SLOVENSKI STANDARD

SIST EN 60601-1:1995/A2:1998

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september 1998

Medical electrical equipment - Part 1: General requirements for safety - Amendment A2 (IEC 60601-1:1988/A2:1995 + ccorigendum jun. 1995)

ICS 11.040.01

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Descriptors: Medical electrical equipment, definitions, requirements, testing, construction, safety, symbols

English version

Medical electrical equipment
Part 1: General requirements for safety
(IEC 601-1:1988/A2:1995 + corrigendum 1995)

Appareils électromédicaux
Première partie: Règles générales de sécurité
(CEI 601-1:1988/A2:1995 + corrigendum 1995)

Medizinische elektrische Geräte
Teil 1: Allgemeine Festlegungen für die Sicherheit
(IEC 601-1:1988/A2:1995 + Corrigendum 1995)

This amendment A2 modifies the European Standard EN 60601-1:1990; it was approved by CENELEC on 1995-03-06. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this amendment 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 amendment 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: rue de Stassart 35, B - 1050 Brussels

Foreword

The text of document 62A(CO)45, future amendment 2 to IEC 601-1:1988, 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 amendment A2 to EN 60601-1:1990 on 1995-03-06.

This European Standard supersedes EN 60601-1:1990/A11:1993.

The following date was fixed:

- latest date by which the amendment has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 1996-03-01

Endorsement notice

The text of amendment 2:1995 to the International Standard IEC 601-1:1988, with its corrigendum June 1995 was approved by CENELEC as an amendment to the European Standard without any modification.

Replace annexes ZA (normative) and ZB (informative) as given in EN 60601-1:1990/A11:1993 by the updated annexes given hereafter.

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 65 (mod)	1985	Safety requirements for mains operated electronic and related apparatus for household and similar general use	EN 60065[1] + corr. November	1993 1993
IEC 68-2-2	1974	Basic environmental testing procedures Part 2: Tests - Test B: Dry heat	EN 60068-2-2[2]	1993
IEC 79		Electrical apparatus for explosive gas atmospheres		
IEC 79-2[3]	1983	Part 2: Electrical apparatus - Type of protection "p"		
IEC 79-5[4]	1967	Part 5: Sand-filled apparatus		
IEC 79-6[5]	1968	Part 6: Oil-immersed apparatus		
IEC 127	1974	Cartridge fuse-links for miniature fuses	HD 109 S3[6]	1983
IEC 227 (mod)	series	Polyvinyl chloride insulated cables of rated voltages up to and including 450/750 V	HD 21	series
IEC 241	1968	Fuses for domestic and similar purposes	-	-
IEC 245 (mod)	series	Rubber insulated cables of rated voltages up to and including 450/750 V	HD 22	series
IEC 245-4 (mod)	1980	Part 4: Cords and flexible cables	HD 22.4 S2[7] + A6	1992 1992
IEC 252	1975[8]	A.C. motor capacitors	-	-

1) EN 60065 includes A1:1987, A2:1989 and A3:1992 to IEC 65.

2) EN 60068-2-2 includes IEC 68-2-2A:1976.

3) Instead of IEC 79-2:1983, EN 50016:1977 + A1:1979, *Electrical apparatus for potentially explosive atmospheres — Pressurized apparatus "p"*, applies.

4) Instead of IEC 79-5:1967, EN 50017:1977 + A1:1979, *Electrical apparatus for potentially explosive atmospheres — Powder filling "q"*, applies.

5) Instead of IEC 79-6:1968, EN 50015:1977 + A1:1979, *Electrical apparatus for potentially explosive atmospheres — Oil immersion "o"*, applies.

6) HD 109 S3:1983 is superseded by the EN 60127 series, which is based on the new IEC 127 series, *Miniature fuses*.

7) HD 22.4 S2 is superseded by HD 22.4 S3:1995, which is based on IEC 245-4:1994, mod.

