMS	193
16.1	* General requirements for the ME SYSTEMS	193
16.2	* ACCOMPANYING DOCUMENTS of an ME SYSTEM	193
16.3	* Power supply	194
16.4	ENCLOSURES	195
16.5	* SEPARATION DEVICES.....	195
16.6	LEAKAGE CURRENTS.....	195
16.7	* Protection against MECHANICAL HAZARDS.....	196
16.8	Interruption of the power supply to parts of an ME SYSTEM	197
16.9	ME SYSTEM connections and wiring.....	197
17	* Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	199
Annex A	(informative) General guidance and rationale.....	200
Annex B	(informative) Sequence of testing	307
Annex C	(informative) Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS.....	311
Annex D	(informative) Symbols on marking (see Clause 7).....	314
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).....	323

Annex F (informative) Suitable measuring supply circuits.....	325
Annex G (normative) Protection against HAZARDS of ignition of flammable anaesthetic mixtures.....	328
Annex H (informative) Pems structure, PEMS DEVELOPMENT LIFE-CYCLE and documentation.....	343
Annex I (informative) ME SYSTEMS aspects.....	351
Annex J (informative) Survey of insulation paths.....	357
Annex K (informative) Simplified PATIENT LEAKAGE CURRENT diagrams.....	360
Annex L (normative) Insulated winding wires for use without interleaved insulation.....	363
Annex M (normative) Reduction of pollution degrees.....	366
Bibliography.....	367
INDEX OF ABBREVIATIONS AND ACRONYMS.....	371
INDEX.....	373
Figure 1 – Detachable mains connection.....	22
Figure 2 – Example of the defined terminals and conductors.....	23
Figure 3 – Example of a CLASS I ME EQUIPMENT.....	24
Figure 4 – Example of a metal-enclosed CLASS II ME EQUIPMENT.....	24
Figure 5 – Schematic flow chart for component qualification.....	46
Figure 6 – Standard test finger.....	51
Figure 7 – Test hook.....	52
Figure 8 – Test pin.....	73
Figure 9 – Application of test voltage to bridged PATIENT CONNECTIONS for DEFIBRILLATION-PROOF APPLIED PARTS.....	79
Figure 10 – Application of test voltage to individual PATIENT CONNECTIONS for DEFIBRILLATION-PROOF APPLIED PARTS.....	80
Figure 11 – Application of test voltage to test the delivered defibrillation energy.....	82
Figure 12 – Example of a measuring device and its frequency characteristics.....	86
Figure 13 – Measuring circuit for EARTH LEAKAGE CURRENT of CLASS I ME EQUIPMENT, with or without APPLIED PART.....	89
Figure 14 – Measuring circuit for TOUCH CURRENT.....	90
Figure 15 – Measuring circuit for PATIENT LEAKAGE CURRENT from the PATIENT CONNECTION to earth.....	91
Figure 16 – Measuring circuit for 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).....	92
Figure 17 – Measuring circuit for PATIENT LEAKAGE CURRENT from PATIENT CONNECTION(s) to earth caused by an external voltage on a SIGNAL INPUT/OUTPUT PART.....	93
Figure 18 – Measuring circuit for PATIENT LEAKAGE CURRENT from PATIENT CONNECTION(s) to earth caused by an external voltage on a metal ACCESSIBLE PART that is not PROTECTIVELY EARTHED.....	94
Figure 19 – Measuring circuit for PATIENT AUXILIARY CURRENT.....	95
Figure 20 – Measuring circuit for 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.....	96
Figure 21 – Ball-pressure test apparatus.....	107
Figure 22 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 1.....	119

Figure 23 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 2	119
Figure 24 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 3	119
Figure 25 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 4	119
Figure 26 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 5	120
Figure 27 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 6	120
Figure 28 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 7	120
Figure 29 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 8	121
Figure 30 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 9	121
Figure 31 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 10	122
Figure 32 – Ratio between hydraulic test pressure and maximum permissible working pressure	144
Figure 33 – Body upper-carriage module	150
Figure 34 – Spark ignition test apparatus	159
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	160
Figure 36 – Maximum allowable voltage U as a function of the capacitance C measured in a capacitive circuit used in an OXYGEN RICH ENVIRONMENT	160
Figure 37 – Maximum allowable current I as a function of the inductance L measured in an inductive circuit in an OXYGEN RICH ENVIRONMENT	161
Figure 38 – Baffle	164
Figure 39 – Area of the bottom of an ENCLOSURE as specified in 11.3 b) 1)	164
Figure A.1 – Identification of ME EQUIPMENT, APPLIED PARTS and PATIENT CONNECTIONS in an ECG monitor	205
Figure A.2 – Example of the insulation of an F-TYPE APPLIED PART with the insulation incorporated in the ME EQUIPMENT	206
Figure A.3 – Identification of ME EQUIPMENT, APPLIED PARTS and PATIENT CONNECTIONS in a PATIENT monitor with invasive pressure monitoring facility	206
Figure A.4 – Identification of ME EQUIPMENT, APPLIED PARTS and PATIENT CONNECTIONS in a multifunction PATIENT monitor with invasive pressure monitoring facilities	207
Figure A.5 – Identification of APPLIED PARTS and PATIENT CONNECTIONS in an X-ray me system	208
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	209
Figure A.7 – Identification of ME EQUIPMENT or ME SYSTEM, APPLIED PARTS and PATIENT CONNECTIONS in a personal computer with an ECG module	210
Figure A.8 – Pictorial representation of the relationship of HAZARD, sequence of events, HAZARDOUS SITUATION and HARM	213
Figure A.9 – Example of PATIENT ENVIRONMENT	218
Figure A.10 – Floating circuit	236
Figure A.11 – Interruption of a power-carrying conductor between ME EQUIPMENT parts in separate ENCLOSURES	238
Figure A.12 – Identification of MEANS OF PATIENT PROTECTION and MEANS OF OPERATOR PROTECTION	241
Figure A.13 – Allowable protective earth impedance where the fault current is limited	248
Figure A.14 – Probability of ventricular fibrillation	254
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	259

