BRITISH STANDARD

BS EN 60601-1:2006 +A11:2011
Incorporating corrigenda December 2006, December 2007 and March 2010

Medical electrical equipment —

Part 1: General requirements for basic safety and essential performance

ICS 11.040.01

BSI British Standards

National foreword

This British Standard is the UK implementation of EN 60601-1:2006+A11:2011. It is identical to IEC 60601-1:2005. It supersedes BS EN 60601-1:2006, which will be withdrawn on 1 October 2014.

The start and finish of text introduced or altered by corrigendum is indicated in the text by tags. Text altered by IEC corrigendum December 2006 is indicated in the text by [AC1⟩ ⟨AC1]. Text altered by IEC corrigendum December 2007 is indicated in the text by [AC2⟩ ⟨AC2].

The UK participation in its preparation was entrusted by Technical Committee CH/62, Electrical Equipment in Medical Practice, to Subcommittee CH/62/1, Common aspects of Electrical Equipment used in Medical Practice.

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with a British Standard cannot confer immunity from legal obligations.

Amendments/corrigenda issued since publication

Date	Comments
31 May 2011	Implementation of IEC corrigenda December 2006 and December 2007 (tagged) and implementation of CENELEC corrigendum March 2010: modification of CENELEC Foreword and Annexes ZA and ZZ
29 February 2012	Implementation of CENELEC amendment A11:2011: Annex ZZ replaced by Annexes ZZA and ZZB

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 November 2006

ISBN 978 0 580 77313 6

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-1:2006+A11

October 2011

ICS 11.040

Supersedes EN 60601-1:2006

English version

Medical electrical equipment
Part 1: General requirements for basic safety and essential performance
(IEC 60601-1:2005)

Appareils électromédicaux
Partie 1: Exigences générales
pour la sécurité de base
et les performances essentielles
(CEI 60601-1:2005)

Medizinische elektrische Geräte
Teil 1: Allgemeine Festlegungen
für die Sicherheit einschließlich
der wesentlichen Leistungsmerkmale
(IEC 60601-1:2005)

CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

Central Secretariat: Avenue Marnix 17, B - 1000 Brussels

Ref. No. EN 60601-1:2006 E

Foreword

The text of document 62A/505A//FDIS, future edition 3 of IEC 60601-1, prepared by SC 62A, Common aspects of electrical equipment used in medical practice, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-1 on 2006-09-12.

The following date was fixed:

– latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2007-07-01
– latest date by which the national standards conflicting with the EN have to be withdrawn.	(dow)	2012-06-01

This European Standard supersedes EN 60601-1:1990 and its amendments.

This EN 60601-1:2006 has been significantly restructured compared to EN 60601-1:1990. Requirements in the electrical section have been further aligned with those for information technology equipment covered by EN 60950-1 and a requirement for including a RISK MANAGEMENT PROCESS has been added. For an expanded description of this revision, see Clause A.3.

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directives 90/385/EEC and 93/42/EEC. See Annex ZZ.

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.

Annexes ZA and ZZ have been added by CENELEC.

_____

Endorsement notice

The text of the International Standard IEC 60601-1:2005 was approved by CENELEC as a European Standard without any modification.

The contents of the corrigendum of March 2010 have been included in this copy.

_____

Foreword to amendment A11

This document (EN 60601-1:2006/A11:2011) has been prepared by CLC/TC 62 “Electrical equipment in medical practice”.

The following dates are fixed:

• latest date by which this document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2012-10-01
• latest date by which the national standards conflicting with this document have to be withdrawn	(dow)	2014-10-01

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

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.

NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Publication	Year	Title	EN/HD	Year
IEC 60065 (mod)	2001	Audio, video and similar electronic apparatus - Safety requirements	EN 60065 + corr. March	2002 2006
IEC 60068-2-2	1974	Environmental testing	EN 60068-2-2 [1)]	1993
A1	1993	Part 2: Tests - Tests B: Dry heat	A1	1993
A2	1994		A2	1994
IEC 60079-0 (mod)	- [2)]	Electrical apparatus for explosive gas atmospheres Part 0: General requirements	EN 60079-0	2006 [3)]
IEC 60079-2	- [2)]	Electrical apparatus for explosive gas atmospheres Part 2: Pressurized enclosures "p"	EN 60079-2 + corr. April	2004 [3)] 2006
IEC 60079-5	- [2)]	Electrical apparatus for explosive gas atmospheres Part 5: Powder filling 'q'	-	-
IEC 60079-6	- [2)]	Electrical apparatus for explosive gas atmospheres Part 6: Oil-immersion "o"	-	-
IEC 60083	- [2)]	Plugs and socket-outlets for domestic and similar general use standardized in member countries of IEC	-	-
IEC 60085	- [2)]	Electrical insulation - Thermal classification	EN 60085	2004 [3)]
IEC 60086-4	- [2)]	Primary batteries Part 4: Safety of lithium batteries	EN 60086-4	2000 [3)]
IEC 60112	- [2)]	Method for the determination of the proof and the comparative tracking indices of solid insulating materials	EN 60112	2003 [3)]
IEC 60127-1	2006	Miniature fuses Part 1: Definitions for miniature fuses and general requirements for miniature fuse-links	EN 60127-1	2006
IEC 60227-1 [4)]	1993	Polyvinyl chloride insulated cables of rated	-	-
A1	1995	voltages up to and including 450/750 V	-	-
A2	1998	Part 1: General requirements	-	-

[1)] EN 60068-2-2 includes supplement A:1976 to IEC 60068-2-2.
[2)] Undated reference.
[3)] Valid edition at date of issue.
[4)] HD 21.1 S4:2002, *Cables of rated voltages up to and including 450/750 V and having thermoplastic insulation - Part 1: General requirements,* which is related to, but not directly equivalent with, IEC 60227-1, applies instead.

Publication	Year	Title	EN/HD	Year
IEC 60245-1 [5)]	2003	Rubber insulated cables - Rated voltages up to and including 450/750 V Part 1: General requirements	-	-
IEC 60252-1	- [2)]	AC motor capacitors Part 1: General - Performance, testing and rating - Safety requirements - Guide for installation and operation	EN 60252-1	2001 [3)]
IEC 60320-1	- [2)]	Appliance couplers for household and similar general purposes Part 1: General requirements	EN 60320-1	2001 [3)]
IEC 60335-1 (mod)	2001	Household and similar electrical appliances - Safety Part 1: General requirements	EN 60335-1 A11 A12 + corr. July	2002 2004 2006 2006
IEC 60364-4-41 (mod)	2005	Low-voltage electrical installations Part 4-41: Protection for safety - Protection against electric shock	HD 60364-4-41	2006
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	EN 60384-14	2005
IEC 60417	Data base	Graphical symbols for use on equipment	-	-
IEC 60445	- [2)]	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	EN 60445	2000 [3)]
IEC 60447	- [2)]	Basic and safety principles for man-machine interface, marking and identification - Actuating principles	EN 60447	2004 [3)]
IEC 60529 A1	1989 1999	Degrees of protection provided by enclosures (IP Code)	EN 60529 + corr. May A1	1991 1993 2000
IEC 60601-1-2	- [2)]	Medical electrical equipment Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2	2001 [3)]
IEC 60601-1-3	- [2)]	Medical electrical equipment Part 1: General requirements for safety - 3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment	EN 60601-1-3	1994 [3)]
IEC 60601-1-6	- [2)]	Medical electrical equipment Part 1-6: General requirements for safety - Collateral standard: Usability	EN 60601-1-6	2004 [3)]

[5)] HD 22.1 S4:2002, *Cables of rated voltages up to and including 450/750 V and having cross-linked insulation - Part 1: General requirements*, which is related to, but not directly equivalent with, IEC 60245-1, applies instead.

