BRITISH STANDARD

BS EN 60601-1:2006 +A1:2013

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

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BSI British Standards

National foreword

This British Standard is the UK implementation of EN 60601-1:2006+A1:2013. It is identical to IEC 60601-1:2005, incorporating amendment A1:2013. It supersedes BS EN 60601-1:2006+A11:2011, which will be withdrawn on 24 December 2018.

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].

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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.

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

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Amendments/corrigenda issued since publication

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29 February 2012	Implementation of CENELEC amendment A11:2011: Annex ZZ replaced by Annexes ZZA and ZZB
31 December 2013	Implementation of IEC amendment 1:2013 with CENELEC endorsement A1:2013. Annex ZA, replaced and Annex ZZ added

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EUROPEAN STANDARD **EN 60601-1:2006+A1**

NORME EUROPÉENNE

EUROPÄISCHE NORM October 2013

ICS 11.040

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)

This European Standard was approved by CENELEC on 2006-09-12. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

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

Central Secretariat: Avenue Marnix 17, B - 1000 Brussels

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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.

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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.

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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.

Foreword to amendment A1

The text of document 62A/805/FDIS, future IEC 60601-1:2005/A1, 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 approved by CENELEC as EN 60601-1:2006/A1:2013.

The following dates are fixed:

• latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2014-06-24
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2018-12-24

In the foreword of EN 60601-1:2006, ***replace*** *the first sentence of the third paragraph by:*

This European Standard supersedes EN 60601-1:1990 and its amendments, EN 60601-1-1:2001 and EN 60601-1-4:1996 + A1:1999.

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.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive(s) see informative Annex ZZ, which is an integral part of this document.

Endorsement notice

The text of the International Standard IEC 60601-1:2005/A1:2012 was approved by CENELEC as a European Standard without any modification.

***Replace** the Bibliography of EN 60601-1:2006 by:*

IEC 60073	NOTE	Harmonized as EN 60073.
IEC 60086-1	NOTE	Harmonized as EN 60086-1.
IEC 60127-6	NOTE	Harmonized as EN 60127-6.
IEC 60309-1	NOTE	Harmonized as EN 60309-1.
IEC 60332-1-2	NOTE	Harmonized as EN 60332-1-2.
IEC 60332-2-2	NOTE	Harmonized as EN 60332-2-2.
IEC 60317-43	NOTE	Harmonized as EN 60317-43.
IEC 60601-1-1:2000	NOTE	Harmonized as EN 60601-1-1:2001 (not modified).
IEC 60601-1-4:1996	NOTE	Harmonized as EN 60601-1-4:1996 + A1:1999 (not modified).
IEC 60601-1-11	NOTE	Harmonized as EN 60601-1-11.
IEC 60601-2-22	NOTE	Harmonized as EN 60601-2-22.
IEC 60601-2-49:2001	NOTE	Harmonized as EN 60601-2-49:2001 (not modified).
IEC 60695-1-10	NOTE	Harmonized as EN 60695-1-10.
IEC 60721 series	NOTE	Harmonized in EN 60721 series.
IEC 60990	NOTE	Harmonized as EN 60990.
IEC 61000-4-11	NOTE	Harmonized as EN 61000-4-11.
IEC 61010 series	NOTE	Harmonized in EN 61010 series.
IEC 61010-1:2010	NOTE	Harmonized as EN 61010-1:2010 (not modified).
IEC 61140:2001	NOTE	Harmonized as EN 61140:2002 (not modified).
IEC 61558-1	NOTE	Harmonized as EN 61558-1.
IEC 61558-2-4	NOTE	Harmonized as EN 61558-2-4.
IEC 61558-2-23	NOTE	Harmonized as EN 61558-2-23.
IEC 62079:2001	NOTE	Harmonized as EN 62079:2001 (not modified).
IEC 62353	NOTE	Harmonized as EN 62353.
IEC 62471:2006	NOTE	Harmonized as EN 62471:2008 (modified).
IEC 80001-1:2010	NOTE	Harmonized as EN 80001-1:2011 (not modified).

