

Elektrisk utrustning för medicinskt bruk – Del 1: Allmänna fordringar beträffande säkerhet och väsentliga prestanda

Medical electrical equipment –

Part 1: General requirements for basic safety and essential performance

Som svensk standard gäller europastandarden EN 60601-1:2006. Den svenska standarden innehåller den officiella engelska språkversionen av EN 60601-1:2006.

Nationellt förord

Europastandarden EN 60601-1:2006

består av:

- **europastandardens ikraftsättningsdokument**, utarbetat inom CENELEC
- **IEC 60601-1, Third edition, 2005 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance**

utarbetad inom International Electrotechnical Commission, IEC.

SS-EN 60601-1, utgåva 1, 1991, SS-EN 60601-1/A1, utgåva 1, 2001, SS-EN 60601-1/A2, utgåva 1, 1996, SS-EN 60601-1/A13, utgåva 1, 1996, SS-EN 60601-1 T2, utgåva 1, 1995, fortsätter att gälla tillsammans med de svenska standarder för olika apparatslag som utgör Del 2 och som hänvisar till dessa.

SS-EN 60601-1, utgåva 2, 2006, gäller endast i det fall det finns en Del 2 för apparatslag som skall provas. Där så befins rimligt kan den dock tillämpas på apparatslag som ej omfattas av någon Del 2, i vilket fall SS-EN 60601-1, utgåva 1, 1991, inte gäller fr o m 2009-09-12.

Standarder underlättar utvecklingen och höjer elsäkerheten

Det finns många fördelar med att ha gemensamma tekniska regler för bl a säkerhet, prestanda, dokumentation, utförande och skötsel av elprodukter, elanläggningar och metoder. Genom att utforma sådana standarder blir säkerhetskraven tydliga och utvecklingskostnaderna rimliga samtidigt som marknadens acceptans för produkten eller tjänsten ökar.

Många standarder inom elområdet beskriver tekniska lösningar och metoder som åstadkommer den elsäkerhet som föreskrivs av svenska myndigheter och av EU.

SEK är Sveriges röst i standardiseringsarbetet inom elområdet

Svenska Elektriska Kommissionen, SEK, svarar för standardiseringen inom elområdet i Sverige och samordnar svensk medverkan i internationell och europeisk standardisering. SEK är en ideell organisation med frivilligt deltagande från svenska myndigheter, företag och organisationer som vill medverka till och påverka utformningen av tekniska regler inom elektrotekniken.

SEK samordnar svenska intressenters medverkan i SEKs tekniska kommittéer och stödjer svenska experters medverkan i internationella och europeiska projekt.

Stora delar av arbetet sker internationellt

Utformningen av standarder sker i allt väsentligt i internationellt och europeiskt samarbete. SEK är svensk nationalkommitté av International Electrotechnical Commission (IEC) och Comité Européen de Normalisation Electrotechnique (CENELEC).

Standardiseringsarbetet inom SEK är organiserat i referensgrupper bestående av ett antal tekniska kommittéer som speglar hur arbetet inom IEC och CENELEC är organiserat.

Arbetet i de tekniska kommittéerna är öppet för alla svenska organisationer, företag, institutioner, myndigheter och statliga verk. Den årliga avgiften för deltagandet och intäkter från försäljning finansierar SEKs standardiseringsverksamhet och medlemsavgift till IEC och CENELEC.

Var med och påverka!

Den som deltar i SEKs tekniska kommittéarbete har möjlighet att påverka framtida standarder och får tidig tillgång till information och dokumentation om utvecklingen inom sitt teknikområde. Arbetet och kontakterna med kollegor, kunder och konkurrenter kan gynnsamt påverka enskilda företags affärsutveckling och bidrar till deltagarnas egen kompetensutveckling.

Du som vill dra nytta av dessa möjligheter är välkommen att kontakta SEKs kansli för mer information.

SEK

Box 1284
164 29 Kista
Tel 08-444 14 00
www.sekom.se

EUROPEAN STANDARD

EN 60601-1

NORME EUROPÉENNE

EUROPÄISCHE NORM

October 2006

ICS 11.040

Supersedes EN 60601-1:1990 + amendments

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.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

CENELEC

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

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

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

This European Standard supersedes EN 60601-1:1990 and its amendments. However, EN 60601-1:1990 remains valid until all the parts 2 that are used in conjunction with it have been withdrawn. No date of withdrawal of conflicting national standards (dow) has therefore been fixed. However, when Part 1 is used for appliances not covered by a part 2, EN 60601-1:1990 is not to be used after 2009-09-12.