Figure A.16 – Instability test conditions.....	270
Figure A.17 – Example of determining TENSILE SAFETY FACTOR using Table 21	277
Figure A.18 – Example of determining design and test loads	277
Figure A.19 – Example of human body mass distribution	278
Figure A.20 – Relationship of the terms used to describe equipment, ACCESSORIES or equipment parts.....	215
Figure A.21 – Example of ME EQUIPMENT having two different functions on one common APPLIED PART circuit.....	246
Figure A.22 – Maximum allowable temperature for surfaces and APPLIED PARTS at higher altitudes	282
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.....	299
Figure E.1 – TYPE B APPLIED PART	323
Figure E.2 – TYPE BF APPLIED PART	323
Figure E.3 – TYPE CF APPLIED PART	324
Figure E.4 – PATIENT AUXILIARY CURRENT	324
Figure E.5 – Loading of the PATIENT CONNECTIONS if specified by the MANUFACTURER	324
Figure F.1 – Measuring supply circuit with one side of the SUPPLY MAINS at approximately earth potential.....	325
Figure F.2 – Measuring supply circuit with SUPPLY MAINS approximately symmetrical to earth potential.....	325
Figure F.3 – Measuring supply circuit for polyphase me equipment specified for connection to a polyphase supply mains	326
Figure F.4 – Measuring supply circuit for single-phase me equipment specified for connection to a polyphase supply mains	326
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	327
Figure G.1– Maximum allowable current IZR as a function of the maximum allowable voltage UZR measured in a purely resistive circuit with the most flammable mixture of ether vapour with air	334
Figure G.2 – Maximum allowable voltage UZC as a function of the capacitance Cmax measured in a capacitive circuit with the most flammable mixture of ether vapour with air.....	335
Figure G.3 – Maximum allowable current IZL as a function of the inductance Lmax measured in an inductive circuit with the most flammable mixture of ether vapour with air.....	335
Figure G.4 – Maximum allowable current IZR as a function of the maximum allowable voltage UZR measured in a purely resistive circuit with the most flammable mixture of ether vapour with oxygen	339
Figure G.5 – Maximum allowable voltage UZC as a function of the capacitance Cmax measured in a capacitive circuit with the most flammable mixture of ether vapour with oxygen.....	340
Figure G.6 – Maximum allowable current IZL as a function of the inductance Lmax measured in an inductive circuit with the most flammable mixture of ether vapour with oxygen.....	340
Figure G.7 – Test apparatus	342
Figure H.1 – Examples of PEMS/ PESS structures	344
Figure H.2 – A PEMS DEVELOPMENT LIFE-CYCLE model	345