ISO 407	NOTE	Harmonized as EN ISO 407.
ISO 7396-1	NOTE	Harmonized as EN ISO 7396-1.
ISO 8041	NOTE	Harmonized as EN ISO 8041.
ISO 13485	NOTE	Harmonized as EN ISO 13485.
ISO 15001	NOTE	Harmonized as EN ISO 15001.

CONTENTS

Annex ZA (normative) Normative references to international publications with their corresponding European publications 6

Annex ZZA (informative) Coverage of Essential Requirements of EC Directives 12

Annex ZZB (informative) Coverage of Essential Requirements of EC Directives 12

Annex ZZ (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on Medical Devices 13

INTRODUCTION 41

1 Scope, object and related standards 43
- 1.1 * Scope 43
- 1.2 Object 43
- 1.3 * Collateral standards 43
- 1.4 * Particular standards 44

2 * Normative references 44

3 * Terminology and definitions 48

4 General requirements 68
- 4.1 * Conditions for application to ME EQUIPMENT or ME SYSTEMS 68
- 4.2 * RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS 69
- 4.3 * ESSENTIAL PERFORMANCE 71
- 4.4 * EXPECTED SERVICE LIFE 72
- 4.5 * Alternative RISK CONTROL measures or test methods for ME EQUIPMENT or ME SYSTEMS 72
- 4.6 * ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT 72
- 4.7 * SINGLE FAULT CONDITION for ME EQUIPMENT 72
- 4.8 * Components of ME EQUIPMENT 74
- 4.9 * Use of COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS in ME EQUIPMENT 74
- 4.10 * Power supply 75
- 4.11 Power input 76

5 * General requirements for testing ME EQUIPMENT 77
- 5.1 * TYPE TESTS 77
- 5.2 * Number of samples 77
- 5.3 Ambient temperature, humidity, atmospheric pressure 77
- 5.4 Other conditions 77
- 5.5 Supply voltages, type of current, nature of supply, frequency. 78
- 5.6 Repairs and modifications 78
- 5.7 * Humidity preconditioning treatment 78
- 5.8 Sequence of tests 79
- 5.9 * Determination of APPLIED PARTS and ACCESSIBLE PARTS 79

6 * Classification of ME EQUIPMENT and ME SYSTEMS 81
6.1 General 81
6.2 * Protection against electric shock 81
6.3 * Protection against harmful ingress of water or particulate matter 82
6.4 Method(s) of sterilization. 82
6.5 Suitability for use in an OXYGEN RICH ENVIRONMENT 82
6.6 * Mode of operation 82
7 ME EQUIPMENT identification, marking and documents 82
7.1 General 82
7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts 84
7.3 Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts 88
7.4 Marking of controls and instruments 90
7.5 Safety signs 91
7.6 Symbols 92
7.7 Colours of the insulation of conductors 92
7.8 * Indicator lights and controls 93
7.9 ACCOMPANYING DOCUMENTS 93
8 * Protection against electrical HAZARDS from ME EQUIPMENT 99
8.1 Fundamental rule of protection against electric shock 99
8.2 Requirements related to power sources 100
8.3 Classification of APPLIED PARTS 101
8.4 Limitation of voltage, current or energy 101
8.5 Separation of parts 104
8.6 * Protective earthing, functional earthing and potential equalization of ME EQUIPMENT 112
8.7 LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS 115
8.8 Insulation 132
8.9 * CREEPAGE DISTANCES and AIR CLEARANCES 138
8.10 Components and wiring 152
8.11 MAINS PARTS, components and layout 154
9 * Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS 160
9.1 MECHANICAL HAZARDS of ME EQUIPMENT 160
9.2 * HAZARDS associated with moving parts 161
9.3 * HAZARD associated with surfaces, corners and edges 167
9.4 * Instability HAZARDS 167
9.5 * Expelled parts HAZARD 172
9.6 Acoustic energy (including infra- and ultrasound) and vibration 172
9.7 * Pressure vessels and parts subject to pneumatic and hydraulic pressure. 174
9.8 * MECHANICAL HAZARDS associated with support systems 177
10 * Protection against unwanted and excessive radiation HAZARDS 183
10.1 X-Radiation 183