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.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 60073	NOTE	Harmonized as EN 60073:2002 (not modified).
IEC 60086-1	NOTE	Harmonized as EN 60086-1:2001 (not modified).
IEC 60127-6	NOTE	Harmonized as EN 60127-6:1994 (not modified).
IEC 60309-1	NOTE	Harmonized as EN 60309-1:1999 (not modified).
IEC 60317-43	NOTE	Harmonized as EN 60317-43:1997 (not modified).
IEC 60601-1-1	NOTE	Harmonized as EN 60601-1-1:2001 (not modified).
IEC 60601-1-4	NOTE	Harmonized as EN 60601-1-4:1996 + A1:1999 (not modified).
IEC 60601-2-49	NOTE	Harmonized as EN 60601-2-49:2001 (not modified).
IEC 60695-1-1	NOTE	Harmonized as EN 60695-1-1:2000 (not modified).
IEC 60721 series	NOTE	Harmonized in EN 60721 series (not modified).
IEC 60990	NOTE	Harmonized as EN 60990:1999 (not modified).
IEC 61000-4-11	NOTE	Harmonized as EN 61000-4-11:2004 (not modified).
IEC 61010-1	NOTE	Harmonized as EN 61010-1:2001 (not modified).
IEC 61140	NOTE	Harmonized as EN 61140:2002 (not modified).
IEC 62079	NOTE	Harmonized as EN 62079:2001 (not modified).
IEC 62304	NOTE	Harmonized as EN 62304:2006 (not modified).
ISO 407	NOTE	Harmonized as EN ISO 13407:2004 (not modified).
ISO 8041	NOTE	Harmonized as EN ISO 8041:2005 (not modified).
ISO 13485	NOTE	Harmonized as EN ISO 13485:2003 (not modified).

Endorsement notice

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

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.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
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⁾

¹⁾ EN 60068-2-2 includes supplement A:1976 to IEC 60068-2-2.

²⁾ Undated reference.

³⁾ Valid edition at date of issue.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
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	-	-
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⁾

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.

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.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 60529	1989	Degrees of protection provided by enclosures (IP Code)	EN 60529 + corr. May	1991 1993
A1	1999		A1	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⁾
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	-	-

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
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⁾
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	-	-

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.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
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 ZZ (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 Directives 90/385/EEC and 93/42/EEC.

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

1	Scope, object and related standards.....	29
1.1	* Scope	29
1.2	Object	29
1.3	* Collateral standards	29
1.4	* Particular standards	31
2	* Normative references	31
3	* Terminology and definitions	39
4	General requirements	79
4.1	* Conditions for application to ME EQUIPMENT or ME SYSTEMS.....	79
4.2	* RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS	79
4.3	* ESSENTIAL PERFORMANCE	81
4.4	* EXPECTED SERVICE LIFE	81
4.5	* Equivalent safety for ME EQUIPMENT or ME SYSTEMS	83
4.6	* ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT	83
4.7	* SINGLE FAULT CONDITION for ME EQUIPMENT.....	83
4.8	Components of ME EQUIPMENT	85
4.9	* Use of COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS in ME EQUIPMENT	85
4.10	* Power supply	87
4.11	Power input	89
5	* General requirements for testing ME EQUIPMENT	91
5.1	* TYPE TESTS.....	91
5.2	* Number of samples	91
5.3	Ambient temperature, humidity, atmospheric pressure.....	91
5.4	Other conditions	91
5.5	Supply voltages, type of current, nature of supply, frequency	93
5.6	Repairs and modifications	93
5.7	* Humidity preconditioning treatment	93
5.8	Sequence of tests	95
5.9	* Determination of APPLIED PARTS and ACCESSIBLE PARTS	95
6	* Classification of ME EQUIPMENT and ME SYSTEMS.....	99
6.1	General	99
6.2	* Protection against electric shock.....	99
6.3	* Protection against harmful ingress of water or particulate matter	101
6.4	Method(s) of sterilization	101
6.5	Suitability for use in an OXYGEN RICH ENVIRONMENT	101
6.6	* Mode of operation	101