Publication	Year	Title	EN/HD	Year
IEC 60601-1-8	- [2)]	Medical electrical equipment Part 1-8: General requirements for safety - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	EN 60601-1-8 + corr. October	2004 [3)] 2006
IEC 60664-1 (mod) + A1 + A2	1992 2000 2002	Insulation coordination for equipment within low-voltage systems Part 1: Principles, requirements and tests	EN 60664-1	2003
IEC 60695-11-10	- [2)]	Fire hazard testing Part 11-10: Test flames - 50 W horizontal and vertical flame test methods	EN 60695-11-10	1999 [3)]
IEC 60730-1 (mod) A1 (mod)	1999 2003	Automatic electrical controls for household and similar use Part 1: General requirements	EN 60730-1 A12 A1 A13 A14	2000 2003 2004 2004 2005
IEC 60825-1 A1 A2	1993 1997 2001	Safety of laser products Part 1: Equipment classification, requirements and user's guide	EN 60825-1 + corr. February A1 A2 + corr. April	1994 1995 2002 2001 2004
IEC 60851-3 A1 A2	1996 1997 2003	Winding wires - Test methods Part 3: Mechanical properties	EN 60851-3 A1 A2	1996 1997 2003
IEC 60851-5 A1 A2	1996 1997 2004	Winding wires - Test methods Part 5: Electrical properties	EN 60851-5 A1 A2	1996 1997 2004
IEC 60851-6 A1	1996 1997	Winding wires - Test methods Part 6: Thermal properties	EN 60851-6 A1	1996 1997
IEC/TR 60878	2003	Graphical symbols for electrical equipment in medical practice	-	-
IEC 60884-1	- [2)]	Plugs and socket-outlets for household and similar purposes Part 1: General requirements	-	-
IEC 60950-1 (mod)	2001	Information technology equipment - Safety Part 1: General requirements	EN 60950-1 [6)] + corr. April A11	2001 2004 2004
IEC 61058-1 (mod) + A1	2000 2001	Switches for appliances Part 1: General requirements	EN 61058-1	2002
IEC 61558-1 (mod) A1	1997 1998	Safety of power transformers, power supply units and similar Part 1: General requirements and tests	EN 61558-1 [7)] + corr. April A1 A11	1997 2003 1998 2003
IEC 61558-2-1	- [2)]	Safety of power transformers, power supply units and similar Part 2-1: Particular requirements for separating transformers for general use	EN 61558-2-1	1997 [3)]
IEC 61672-1	- [2)]	Electroacoustics - Sound level meters Part 1: Specifications	EN 61672-1	2003 [3)]

[6)] EN 60950-1 is superseded by EN 60950-1:2006, which is based on IEC 60950-1:2005, mod.

[7)] EN 61558-1 is superseded by EN 61558-1:2005, which is based on IEC 61558-1:2005.

Publication	Year	Title	EN/HD	Year
IEC 61672-2	- [2)]	Electroacoustics - Sound level meters Part 2: Pattern evaluation tests	EN 61672-2	2003 [3)]
IEC 61965	- [2)]	Mechanical safety of cathode ray tubes	EN 61965	2003 [3)]
ISO 31	Series	Quantities and units of space and time	-	-
ISO 780	- [2)]	Packaging - Pictorial marking for handling of goods	EN ISO 780	1999
ISO 1000	- [2)]	SI units and recommendations for the use of their multiples and of certain other units	-	-
ISO 1853	- [2)]	Conducting and dissipative rubbers, vulcanized or thermoplastic - Measurement of resistivity	-	-
ISO 2878	- [2)]	Rubber, vulcanized - Antistatic and conductive products - Determination of electrical resistance	-	-
ISO 2882	- [2)]	Rubber, vulcanized - Antistatic and conductive products for hospital use - Electrical resistance limits	-	-
ISO 3746	- [2)]	Acoustics - Determination of sound power levels of noise sources using sound pressure - Survey method using an enveloping measurement surface over a reflecting plane	EN ISO 3746	1995
ISO 3864-1	2002	Graphical symbols - Safety colours and safety signs Part 1: Design principles for safety signs in workplaces and public areas	-	-

Annex ZZA
(informative)

Coverage of Essential Requirements of EC Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers all relevant essential requirements as given in Annex I of the EC Directive 93/42/EEC except the following:

– Essential Requirement 6a

– Essential Requirement 7.4

– Essential Requirement 7.5 paragraph 2 & 3

– Essential Requirement 13.6 (q)

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directives concerned.