10.2 Alpha, beta, gamma, neutron and other particle radiation 183
10.3 Microwave radiation 184
10.4 * Lasers 184
10.5 Other visible electromagnetic radiation 184
10.6 Infrared radiation 184
10.7 Ultraviolet radiation. 185
11 * Protection against excessive temperatures and other HAZARDS 185
11.1 * Excessive temperatures in ME EQUIPMENT 185
11.2 * Fire prevention 189
11.3 * Constructional requirements for fire ENCLOSURES of ME EQUIPMENT 194
11.4 * ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics 197
11.5 * ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents 197
11.6 Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT 197
11.7 Biocompatibility of ME EQUIPMENT and ME SYSTEMS 199
11.8 * Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT 199
12 * Accuracy of controls and instruments and protection against hazardous outputs 199
12.1 Accuracy of controls and instruments 199
12.2 USABILITY of ME EQUIPMENT 199
12.3 Alarm systems 199
12.4 Protection against hazardous output 200
13 * HAZARDOUS SITUATIONS and fault conditions 201
13.1 Specific HAZARDOUS SITUATIONS 201
13.2 SINGLE FAULT CONDITIONS 202
14 * PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) 208
14.1 * General 208
14.2 * Documentation 209
14.3 * RISK MANAGEMENT plan 209
14.4 * PEMS DEVELOPMENT LIFE-CYCLE 209
14.5 * Problem resolution 209
14.6 RISK MANAGEMENT PROCESS 209
14.7 * Requirement specification 210
14.8 * Architecture 210
14.9 * Design and implementation 211
14.10 * VERIFICATION 211
14.11 * PEMS VALIDATION 211
14.12 * Modification 212
14.13 * PEMS intended to be incorporated into an IT-NETWORK 212
15 Construction of ME EQUIPMENT 213
15.1 * Arrangements of controls and indicators of ME EQUIPMENT 213

15.2 * Serviceability 213
15.3 Mechanical strength 213
15.4 ME EQUIPMENT components and general assembly 217
15.5 * MAINS SUPPLY TRANSFORMERS of ME EQUIPMENT and transformers providing separation in accordance with 8.5 222
16 * ME SYSTEMS 226
16.1 * General requirements for the ME SYSTEMS 226
16.2 * ACCOMPANYING DOCUMENTS of an ME SYSTEM 227
16.3 * Power supply 228
16.4 ENCLOSURES 228
16.5 * SEPARATION DEVICES 228
16.6 * LEAKAGE CURRENTS 229
16.7 * Protection against MECHANICAL HAZARDS 230
16.8 Interruption of the power supply to parts of an ME SYSTEM 230
16.9 ME SYSTEM connections and wiring 230
17 * Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS 232

Annex A (informative) General guidance and rationale 233
Annex B (informative) Sequence of testing 347
Annex C (informative) Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS 351
Annex D (informative) Symbols on marking 355
Annex E (informative) Examples of the connection of the measuring device (MD) for measurement of the PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT 364
Annex F (informative) Suitable measuring supply circuits. 366
Annex G (normative) Protection against HAZARDS of ignition of flammable anaesthetic mixtures 369
Annex H (informative) PEMS structure, PEMS DEVELOPMENT LIFE-CYCLE and documentation 384
Annex I (informative) ME SYSTEMS aspects 392
Annex J (informative) Survey of insulation paths 398
Annex K (informative) Simplified PATIENT LEAKAGE CURRENT diagrams 401
Annex L (normative) Insulated winding wires for use without interleaved insulation 404
Annex M (normative) Reduction of pollution degrees 407