8) IEC 252:1993, mod., is harmonized as EN 60252:1994 + corr. May 1994.

Publication	Year	Title	EN/HD	Year
IEC 320 (mod)	1981	Appliance couplers for household and similar general purposes	EN 60320-1[9] + corr. November A11	1987 1993 1994
IEC 328[10]	1972	Switches for appliances	-	-
IEC 384-14	1993	Fixed capacitors for use in electronic equipment - Part 14: Sectional specification: Fixed capacitors for radio interference suppression and connection to the supply mains	-	-
IEC 417	1973	Graphical symbols for use on equipment Index, survey and compilation of the single sheets	HD 243 S12[11]	1995
IEC 445	1973	Identification of apparatus terminals and general rules for a uniform system of terminal marking, using an alphanumeric notations	HD 241 S1[12]	1979
IEC 447	1974	Standard directions of movement for actuators which control the operation of electrical apparatus	HD 331 S1[13]	1977
IEC 529	1989	Degrees of protection provided by enclosures (IP Code)	EN 60529 + corr. May 1993	1991
IEC 601-1-1	1992	Medical electrical equipment Part 1: General requirements for safety 1. Collateral Standard: Safety requirements for medical electrical systems	EN 60601-1-1	1993
IEC 601-1-2	1993	2. Collateral Standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2	1993
IEC 601-1-3	1994	3. Collateral Standard: General requirements for radiation protection in diagnostic X-ray equipment	EN 60601-1-3	1994
IEC 601-1-4	199X[14]	4. Collateral Standard: Safety requirements for programmable electronic medical systems	-	-
ISO R 32	1977	Gas cylinders for medical use - Marking for identification of content	-	-
ISO R 407	1983	Small medical gas cylinders - Yoke-type valve connections		--

9) EN 60320-1 incudes A1:1984 + A2:1985 to IEC 320. A3:1987 to IEC 320 was harmonized as A1:1989 to EN 60320-1.

10) IEC 328 is superseded by IEC 1058-1:1991, which was harmonized as EN 61058-1:1992.

11) HD 243 S12 includes supplements A:1974 to M:1994 to IEC 417.

12) HD 241 S1 is superseded by EN 60445:1990 which is based on IEC 445:1988, *Identification of equipment terminals and of terminations of certain designated conductors, including general rules of an alphanumeric system*.

13) HD 331 S1 is superseded by EN 60447:1993, which is based on IEC 447:1993, *Man-machine interface (MMI) - Actuating principles*.

14) Currently under consideration by IEC/TC 62.

Publication	Year	Title	EN/HD	Year
ISO 471	1983	Rubber - Standard temperatures, humidities and times for the conditioning and testing of test pieces	-	-
ISO 1000	1981	SI units and recommendations for the use of their multiples and of certain other units	-	-
ISO 1853	1975	Conducting and antistatic rubbers Measurement of resistivity	-	-
ISO 2878	1987	Rubber, vulcanized - Antistatic and conductive products - Determination of electrical resistance	-	-
ISO 2882	1979	Rubber, vulcanized - Antistatic and conductive products for hospital use - Electrical resistance limits	-	-
ISO 10993-1	1992	Biological evaluation of medical devices Part 1: Guidance on selection of tests	-	-

Annex ZB (informative)

Normative references to international publications with their corresponding European publications