7	ME EQUIPMENT identification, marking and documents	101
7.1	General	101
7.2	Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts	105
7.3	Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts	113
7.4	Marking of controls and instruments	117
7.5	Safety signs	119
7.6	Symbols	121
7.7	Colours of the insulation of conductors	121
7.8	* Indicator lights and controls	123
7.9	ACCOMPANYING DOCUMENTS	123
8	* Protection against electrical HAZARDS from ME EQUIPMENT	135
8.1	Fundamental rule of protection against electric shock	135
8.2	Requirements related to power sources	137
8.3	Classification of APPLIED PARTS	137
8.4	Limitation of voltage, current or energy	139
8.5	Separation of parts	145
8.6	* Protective earthing, functional earthing and potential equalization of ME EQUIPMENT	161
8.7	LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS	167
8.8	Insulation	201
8.9	* CREEPAGE DISTANCES and AIR CLEARANCES	213
8.10	Components and wiring	243
8.11	MAINS PARTS, components and layout	247
9	* Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS	259
9.1	MECHANICAL HAZARDS of ME EQUIPMENT	259
9.2	* HAZARDS associated with moving parts	261
9.3	* HAZARD associated with surfaces, corners and edges	271
9.4	* Instability HAZARDS	271
9.5	* Expelled parts HAZARD	281
9.6	Acoustic energy (including infra- and ultrasound) and vibration	281
9.7	* Pressure vessels and parts subject to pneumatic and hydraulic pressure	285
9.8	* HAZARDS associated with support systems	291
10	* Protection against unwanted and excessive radiation HAZARDS	301
10.1	X-Radiation	301
10.2	Alpha, beta, gamma, neutron and other particle radiation	303
10.3	Microwave radiation	303
10.4	* Lasers and light emitting diodes (LEDs)	303
10.5	Other visible electromagnetic radiation	303
10.6	Infrared radiation	305
10.7	Ultraviolet radiation	305
11	* Protection against excessive temperatures and other HAZARDS	305
11.1	* Excessive temperatures in ME EQUIPMENT	305
11.2	* Fire prevention	313
11.3	* Constructional requirements for fire ENCLOSURES of ME EQUIPMENT	323

11.4	* ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics	329
11.5	* ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents	329
11.6	Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT	329
11.7	Biocompatibility of ME EQUIPMENT and ME SYSTEMS	333
11.8	* Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT	333
12	* Accuracy of controls and instruments and protection against hazardous outputs	333
12.1	Accuracy of controls and instruments	333
12.2	USABILITY	333
12.3	Alarm systems	333
12.4	Protection against hazardous output	333
13	* HAZARDOUS SITUATIONS and fault conditions	337
13.1	Specific HAZARDOUS SITUATIONS	337
13.2	SINGLE FAULT CONDITIONS	339
14	* PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	351
14.1	* General	351
14.2	* Documentation	351
14.3	* RISK MANAGEMENT plan	353
14.4	* PEMS DEVELOPMENT LIFE-CYCLE	353
14.5	* Problem resolution	353
14.6	RISK MANAGEMENT PROCESS	353
14.7	* Requirement specification	355
14.8	* Architecture	355
14.9	* Design and implementation	357
14.10	* VERIFICATION	357
14.11	* PEMS VALIDATION	357
14.12	* Modification	359
14.13	* Connection of PEMS by NETWORK/DATA COUPLING to other equipment	359
15	Construction of ME EQUIPMENT	359
15.1	* Arrangements of controls and indicators of ME EQUIPMENT	359
15.2	* Serviceability	359
15.3	Mechanical strength	361
15.4	ME EQUIPMENT components and general assembly	369
15.5	* MAINS SUPPLY TRANSFORMERS of ME EQUIPMENT and transformers providing separation in accordance with 8.5	379
16	* ME SYSTEMS	387
16.1	* General requirements for the ME SYSTEMS	387
16.2	* ACCOMPANYING DOCUMENTS of an ME SYSTEM	389
16.3	* Power supply	391
16.4	ENCLOSURES	391
16.5	* SEPARATION DEVICES	391
16.6	* LEAKAGE CURRENTS	393
16.7	* Protection against MECHANICAL HAZARDS	395