WARNING: Other requirements and other EC Directives may be applicable to the products falling within the scope of this standard.

Annex ZZB
(informative)

Coverage of Essential Requirements of EC Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers all relevant essential requirements as given in Annex I of the EC Directive 90/385/EEC except the following:

– Essential Requirement 5a

– Essential Requirement 7

– Essential Requirement 8 bullet 5

– Essential Requirement 10

– Essential Requirement 11

– Essential Requirement 12

– Essential Requirement 14

– Essential Requirement 15

– Essential Requirement 16

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directives concerned.

WARNING: Other requirements and other EC Directives may be applicable to the products falling within the scope of this standard.

_____

CONTENTS

Annex ZA (normative) Normative references to international publications with their corresponding European publications 4
Annex ZZA (informative) Coverage of Essential Requirements of EC Directives 8
Annex ZZB (informative) Coverage of Essential Requirements of EC Directives 8

INTRODUCTION 19

1 Scope, object and related standards 21
1.1 * Scope 21
1.2 Object 21
1.3 * Collateral standards 21
1.4 * Particular standards 22
2 * Normative references 22
3 * Terminology and definitions 26
4 General requirements 46
4.1 * Conditions for application to ME EQUIPMENT or ME SYSTEMS 46
4.2 * RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS 46
4.3 * ESSENTIAL PERFORMANCE 47
4.4 * EXPECTED SERVICE LIFE 47
4.5 * Equivalent safety for ME EQUIPMENT or ME SYSTEMS 48
4.6 * ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT 48
4.7 * SINGLE FAULT CONDITION for ME EQUIPMENT 48
4.8 Components of ME EQUIPMENT 49
4.9 * Use of COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS in ME EQUIPMENT 49
4.10 * Power supply 50
4.11 Power input 51
5 * General requirements for testing ME EQUIPMENT 52
5.1 * TYPE TESTS 52
5.2 * Number of samples 52
5.3 Ambient temperature, humidity, atmospheric pressure 52
5.4 Other conditions 52
5.5 Supply voltages, type of current, nature of supply, frequency 53
5.6 Repairs and modifications 53
5.7 * Humidity preconditioning treatment 53
5.8 Sequence of tests 54
5.9 * Determination of APPLIED PARTS and ACCESSIBLE PARTS 54
6 * Classification of ME EQUIPMENT and ME SYSTEMS 56
6.1 General 56
6.2 * Protection against electric shock 56
6.3 * Protection against harmful ingress of water or particulate matter 57
6.4 Method(s) of sterilization 57
6.5 Suitability for use in an OXYGEN RICH ENVIRONMENT 57
6.6 * Mode of operation 57

