ELEKTRILISED MEDITSIINISEADMED
OSA 1: ÜLDISED NÕUDED ESMASELE OHUTUSELE JA OLULISTELE TOIMIMISNÄITAJATELE

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

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 60601-1:2006+A1:2013+A12:2014 sisaldab Euroopa standardi EN 60601-1:2006 ja selle parandusi Cor 1 ja cor 2 ning AC:2010, standardi muudatuse A1:2013 ja selle paranduse AC:2014 ning standardi muudatuse A12:2014 ingliskeelset teksti.	This Estonian standard EVS-EN 60601-1:2006+A1:2013+A12:2014 consists of the English text of the European standard EN 60601-1:2006, its corrigendums cor 1, cor 2 and AC:2010, Amendment A1:2013 with corrigendum AC:2014 and Amendment A12:2014.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 20.10.2006, muudatus A1 04.10.2013 ja muudatus A2 03.10.2014.	Date of Availability of the European standard is 20.10.2006, for Amendment A1 04.10.2013 and for Amendment A2 03.10.2014.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.040

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-1

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)

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

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

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.

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 A1 A2	1974 1993 1994	Environmental testing Part 2: Tests - Tests B: Dry heat	EN 60068-2-2 [1] A1 A2	1993 1993 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.

Publication	Year	Title	EN/HD	Year
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)] A1 A2	1993 1995 1998	Polyvinyl chloride insulated cables of rated voltages up to and including 450/750 V 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.

Publication	Year	Title	EN/HD	Year
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	-	-

Publication	Year	Title	EN/HD	Year
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.

Publication	Year	Title	EN/HD	Year
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	-	-

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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.

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CONTENTS

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.

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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*