16.8	Interruption of the power supply to parts of an ME SYSTEM	395
16.9	ME SYSTEM connections and wiring	395
17	* Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	399
Annex A	(informative) General guidance and rationale.....	401
Annex B	(informative) Sequence of testing	613
Annex C	(informative) Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS.....	621
Annex D	(informative) Symbols on marking.....	629
Annex E	(informative) Examples of the connection of the measuring device (MD) for measurement of the PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT	647
Annex F	(informative) Suitable measuring supply circuits.....	651
Annex G	(normative) Protection against HAZARDS of ignition of flammable anaesthetic mixtures.....	657
Annex H	(informative) PEMS structure, PEMS DEVELOPMENT LIFE-CYCLE and documentation	687
Annex I	(informative) ME SYSTEMS aspects.....	713
Annex J	(informative) Survey of insulation paths.....	725
Annex K	(informative) Simplified PATIENT LEAKAGE CURRENT diagrams	731
Annex L	(normative) Insulated winding wires for use without interleaved insulation.....	737
	Bibliography.....	743
	INDEX	749
	INDEX OF ABBREVIATIONS AND ACRONYMS	775
Figure 1	– Detachable mains connection.....	43
Figure 2	– Example of the defined terminals and conductors.....	45
Figure 3	– Example of a CLASS I ME EQUIPMENT.....	47
Figure 4	– Example of a metal-enclosed CLASS II ME EQUIPMENT	47
Figure 5	– Schematic flow chart for component qualification	87
Figure 6	– Standard test finger.....	97
Figure 7	– Test hook	99
Figure 8	– Test pin.....	141
Figure 9	– Application of test voltage to bridged PATIENT CONNECTIONS for DEFIBRILLATION-PROOF APPLIED PARTS.....	155
Figure 10	– Application of test voltage to individual PATIENT CONNECTIONS for DEFIBRILLATION-PROOF APPLIED PARTS.....	159
Figure 11	– Application of test voltage to test the delivered defibrillation energy	161

Figure 12 – Example of a measuring device and its frequency characteristics.....	169
Figure 13 – Measuring circuit for the EARTH LEAKAGE CURRENT of CLASS I ME equipment, with or without APPLIED PART	175
Figure 14 – Measuring circuit for the TOUCH CURRENT.....	177
Figure 15 – Measuring circuit for the PATIENT LEAKAGE CURRENT from the PATIENT CONNECTION to earth.....	179
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)	181
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	183
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	185
Figure 19 – Measuring circuit for the PATIENT AUXILIARY CURRENT	187
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.....	189
Figure 21 – Ball-pressure test apparatus	213
Figure 22 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 1	239
Figure 23 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 2	239
Figure 24 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 3	239
Figure 25 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 4	239
Figure 26 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 5	239
Figure 27 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 6	241
Figure 28 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 7	241
Figure 29 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 8	241
Figure 30 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 9	241
Figure 31 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 10	243
Figure 32 – Ratio between HYDRAULIC TEST PRESSURE and MAXIMUM PERMISSIBLE WORKING PRESSURE	289
Figure 33 – Human body test mass.....	299
Figure 34 – Spark ignition test apparatus.....	317
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	317
Figure 36 – Maximum allowable voltage U as a function of the capacitance C measured in a capacitive circuit used in an OXYGEN RICH ENVIRONMENT	319
Figure 37 – Maximum allowable current I as a function of the inductance L measured in an inductive circuit in an OXYGEN RICH ENVIRONMENT	319
Figure 38 – Baffle	327
Figure 39 – Area of the bottom of an ENCLOSURE as specified in 11.3 b) 1)	327
Figure A.1 – Identification of ME EQUIPMENT, APPLIED PARTS and PATIENT CONNECTIONS in an ECG monitor	413