7 ME EQUIPMENT identification, marking and documents 57
7.1 General 57
7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts 59
7.3 Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts 63
7.4 Marking of controls and instruments 65
7.5 Safety signs 66
7.6 Symbols 67
7.7 Colours of the insulation of conductors 67
7.8 * Indicator lights and controls 68
7.9 ACCOMPANYING DOCUMENTS 68
8 * Protection against electrical HAZARDS from ME EQUIPMENT 74
8.1 Fundamental rule of protection against electric shock 74
8.2 Requirements related to power sources 75
8.3 Classification of APPLIED PARTS 75
8.4 Limitation of voltage, current or energy 76
8.5 Separation of parts 79
8.6 * Protective earthing, functional earthing and potential equalization of ME EQUIPMENT 87
8.7 LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS 90
8.8 Insulation 107
8.9 * CREEPAGE DISTANCES and AIR CLEARANCES 113
8.10 Components and wiring 128
8.11 MAINS PARTS, components and layout 130
9 * Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS 136
9.1 MECHANICAL HAZARDS of ME EQUIPMENT 136
9.2 * HAZARDS associated with moving parts 137
9.3 * HAZARD associated with surfaces, corners and edges 142
9.4 * Instability HAZARDS 142
9.5 * Expelled parts HAZARD 147
9.6 Acoustic energy (including infra- and ultrasound) and vibration 147
9.7 * Pressure vessels and parts subject to pneumatic and hydraulic pressure 149
9.8 * HAZARDS associated with support systems 152
10 * Protection against unwanted and excessive radiation HAZARDS 157
10.1 X-Radiation 157
10.2 Alpha, beta, gamma, neutron and other particle radiation 158
10.3 Microwave radiation 158
10.4 * Lasers and light emitting diodes (LEDs) 158
10.5 Other visible electromagnetic radiation 158
10.6 Infrared radiation 159
10.7 Ultraviolet radiation 159
11 * Protection against excessive temperatures and other HAZARDS 159
11.1 * Excessive temperatures in ME EQUIPMENT 159
11.2 * Fire prevention 163
11.3 * Constructional requirements for fire ENCLOSURES of ME EQUIPMENT 168

11.4 * ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics 171
11.5 * ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents 171
11.6 Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT 171
11.7 Biocompatibility of ME EQUIPMENT and ME SYSTEMS 173
11.8 * Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT 173
12 * Accuracy of controls and instruments and protection against hazardous outputs 173
12.1 Accuracy of controls and instruments 173
12.2 USABILITY 173
12.3 Alarm systems 173
12.4 Protection against hazardous output 173
13 * HAZARDOUS SITUATIONS and fault conditions 175
13.1 Specific HAZARDOUS SITUATIONS 175
13.2 SINGLE FAULT CONDITIONS 176
14 * PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) 182
14.1 * General 182
14.2 * Documentation 182
14.3 * RISK MANAGEMENT plan 183
14.4 * PEMS DEVELOPMENT LIFE-CYCLE 183
14.5 * Problem resolution 183
14.6 RISK MANAGEMENT PROCESS 183
14.7 * Requirement specification 184
14.8 * Architecture 184
14.9 * Design and implementation 185
14.10 * VERIFICATION 185
14.11 * PEMS VALIDATION 185
14.12 * Modification 186
14.13 * Connection of PEMS by NETWORK/DATA COUPLING to other equipment 186
15 Construction of ME EQUIPMENT 186
15.1 * Arrangements of controls and indicators of ME EQUIPMENT 186
15.2 * Serviceability 186
15.3 Mechanical strength 187
15.4 ME EQUIPMENT components and general assembly 191
15.5 * MAINS SUPPLY TRANSFORMERS of ME EQUIPMENT and transformers providing separation in accordance with 8.5 196
16 * ME SYSTEMS 200
16.1 * General requirements for the ME SYSTEMS 200
16.2 * ACCOMPANYING DOCUMENTS of an ME SYSTEM 201
16.3 * Power supply 202
16.4 ENCLOSURES 202
16.5 * SEPARATION DEVICES 202
16.6 * LEAKAGE CURRENTS 203
16.7 * Protection against MECHANICAL HAZARDS 204
16.8 Interruption of the power supply to parts of an ME SYSTEM 204
16.9 ME SYSTEM connections and wiring 204
17 * Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS 206