Bibliography 408

INDEX OF ABBREVIATIONS AND ACRONYMS 412

Figure 1 – Detachable mains connection 49
Figure 2 – Example of the defined terminals and conductors. 50
Figure 3 – Example of a CLASS I ME EQUIPMENT 51
Figure 4 – Example of a metal-enclosed CLASS II ME EQUIPMENT 51
Figure 5 – Schematic flow chart for component qualification 75
Figure 6 – Standard test finger. 80
Figure 7 – Test hook 81
Figure 8 – Test pin 103
Figure 9 – Application of test voltage to bridged PATIENT CONNECTIONS for DEFIBRILLATION-PROOF APPLIED PARTS 109
Figure 10 – Application of test voltage to individual PATIENT CONNECTIONS for DEFIBRILLATION-PROOF APPLIED PARTS 110
Figure 11 – Application of test voltage to test the delivered defibrillation energy 112
Figure 12 – Example of a measuring device and its frequency characteristics 116
Figure 13 – Measuring circuit for EARTH LEAKAGE CURRENT of CLASS I ME equipment, with or without APPLIED PART 119
Figure 14 – Measuring circuit for TOUCH CURRENT 120
Figure 15 – Measuring circuit for PATIENT LEAKAGE CURRENT from the PATIENT CONNECTION to earth 121
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) 122
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 123
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 124
Figure 19 – Measuring circuit for PATIENT AUXILIARY CURRENT 125
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 126
Figure 21 – Ball-pressure test apparatus 138
Figure 22 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 1 150
Figure 23 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 2 150
Figure 24 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 3 150
Figure 25 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 4 150
Figure 26 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 5 150
Figure 27 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 6 151
Figure 28 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 7 151
Figure 29 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 8 151
Figure 30 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 9 151
Figure 31 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 10 152
Figure 32 – Ratio between HYDRAULIC TEST PRESSURE and MAXIMUM PERMISSIBLE WORKING PRESSURE 176
Figure 33 – Human body test mass 181

Figure 34 – Spark ignition test apparatus 191

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 191

Figure 36 – Maximum allowable voltage *U* as a function of the capacitance *C* measured in a capacitive circuit used in an OXYGEN RICH ENVIRONMENT 192

Figure 37 – Maximum allowable current *I* as a function of the inductance *L* measured in an inductive circuit in an OXYGEN RICH ENVIRONMENT 192

Figure 38 – Baffle 196

Figure 39 – Area of the bottom of an ENCLOSURE as specified in 11.3 b) 1) 196

Figure A.1 – Identification of ME EQUIPMENT, APPLIED PARTS and PATIENT CONNECTIONS in an ECG monitor 239

Figure A.2 – Example of the insulation of an F-TYPE APPLIED PART with the insulation incorporated in the ME EQUIPMENT 240

Figure A.3 – Identification of ME EQUIPMENT, APPLIED PARTS and PATIENT CONNECTIONS in a PATIENT monitor with invasive pressure monitoring facility 241

Figure A.4 – Identification of ME EQUIPMENT, APPLIED PARTS and PATIENT CONNECTIONS in a multifunction PATIENT monitor with invasive pressure monitoring facilities 242

Figure A.5 – Identification of APPLIED PARTS and PATIENT CONNECTIONS in an X-ray ME SYSTEM 243

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 243

Figure A.7 – Identification of ME EQUIPMENT or ME SYSTEM, APPLIED PARTS and PATIENT CONNECTIONS in a personal computer with an ECG module 244

Figure A.8 – Pictorial representation of the relationship of HAZARD, sequence of events, HAZARDOUS SITUATION and HARM 247

Figure A.20 – Relationship of the terms used to describe equipment, ACCESSORIES or equipment parts 249