Figure A.2 – Example of the insulation of an F-TYPE APPLIED PART with the insulation incorporated in the ME EQUIPMENT	415
Figure A.3 – Identification of ME EQUIPMENT, APPLIED PARTS and PATIENT CONNECTIONS in a PATIENT monitor with invasive pressure monitoring facility	417
Figure A.4 – Identification of ME EQUIPMENT, APPLIED PARTS and PATIENT CONNECTIONS in a multifunction PATIENT monitor with invasive pressure monitoring facilities	419
Figure A.5 – Identification of APPLIED PARTS and PATIENT CONNECTIONS in an X-ray ME SYSTEM	421
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.....	421
Figure A.7 – Identification of ME EQUIPMENT or ME SYSTEM, APPLIED PARTS and PATIENT CONNECTIONS in a personal computer with an ECG module	423
Figure A.8 – Pictorial representation of the relationship of HAZARD, sequence of events, HAZARDOUS SITUATION and HARM	429
Figure A.9 – Example of PATIENT ENVIRONMENT.....	441
Figure A.10 – Floating circuit	469
Figure A.11 – Interruption of a power-carrying conductor between ME EQUIPMENT parts in separate ENCLOSURES.....	475
Figure A.12 – Identification of MEANS OF PATIENT PROTECTION and MEANS OF OPERATOR PROTECTION.....	483
Figure A.13 – Allowable protective earth impedance where the fault current is limited	497
Figure A.14 – Probability of ventricular fibrillation	509
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	519
Figure A.16 – Instability test conditions.....	543
Figure A.17 – Example of determining TENSILE SAFETY FACTOR using Table 21	555
Figure A.18 – Example of determining design and test loads	557
Figure A.19 – Example of human body mass distribution	557
Figure E.1 – TYPE B APPLIED PART	647
Figure E.2 – TYPE BF APPLIED PART	647
Figure E.3 – TYPE CF APPLIED PART	649
Figure E.4 – PATIENT AUXILIARY CURRENT	649
Figure E.5 – Loading of the PATIENT CONNECTIONS if specified by the MANUFACTURER	649
Figure F.1 – Measuring supply circuit with one side of the SUPPLY MAINS at approximately earth potential.....	651
Figure F.2 – Measuring supply circuit with SUPPLY MAINS approximately symmetrical to earth potential.....	651
Figure F.3 – Measuring supply circuit for polyphase ME EQUIPMENT specified for connection to a polyphase SUPPLY MAINS	653
Figure F.4 – Measuring supply circuit for single-phase ME EQUIPMENT specified for connection to a polyphase SUPPLY MAINS	653

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.....	655
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	669
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 ..	671
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 ..	671
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	679
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.....	681
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.....	681
Figure G.7 – Test apparatus	685
Figure H.1 – Examples of PEMS/ PESS structures	689
Figure H.2 – A PEMS DEVELOPMENT LIFE-CYCLE model	691
Figure H.3 – PEMS documentation requirements from Clause 14 and ISO 14971:2000	699
Figure H.4 – Example of potential parameters required to be specified for NETWORK/DATA COUPLING	711
Figure I.1 – Example of the construction of a MULTIPLE SOCKET-OUTLET (MSO).....	721
Figure I.2 – Examples of application of MULTIPLE SOCKET-OUTLETS (MSO)	723
Figure J.1 – Insulation example 1	725
Figure J.2 – Insulation example 2	725
Figure J.3 – Insulation example 3	725
Figure J.4 – Insulation example 4	727
Figure J.5 – Insulation example 5	727
Figure J.6 – Insulation example 6	727
Figure J.7 – Insulation example 7	729
Figure K.1 – ME EQUIPMENT with an ENCLOSURE made of insulating material.....	731
Figure K.2 – ME EQUIPMENT with an F-TYPE APPLIED PART.....	731
Figure K.3 – ME EQUIPMENT with an APPLIED PART and a SIGNAL INPUT/OUTPUT PART	733
Figure K.4 – ME EQUIPMENT with a PATIENT CONNECTION of a TYPE B APPLIED PART that is not PROTECTIVELY EARTHED	733
Figure K.5 – ME EQUIPMENT with a PATIENT CONNECTION of a TYPE BF APPLIED PART that is not PROTECTIVELY EARTHED	735