Annex A (informative) General guidance and rationale 207
Annex B (informative) Sequence of testing 313
Annex C (informative) Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS 317
Annex D (informative) Symbols on marking 321
Annex E (informative) Examples of the connection of the measuring device (MD) for measurement of the PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT 330
Annex F (informative) Suitable measuring supply circuits 332
Annex G (normative) Protection against HAZARDS of ignition of flammable anaesthetic mixtures 335
Annex H (informative) PEMS structure, PEMS DEVELOPMENT LIFE-CYCLE and documentation 350
Annex I (informative) ME SYSTEMS aspects 353
Annex J (informative) Survey of insulation paths 369
Annex K (informative) Simplified PATIENT LEAKAGE CURRENT diagrams 372
Annex L (normative) Insulated winding wires for use without interleaved insulation 375

Bibliography 378

INDEX OF ABBREVIATIONS AND ACRONYMS 381

Figure 1 – Detachable mains connection 28
Figure 2 – Example of the defined terminals and conductors 29
Figure 3 – Example of a CLASS I ME EQUIPMENT 30
Figure 4 – Example of a metal-enclosed CLASS II ME EQUIPMENT 30
Figure 5 – Schematic flow chart for component qualification 50
Figure 6 – Standard test finger 55
Figure 7 – Test hook 56
Figure 8 – Test pin 77
Figure 9 – Application of test voltage to bridged PATIENT CONNECTIONS for DEFIBRILLATION-PROOF APPLIED PARTS 84
Figure 10 – Application of test voltage to individual PATIENT CONNECTIONS for DEFIBRILLATION-PROOF APPLIED PARTS 86
Figure 11 – Application of test voltage to test the delivered defibrillation energy 87
Figure 12 – Example of a measuring device and its frequency characteristics 91

Figure 13 – Measuring circuit for the EARTH LEAKAGE CURRENT of CLASS I ME equipment, with or without APPLIED PART 94
Figure 14 – Measuring circuit for the TOUCH CURRENT 95
Figure 15 – Measuring circuit for the PATIENT LEAKAGE CURRENT from the PATIENT CONNECTION to earth 96
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) 97
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 98
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 99
Figure 19 – Measuring circuit for the PATIENT AUXILIARY CURRENT 100
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 101
Figure 21 – Ball-pressure test apparatus 113
Figure 22 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 1 126
Figure 23 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 2 126
Figure 24 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 3 126
Figure 25 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 4 126
Figure 26 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 5 126
Figure 27 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 6 127
Figure 28 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 7 127
Figure 29 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 8 127
Figure 30 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 9 127
Figure 31 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 10 128
Figure 32 – Ratio between HYDRAULIC TEST PRESSURE and MAXIMUM PERMISSIBLE WORKING PRESSURE 151
Figure 33 – Human body test mass 156
Figure 34 – Spark ignition test apparatus 165
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 165
Figure 36 – Maximum allowable voltage *U* as a function of the capacitance *C* measured in a capacitive circuit used in an OXYGEN RICH ENVIRONMENT 166
Figure 37 – Maximum allowable current *I* as a function of the inductance *L* measured in an inductive circuit in an OXYGEN RICH ENVIRONMENT 166
Figure 38 – Baffle 170
Figure 39 – Area of the bottom of an ENCLOSURE as specified in 11.3 b) 1) 170
Figure A.1 – Identification of ME EQUIPMENT , APPLIED PARTS and PATIENT CONNECTIONS in an ECG monitor 213
Figure A.2 – Example of the insulation of an F-TYPE APPLIED PART with the insulation incorporated in the ME EQUIPMENT 214
Figure A.3 – Identification of ME EQUIPMENT, APPLIED PARTS and PATIENT CONNECTIONS in a PATIENT monitor with invasive pressure monitoring facility 215

Figure A.4 – Identification of ME EQUIPMENT, APPLIED PARTS and PATIENT CONNECTIONS in a multifunction PATIENT monitor with invasive pressure monitoring facilities 216

Figure A.5 – Identification of APPLIED PARTS and PATIENT CONNECTIONS in an X-ray ME SYSTEM 217

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 217

Figure A.7 – Identification of ME EQUIPMENT or ME SYSTEM, APPLIED PARTS and PATIENT CONNECTIONS in a personal computer with an ECG module 218