Figure H.3 – Not used.....	346
Figure H.4 – Example of potential parameters required to be specified for an IT-NETWORK.....	350
Figure I.1 – Example of the construction of a MULTIPLE SOCKET-OUTLET (MSO).....	355
Figure I.2 – Examples of application of MULTIPLE SOCKET-OUTLETS (MSO).....	356
Figure J.1 – Insulation example 1.....	357
Figure J.2 – Insulation example 2.....	357
Figure J.3 – Insulation example 3.....	357
Figure J.4 – Insulation example 4.....	358
Figure J.5 – Insulation example 5.....	358
Figure J.6 – Insulation example 6.....	359
Figure J.7 – Insulation example 7.....	359
Figure K.1 – ME EQUIPMENT with an ENCLOSURE made of insulating material.....	360
Figure K.2 – ME EQUIPMENT with an F-TYPE APPLIED PART.....	360
Figure K.3 – ME EQUIPMENT with an APPLIED PART and a SIGNAL INPUT/OUTPUT PART.....	361
Figure K.4 – Me equipment with a PATIENT CONNECTION of a TYPE B APPLIED PART that is not PROTECTIVELY EARTHED.....	361
Figure K.5 – Me equipment with a PATIENT CONNECTION of a TYPE BF APPLIED PART that is not PROTECTIVELY EARTHED.....	362
Table 1 – Units outside the SI units system that may be used on ME EQUIPMENT.....	61
Table 2 – Colours of indicator lights and their meaning for ME EQUIPMENT.....	64
Table 3 – * Allowable values of PATIENT LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS under NORMAL CONDITION and SINGLE FAULT CONDITION.....	87
Table 4 – * Allowable values of PATIENT LEAKAGE CURRENTS under the special test conditions identified in 8.7.4.7.....	88
Table 5 – Legends of symbols for Figure 9 to Figure 11, Figure 13 to Figure 20, Figure A.15, Annexes E and F.....	97
Table 6 – Test voltages for solid insulation forming a MEANS OF PROTECTION.....	104
Table 7 – Test voltages for MEANS OF OPERATOR PROTECTION.....	105
Table 8 – Multiplication factors for AIR CLEARANCES for altitudes up to 5 000 m.....	108
Table 9 – Material group classification.....	108
Table 10 – MAINS TRANSIENT VOLTAGE.....	110
Table 11 – Not used.....	111
Table 12 – Minimum CREEPAGE DISTANCES and AIR CLEARANCES providing MEANS OF PATIENT PROTECTION.....	112
Table 13 – Minimum AIR CLEARANCES providing MEANS OF OPERATOR PROTECTION from the MAINS PART.....	113
Table 14 – Additional AIR CLEARANCES for insulation in MAINS PARTS with PEAK WORKING VOLTAGES exceeding the peak value of the NOMINAL MAINS VOLTAGE ^a	114
Table 15 – Minimum AIR CLEARANCES for MEANS OF OPERATOR PROTECTION in SECONDARY CIRCUITS.....	115
Table 16 – Minimum CREEPAGE DISTANCES providing MEANS OF OPERATOR PROTECTION ^a	116
Table 17 – NOMINAL cross-sectional area of conductors of a POWER SUPPLY CORD.....	125
Table 18 – Testing of cord anchorages.....	126
Table 19 – MECHANICAL HAZARDS covered by this clause.....	130

Table 20 – Acceptable gaps ^a	132
Table 21 – Determination of TENSILE SAFETY FACTOR	146
Table 22 – Allowable maximum temperatures of parts.....	154
Table 23 – Allowable maximum temperatures for ME EQUIPMENT parts that are likely to be touched.....	154
Table 24 – Allowable maximum temperatures for skin contact with ME EQUIPMENT APPLIED PARTS	155
Table 25 – Acceptable perforation of the bottom of an ENCLOSURE	163
Table 26 – * Temperature limits of motor windings.....	172
Table 27 – Maximum motor winding steady-state temperature	174
Table 28 – Mechanical strength test applicability	181
Table 29 – Drop height	182
Table 30 – Test torques for rotating controls.....	188
Table 31 – Maximum allowable temperatures of transformer windings under overload and short-circuit conditions at 25 °C (± 5 °C) ambient temperature	190
Table 32 – Test current for transformers	191
Table 33 – Test conditions for overtravel end stop test	135
Table A.1 – Values of AIR CLEARANCE and CREEPAGE DISTANCE derived from Table 7 of IEC 61010-1:2001 and Table 12	262
Table A.2 – CREEPAGE DISTANCES to avoid failure due to tracking from IEC 60664-1	263
Table A.3 – Instability test conditions.....	270
Table A.4 – Allowable time exposure for level of acceleration	272
Table A.5 – Guidance on surface temperatures for ME EQUIPMENT that creates low temperatures (cools) for therapeutic purposes or as part of its operation	282
Table C.1– Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts	311
Table C.2 – Marking on the inside of ME EQUIPMENT, ME SYSTEMS or their parts	312
Table C.3 – Marking of controls and instruments.....	312
Table C.4 – ACCOMPANYING DOCUMENTS, general.....	312
Table C.5 – ACCOMPANYING DOCUMENTS, instructions for use.....	313
Table D.1 – General symbols.....	315
Table D.2 – Safety signs.....	320
Table D.3 – General codes	322
Table G.1 – Gas-tightness of cord inlets	337
Table H.1 – Not used	349
Table I.1 – Some examples of ME SYSTEMS for illustration	353
Table L.1– Mandrel diameter	364
Table L.2 – Oven temperature	364
Table M.1 – Reduction of the pollution degree of internal environment through the use of additional protection	366

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

FOREWORD

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DISCLAIMER

This Consolidated version is not an official IEC Standard and has been prepared for user convenience. Only the current versions of the standard and its amendment(s) are to be considered the official documents.

This Consolidated version of IEC 60601-1 bears the edition number 3.1. It consists of the third edition (2005-12) [documents 62A/505A/FDIS and 62A/512/RVD] and its amendment 1 (2012-07) [documents 62A/805/FDIS and 62A/820/RVD]. The technical content is identical to the base edition and its amendment.

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).

This Final version does not show where the technical content is modified by amendment 1. A separate Redline version with all changes highlighted 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 amendment 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 Issue 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.

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.

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. The IEC maintains a catalogue of valid International Standards. Users of this standard should consult this 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.