Figure A.9 – Example of PATIENT ENVIRONMENT 253

Figure A.10 – Floating circuit 272

Figure A.11 – Interruption of a power-carrying conductor between ME EQUIPMENT parts in separate ENCLOSURES 274

Figure A.12 – Identification of MEANS OF PATIENT PROTECTION and MEANS OF OPERATOR PROTECTION 278

Figure A.21 – Example of ME EQUIPMENT having two different functions on one common APPLIED PART circuit 283

Figure A.13 – Allowable protective earth impedance where the fault current is limited 285

Figure A.14 – Probability of ventricular fibrillation 291

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 296

Figure A.16 – Instability test conditions 308

Figure A.17 – Example of determining TENSILE SAFETY FACTOR using Table 21 315

Figure A.18 – Example of determining design and test loads 316

Figure A.19 – Example of human body mass distribution 316

Figure A.22 – Maximum allowable temperature for surfaces and APPLIED PARTS at higher altitudes 321

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 339

Figure E.1 – TYPE B APPLIED PART 364

Figure E.2 – TYPE BF APPLIED PART 364

Figure E.3 – TYPE CF APPLIED PART 365

Figure E.4 – PATIENT AUXILIARY CURRENT 365

Figure E.5 – Loading of the PATIENT CONNECTIONS if specified by the MANUFACTURER 365

Figure F.1 – Measuring supply circuit with one side of the SUPPLY MAINS at approximately earth potential 366

Figure F.2 – Measuring supply circuit with SUPPLY MAINS approximately symmetrical to earth potential 366

Figure F.3 – Measuring supply circuit for polyphase ME EQUIPMENT specified for connection to a polyphase SUPPLY MAINS 367

Figure F.4 – Measuring supply circuit for single-phase ME EQUIPMENT specified for connection to a polyphase SUPPLY MAINS 367

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 368

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 375

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 376

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 376

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 380

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 381

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 381

Figure G.7 – Test apparatus 383

Figure H.1 – Examples of PEMS/PESS structures 385

Figure H.2 – A PEMS DEVELOPMENT LIFE-CYCLE model 386

Figure H.4 – Example of potential parameters required to be specified for NETWORK/DATA COUPLING 391

Figure I.1 – Example of the construction of a MULTIPLE SOCKET-OUTLET (MSO) 396

Figure I.2 – Examples of application of MULTIPLE SOCKET-OUTLETS (MSO) 397

Figure J.1 – Insulation example 1 398

Figure J.2 – Insulation example 2 398

Figure J.3 – Insulation example 3 398

Figure J.4 – Insulation example 4 399

Figure J.5 – Insulation example 5 399

Figure J.6 – Insulation example 6 399

Figure J.7 – Insulation example 7 400
Figure K.1 – ME EQUIPMENT with an ENCLOSURE made of insulating material 401
Figure K.2 – ME EQUIPMENT with an F-TYPE APPLIED PART 401
Figure K.3 – ME EQUIPMENT with an APPLIED PART and a SIGNAL INPUT/OUTPUT PART 402
Figure K.4 – ME EQUIPMENT with a PATIENT CONNECTION of a TYPE B APPLIED PART that is not PROTECTIVELY EARTHED 402
Figure K.5 – ME EQUIPMENT with a PATIENT CONNECTION of a TYPE BF APPLIED PART that is not PROTECTIVELY EARTHED 403