Figure A.8 – Pictorial representation of the relationship of HAZARD, sequence of events, HAZARDOUS SITUATION and HARM..... 221

Figure A.9 – Example of PATIENT ENVIRONMENT 227

Figure A.10 – Floating circuit 241

Figure A.11 – Interruption of a power-carrying conductor between ME EQUIPMENT parts in separate ENCLOSURES..... 244

Figure A.12 – Identification of MEANS OF PATIENT PROTECTION and MEANS OF OPERATOR PROTECTION 248

Figure A.13 – Allowable protective earth impedance where the fault current is limited..... 255

Figure A.14 – Probability of ventricular fibrillation 261

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..... 266

Figure A.16 – Instability test conditions 278

Figure A.17 – Example of determining TENSILE SAFETY FACTOR using Table 21..... 284

Figure A.18 – Example of determining design and test loads 285

Figure A.19 – Example of human body mass distribution 285

Figure E.1 – TYPE B APPLIED PART 330

Figure E.2 – TYPE BF APPLIED PART 330

Figure E.3 – TYPE CF APPLIED PART 331

Figure E.4 – PATIENT AUXILIARY CURRENT 331

Figure E.5 – Loading of the PATIENT CONNECTIONS if specified by the MANUFACTURER..... 331

Figure F.1 – Measuring supply circuit with one side of the SUPPLY MAINS at approximately earth potential 332

Figure F.2 – Measuring supply circuit with SUPPLY MAINS approximately symmetrical to earth potential 335

Figure F.3 – Measuring supply circuit for polyphase ME EQUIPMENT specified for connection to a polyphase SUPPLY MAINS 333

Figure F.4 – Measuring supply circuit for single-phase ME EQUIPMENT specified for connection to a polyphase SUPPLY MAINS 333

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..... 334

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 341

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 342

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 . 342

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 346
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 347
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 347
Figure G.7 – Test apparatus 349
Figure H.1 – Examples of PEMS/ PESS structures 351
Figure H.2 – A PEMS DEVELOPMENT LIFE-CYCLE model 352
Figure H.3 – PEMS documentation requirements from Clause 14 and ISO 14971:2000 356
Figure H.4 – Example of potential parameters required to be specified for NETWORK/DATA COUPLING 362
Figure I.1 – Example of the construction of a MULTIPLE SOCKET-OUTLET (MSO) 367
Figure I.2 – Examples of application of MULTIPLE SOCKET-OUTLETS (MSO) 368
Figure J.1 – Insulation example 1 369
Figure J.2 – Insulation example 2 369
Figure J.3 – Insulation example 3 369
Figure J.4 – Insulation example 4 370
Figure J.5 – Insulation example 5 370
Figure J.6 – Insulation example 6 370
Figure J.7 – Insulation example 7 371
Figure K.1 – ME EQUIPMENT with an ENCLOSURE made of insulating material 372
Figure K.2 – ME EQUIPMENT with an F-TYPE APPLIED PART 372
Figure K.3 – ME EQUIPMENT with an APPLIED PART and a SIGNAL INPUT/OUTPUT PART 373
Figure K.4 – ME EQUIPMENT with a PATIENT CONNECTION of a TYPE B APPLIED PART that is not PROTECTIVELY EARTHED 373
Figure K.5 – ME EQUIPMENT with a PATIENT CONNECTION of a TYPE BF APPLIED PART that is not PROTECTIVELY EARTHED 374

