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National Standards Authority of Ireland

IRISH STANDARD

I.S. EN 60601-1-1:2001

ICS 11.040.01

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MEDICAL ELECTRICAL EQUIPMENT

PART 1-1: GENERAL REQUIREMENTS FOR SAFETY COLLATERAL STANDARD: SAFETY REQUIREMENTS FOR MEDICAL ELECTRICAL SYSTEMS

This Irish Standard was published under the authority of the National Standards Authority of Ireland and comes into effect on June 22, 2001

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-1-1

April 2001

ICS 11 040 01

Supersedes EN 60601-1-1:1993 + A1:1996

English version

Medical electrical equipment
Part 1-1: General requirements for safety
Collateral standard: Safety requirements for medical electrical systems
(IEC 60601-1-1:2000)

Appareils électromédicaux
Partie 1-1: Règles générales de sécurité -
Norme collatérale: Règles de sécurité
pour systèmes électromédicaux
(CEI 60601-1-1:2000)

Medizinische elektrische Geräte
Teil 1-1: Allgemeine Festlegungen
für die Sicherheit -
Ergänzungsnorm: Festlegungen für die
Sicherheit von medizinischen elektrischen
Systemen
(IEC 60601-1-1:2000)

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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, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and 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

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Ref. No. EN 60601-1-1:2001 E

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Foreword

The text of document 62A/312/FDIS, future edition 2 of IEC 60601-1-1, 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 60601-1-1 on 2000-12-01.

This European Standard supersedes EN 60601-1-1:1993 + A1:1996.

The following dates were 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) 2001-10-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2003-12-01

This European Standard is a Collateral Standard to EN 60601-1:1990, hereinafter referred to as the General Standard, and is the first of a series of Collateral Standards amplifying the General Standard.

In the 60601 series of publications, Collateral Standards specify general requirements for safety applicable to
- a group of MEDICAL ELECTRICAL EQUIPMENT (for example, radiological equipment);
- a specific characteristic of all MEDICAL ELECTRICAL EQUIPMENT, not fully addressed in the General Standard (for example, electromagnetic compatibility).

The numbering of sections, clauses and subclauses of this Collateral Standard corresponds with that of the General Standard.

Subclauses and figures which are additional to those of the General Standard are numbered starting from 201; additional annexes are lettered AAA, BBB, etc.

In this Collateral Standard, the following print types are used:
- requirements, compliance with which can be tested and definitions: in roman type;
- explanations, advice, general statements, exceptions and references: in smaller roman type;
- *test specifications: in italic type*;
- TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD OR OF THIS COLLATERAL STANDARD: SMALL CAPITALS.

The requirements are followed by specifications for the relevant tests.

Some provisions or statements in the body of this Collateral Standard require additional information. Such information is presented in the informative annex AAA, General guidance and rationale. An asterisk (*) at the left margin of a clause or subclause indicates the presence of additional information.

Annexes designated "normative" are part of the body of the standard.
Annexes designated "informative" are given for information only.
In this standard, annexes EEE and ZA are normative and annexes AAA, BBB, FFF and ZB are informative.
Annexes ZA and ZB replace annexes CCC and DDD of IEC 60601-1-1:2000.

Endorsement notice

The text of the International Standard IEC 60601-1-1:2000 was approved by CENELEC as a European Standard without any modification.

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Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

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 60083	1997	Plugs and socket-outlets for domestic and similar general use standardized in member countries of IEC	-	-
IEC 60529	1989	Degrees of protection provided by enclosures (IP Code)	EN 60529	1991
IEC 60601-1	1988	Medical electrical equipment Part 1: General requirements for safety	EN 60601-1 + corr. July	1990 1994
A1	1991		A1 + corr. July	1993 1994
A2 + corr. June	1995 1995		A2 A13	1995 1996
IEC 60884-1	1994	Plugs and socket-outlets for household and similar purposes Part 1: General requirements	-	-
A1	1994		-	-
A2	1995		-	-
IEC 60989	1991	Separating transformers, autotransformers, variable transformers and reactors	-	-

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Annex ZB
(informative)

Bibliography

Publication	Year	Title	EN/HD	Year
IEC 60065 (mod)	1998	Audio, video and similar electronic apparatus - Safety requirements	EN 60065	1998
IEC 60335-1 (mod)	1991	Safety of household and similar electrical appliances Part 1: General requirements	EN 60335-1 + corr. January	1994 1995
A1 (mod)	1994		A1	1996
IEC 60601-1-4	1996	Medical electrical equipment Part 1-4: General requirements for safety -- Collateral standard: Programmable electrical medical systems	EN 60601-1-4	1996
A1	1999		A1	1999
IEC 60825-1	1993	Safety of laser products Part 1: Equipment classification, requirements and user's guide	EN 60825-1 + corr. February	1994 1995
A1	1997		-	-
IEC 60950 (mod) + corr. January	1999 2000	Safety of information technology equipment	EN 60950	2000
IEC 61010-1 (mod)	1990	Safety requirements for electrical equipment for measurement, control and laboratory use Part 1: General requirements		
+ A1 (mod)	1992		EN 61010-1[1)]	1993
A2	1995		A2[1)]	1995
ISO 7767	1997	Oxygen monitors for monitoring patient breathing mixtures - Safety requirements	-	-
ISO 8185	1997	Humidifiers for medical use - General requirements for humidification systems	EN ISO 8185	1997
ISO 8359	1996	Oxygen concentrators for medical use Safety requirements	-	-
ISO 9918	1993	Capnometers for use with humans - Requirements	-	-
ISO 10079-1	1991	Medical suction equipment Part 1: Electrically powered suction equipment - Safety requirements	EN ISO 10079-1	1996

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1) EN 61010-1 1993 + A2 1995 are superseded by EN 61010-1:2001, which is based on IEC 61010-1:2001.

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