Table 1 – Units outside the SI units system that may be used on ME EQUIPMENT 91
Table 2 – Colours of indicator lights and their meaning for ME EQUIPMENT 93
Table 3 – * Allowable values of PATIENT LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS under NORMAL CONDITION and SINGLE FAULT CONDITION 117
Table 4 – * Allowable values of PATIENT LEAKAGE CURRENTS under the special test conditions identified in 8.7.4.7 118
Table 5 – Legends of symbols for Figure 9 to Figure 11, Figure 13 to Figure 20, Figure A.15, Annex E and Annex 127
Table 6 – Test voltages for solid insulation forming a MEANS OF PROTECTION 135
Table 7 – Test voltages for MEANS OF OPERATOR PROTECTION 136
Table 8 – Multiplication factors for AIR CLEARANCES for altitudes up to 5 000 m 139
Table 9 – Material group classification 140
Table 10 – MAINS TRANSIENT VOLTAGE 141
Table 12 – Minimum CREEPAGE DISTANCES and AIR CLEARANCES providing MEANS OF PATIENT PROTECTION 143
Table 13 – Minimum AIR CLEARANCES providing MEANS OF OPERATOR PROTECTION from the MAINS PART 144
Table 14 – Additional AIR CLEARANCES for insulation in MAINS PARTS with PEAK WORKING VOLTAGES exceeding the peak value of the NOMINAL MAINS VOLTAGE 145
Table 15 – Minimum AIR CLEARANCES for MEANS OF OPERATOR PROTECTION in SECONDARY CIRCUITS 146
Table 16 – Minimum CREEPAGE DISTANCES providing MEANS OF OPERATOR PROTECTION 147
Table 17 – NOMINAL cross-sectional area of conductors of a POWER SUPPLY CORD 156
Table 18 – Testing of cord anchorages 157
Table 19 – MECHANICAL HAZARDS covered by this clause 161
Table 20 – Acceptable gaps 163
Table 33 – Test conditions for overtravel end stop test 166
Table 21 – Determination of TENSILE SAFETY FACTOR 178
Table 22 – Allowable maximum temperatures of parts 185
Table 23 – Allowable maximum temperatures for ME EQUIPMENT parts that are likely to be touched 186
Table 24 – Allowable maximum temperatures for skin contact with ME EQUIPMENT APPLIED PARTS 186
Table 25 – Acceptable perforation of the bottom of an ENCLOSURE 195

Table 26 – * Temperature limits of motor windings 205
Table 27 – Maximum motor winding steady-state temperature 207
Table 28 – Mechanical strength test applicability 214
Table 29 – Drop height 215
Table 30 – Test torques for rotating controls 221
Table 31 – Maximum allowable temperatures of transformer windings under overload and short-circuit conditions at 25 °C (± 5 °C) ambient temperature 223
Table 32 – Test current for transformers 224
Table A.1 – Values of AIR CLEARANCE and CREEPAGE DISTANCE derived from Table 7 of IEC 61010-1:2001 and Table 12 299
Table A.2 – CREEPAGE DISTANCES to avoid failure due to tracking from IEC 60664-1 300
Table A.3 – Instability test conditions 308
Table A.4 – Allowable time exposure for level of acceleration 311
Table A.5 – Guidance on surface temperatures for ME EQUIPMENT that creates low temperatures (cools) for therapeutic purposes or as part of its operation 320
Table C.1 – Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts 351
Table C.2 – Marking on the inside of ME EQUIPMENT, ME SYSTEMS or their parts 352
Table C.3 – Marking of controls and instruments 352
Table C.4 – ACCOMPANYING DOCUMENTS, general 353
Table C.5 – ACCOMPANYING DOCUMENTS, instructions for use 353
Table D.1 – General symbols 354
Table D.2 – Safety signs 361
Table D.3 – General codes 363
Table G.1 – Gas-tightness of cord inlets 378
Table I.1 – Some examples of ME SYSTEMS for illustration 394
Table L.1 – Mandrel diameter 405
Table L.2 – Oven temperature 405
Table M.1 – Reduction of the pollution degree of internal environment through the use of additional protection 407

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. ▌A1⟩ 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). ⟨A1▐

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.

▌A1⟩ 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. ⟨A1▐

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.

〖A1〗 NOTE 1 〈A1〉 See also 4.2.

〖A1〗 *text deleted* 〈A1〉

〖A1〗 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. 〈A1〉

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.