Table 1 – Units outside the SI units system that may be used on ME EQUIPMENT 66
Table 2 – Colours of indicator lights and their meaning for ME EQUIPMENT 68
Table 3 – * Allowable values of PATIENT LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS under NORMAL CONDITION and SINGLE FAULT CONDITION 92
Table 4 – * Allowable values of PATIENT LEAKAGE CURRENTS under the special test conditions identified in 8.7.4.7 93
Table 5 – Legends of symbols for Figure 9 to Figure 11, Figure 13 to Figure 20, Figure A.15, Annex E and Annex F 102
Table 6 – Test voltages for solid insulation forming a MEANS OF PROTECTION 110
Table 7 – Test voltages for MEANS OF OPERATOR PROTECTION 111
Table 8 – Multiplication factors for AIR CLEARANCES for altitudes up to 5 000 m 114
Table 9 – Material group classification 115

Table 10 – MAINS TRANSIENT VOLTAGE 116
Table 11 – Minimum CREEPAGE DISTANCES and AIR CLEARANCES between parts of opposite polarity of the MAINS PART 118
Table 12 – Minimum CREEPAGE DISTANCES and AIR CLEARANCES providing MEANS OF PATIENT PROTECTION 119
Table 13 – Minimum AIR CLEARANCES providing MEANS OF OPERATOR PROTECTION from the MAINS PART 120
Table 14 – Additional AIR CLEARANCES for insulation in MAINS PARTS with PEAK WORKING VOLTAGES exceeding the peak value of the NOMINAL MAINS VOLTAGE [a] 121
Table 15 – Minimum AIR CLEARANCES for MEANS OF OPERATOR PROTECTION in SECONDARY CIRCUITS 122
Table 16 – Minimum CREEPAGE DISTANCES providing MEANS OF OPERATOR PROTECTION 123
Table 17 – NOMINAL cross-sectional area of conductors of a POWER SUPPLY CORD 132
Table 18 – Testing of cord anchorages 133
Table 19 – MECHANICAL HAZARDS covered by this clause 137
Table 20 – Acceptable gaps 139
Table 21 – Determination of TENSILE SAFETY FACTOR 153
Table 22 – Allowable maximum temperatures of parts 159
Table 23 – Allowable maximum temperatures for ME EQUIPMENT parts that are likely to be touched 160
Table 24 – Allowable maximum temperatures for skin contact with ME EQUIPMENT APPLIED PARTS 160
Table 25 – Acceptable perforation of the bottom of an ENCLOSURE 169
Table 26 – * Temperature limits of motor windings 179
Table 27 – Maximum motor winding steady-state temperature 181
Table 28 – Mechanical strength test applicability 187
Table 29 – Drop height 189
Table 30 – Test torques for rotating controls 195
Table 31 – Maximum allowable temperatures of transformer windings under overload and short-circuit conditions at 25 °C (± 5 °C) ambient temperature 197
Table 32 – Test current for transformers 198
Table A.1 – Values of AIR CLEARANCE and CREEPAGE DISTANCE derived from Table 7 of IEC 61010-1:2001 and Table 12 269
Table A.2 – CREEPAGE DISTANCES to avoid failure due to tracking from IEC 60664-1 270
Table A.3 – Instability test conditions 278
Table A.4 – Allowable time exposure for level of acceleration 280
Table A.5 – Guidance on surface temperatures for ME EQUIPMENT that creates low temperatures (cools) for therapeutic purposes or as part of its operation 289
Table C.1– Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts 317
Table C.2 – Marking on the inside of ME EQUIPMENT, ME SYSTEMS or their parts 318
Table C.3 – Marking of controls and instruments 318
Table C.4 – ACCOMPANYING DOCUMENTS, general 319
Table C.5 – ACCOMPANYING DOCUMENTS, instructions for use 319
Table D.1 – General symbols 322
Table D.2 – Safety signs 327
Table D.3 – General codes 329

Table G.1 – Gas-tightness of cord inlets 344
Table H.1 – NETWORK/DATA COUPLING classification 360
Table I.1 – Some examples of ME SYSTEMS for illustration 365
Table L.1– Mandrel diameter 376
Table L.2 – Oven temperature 376

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 a RISK MANAGEMENT PROCESS complying with ISO 14971 in place (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.

1) Figures in square brackets refer to the Bibliography.

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 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].

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.

---

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*