Table 1 – Units outside the SI units system that may be used on ME EQUIPMENT	119
Table 2 – Colours of indicator lights and their meaning for ME EQUIPMENT	123
Table 3 – * Allowable values of PATIENT LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS under NORMAL CONDITION and SINGLE FAULT CONDITION.....	171
Table 4 – * Allowable values of PATIENT LEAKAGE CURRENTS under the special test conditions identified in 8.7.4.7	173
Table 5 – Legends of symbols for Figure 9 to Figure 11, Figure 13 to Figure 20, Figure A.15, Annex E and Annex F	191
Table 6 – Test voltages for solid insulation forming a MEANS OF PROTECTION	207
Table 7 – Test voltages for MEANS OF OPERATOR PROTECTION.....	209
Table 8 – Multiplication factors for AIR CLEARANCES for altitudes up to 5 000 m.....	215
Table 9 – Material group classification	217
Table 10 – MAINS TRANSIENT VOLTAGE.....	219
Table 11 – Minimum CREEPAGE DISTANCES and AIR CLEARANCES between parts of opposite polarity of the MAINS PART	223
Table 12 – Minimum CREEPAGE DISTANCES and AIR CLEARANCES providing MEANS OF PATIENT PROTECTION	225
Table 13 – Minimum AIR CLEARANCES providing MEANS OF OPERATOR PROTECTION from the MAINS PART	227
Table 14 – Additional AIR CLEARANCES for insulation in MAINS PARTS with PEAK WORKING VOLTAGES exceeding the peak value of the NOMINAL MAINS VOLTAGE ^a	229
Table 15 – Minimum AIR CLEARANCES for MEANS OF OPERATOR PROTECTION in SECONDARY CIRCUITS.....	231
Table 16 – Minimum CREEPAGE DISTANCES providing MEANS OF OPERATOR PROTECTION	233
Table 17 – NOMINAL cross-sectional area of conductors of a POWER SUPPLY CORD	251
Table 18 – Testing of cord anchorages	253
Table 19 – MECHANICAL HAZARDS covered by this clause	261
Table 20 – Acceptable gaps.....	265
Table 21 – Determination of TENSILE SAFETY FACTOR	293
Table 22 – Allowable maximum temperatures of parts.....	305
Table 23 – Allowable maximum temperatures for ME EQUIPMENT parts that are likely to be touched.....	307
Table 24 – Allowable maximum temperatures for skin contact with ME EQUIPMENT APPLIED PARTS	307
Table 25 – Acceptable perforation of the bottom of an ENCLOSURE	325
Table 26 – * Temperature limits of motor windings.....	345
Table 27 – Maximum motor winding steady-state temperature	349
Table 28 – Mechanical strength test applicability	361
Table 29 – Drop height	365
Table 30 – Test torques for rotating controls.....	377

Table 31 – Maximum allowable temperatures of transformer windings under overload and short-circuit conditions at 25 °C (± 5 °C) ambient temperature	381
Table 32 – Test current for transformers	383
Table A.1 – Values of AIR CLEARANCE and CREEPAGE DISTANCE derived from Table 7 of IEC 61010-1:2001 and Table 12	525
Table A.2 – CREEPAGE DISTANCES to avoid failure due to tracking from IEC 60664-1	527
Table A.3 – Instability test conditions	543
Table A.4 – Allowable time exposure for level of acceleration	547
Table A.5 – Guidance on surface temperatures for ME EQUIPMENT that creates low temperatures (cools) for therapeutic purposes or as part of its operation	565
Table C.1– Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts	621
Table C.2 – Marking on the inside of ME EQUIPMENT, ME SYSTEMS or their parts	623
Table C.3 – Marking of controls and instruments	623
Table C.4 – ACCOMPANYING DOCUMENTS, general	625
Table C.5 – ACCOMPANYING DOCUMENTS, instructions for use	625
Table D.1 – General symbols	631
Table D.2 – Safety signs	641
Table D.3 – General codes	645
Table G.1 – Gas-tightness of cord inlets	675
Table H.1 – NETWORK/DATA COUPLING classification	707
Table I.1 – Some examples of ME SYSTEMS for illustration	717
Table L.1– Mandrel diameter	739
Table L.2 – Oven temperature	739

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*

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 Members of IEC maintain a register of valid International Standards. Users of this standard should consult this register to determine which collateral standards have been published.

If a collateral standard applies to ME EQUIPMENT for which a particular standard exists, then the particular standard takes priority over the collateral standard.

1.4 * Particular standards

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in this standard as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

NOTE Members of IEC and ISO maintain registers of valid International Standards. Users of this standard should consult these registers to determine which particular standards have been published.

A requirement of a particular standard takes priority over this standard.

2 * Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ATTENTION: Additional collateral standards of the IEC 60601 series, which are issued subsequent to publication of this standard, become normative at the date of their publication and shall be considered as being included among the normative references below. See 1.3.

NOTE Informative references are listed in the Bibliography on page 743.

IEC 60065:2001, *Audio, video and similar electronic apparatus – Safety requirements*

IEC 60068-2-2:1974, *Environmental testing – Part 2: Tests. Tests B: Dry heat*
Amendment 1 (1993)
Amendment 2 (1994)

IEC 60079-0, *Electrical apparatus for explosive gas atmospheres – Part 0: General requirements*

IEC 60079-2, *Electrical apparatus for explosive gas atmospheres – Part 2: Pressurized enclosures “p”*

IEC 60079-5, *Electrical apparatus for explosive gas atmospheres – Part 5: Powder filling “q”*

IEC 60079-6, *Electrical apparatus for explosive gas atmospheres – Part 6: Oil-immersion “o”*