Publication	Year	Title	EN/HD	Year
IEC 73	1984	Colours of indicator lights and push-buttons	HD 354 S2[1)]	1987
IEC 85	1984	Thermal evaluation and classification of electrical insulation	HD 566 S1	1990
IEC 112	1979	Method for determining the comparative and the proof tracking indices of solid insulating materials under moist conditions	HD 214 S2	1980
IEC 335-1[2)]	1970	Safety of household and similar electrical appliances - Part 1: General requirements	-	-
IEC 364-4-41	1982[3)]	Electrical installations of buildings Part 4: Protection for safety Chapter 41: Protection against electric shock	-	-
IEC 513	1994	Fundamental aspects of safety standards for medical electrical equipment	-	-
IEC 536	1976	Classification of electrical and electronic equipment with regard to protection against electric shock	HD 366 S1	1977
IEC 601-1	1977	Safety of medical electrical equipment Part 1: General requirements	HD 395.1 S2 + A1	1988 1993
IEC 664	1980	Insulation co-ordination within low-voltage systems including clearances and creepage distances for equipment	-	-
IEC 695	series	Fire hazard testing	HD 444 EN 60695	series series
IEC 707	1981	Methods of test for the determination of the flammability of solid electrical insulating materials when exposed to an igniting source	HD 441 S1	1983
IEC 742 (mod)	1983	Isolating transformers and safety isolating transformers - Requirements	EN 60742[4)]	1995
IEC 878	1988	Graphical symbols for electrical equipment in medical practice	-	-
ISO R 780	1985	Packaging - Pictorial marking for handling of goods	EN 20780	1993
ISO 8185	1988	Humidifiers for medical use - Safety requirements	-	-

NOTE: The following publications are not mentioned in IEC 601-1:1988 and consequently have been removed from this list: IEC 309, IEC 336:1982 and IEC 348:1978.

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1) HD 354 S2 is superseded by EN 60073:1993 + corr. April 1993, which is based on IEC 73:1991, *Coding of indicating devices and actuators by colours and supplementary means.*

2) (printing error in English text of IEC 601-1) - IEC 335-1:1976, mod., and its amendments have been harmonized as EN 60335-1:1988 and its amendments; IEC 335-1:1991, mod., has been harmonized as EN 60335-1:1994.

3) IEC 364-4-41:1977 is harmonized as HD 384.4.41 S1:1980.

4) EN 60742 includes A1:1992 to IEC 742:1983.

NORME INTERNATIONALE
INTERNATIONAL STANDARD

CEI
IEC
601-1

1988

AMENDEMENT 2
AMENDMENT 2

1995-03

Amendement 2

Appareils électromédicaux

Première partie:
Règles générales de sécurité

Amendment 2

Medical electrical equipment

Part 1:
General requirements for safety

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Amendement 2 à la
Publication 601-1 de la CEI
(1995-03)

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Amendment 2 to
IEC Publication 601-1
(1995-03)

Medical electrical equipment

Part 1: General requirements for safety

CORRIGENDUM

Page 14

6.1 *l) Classification*

A la fin du deuxième tiret de 6.1 l), ajouter la note suivante:

NOTE – Un APPAREIL de classification IPX0 n'a pas à être marqué en tant que tel.

Page 15

6.1 *l) Classification*

At the end of 6.1 l), second dash, add the following note:

NOTE – EQUIPMENT of IPX0 classification is not required to be marked as such.

FOREWORD

This amendment has been prepared by sub-committee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this amendment is based on the following documents:

DIS	Report on voting
62A(CO)45	62A/181/RVD

Full information on the voting for the approval of this amendment can be found in the report on voting indicated in the above table.

INTRODUCTION

This amendment contains a second series of revisions to IEC 601-1 (second edition, 1988): *Medical electrical equipment – Part 1: General requirements for safety.*

It is intended to facilitate interpretation and application of the General Standard. It also identifies additional aspects of safety which were not previously covered. Significant changes include the following:

– APPLIED PARTS are now identified by requirements covering the possibility of physical contact with the PATIENT during NORMAL USE, without electrical considerations; individual PATIENT CONNECTIONS are then defined by requirements concerning electrical contact with the PATIENT during NORMAL USE;

– classification of the degree of protection against electric shock (TYPES CF/BF/B) is not related any more to the word EQUIPMENT but now clearly relates to individual APPLIED PARTS; it is more logical because the degree of protection is determined in fact by that of the APPLIED PART; this means no extra requirements and tests but more differentiation and clarification of the required actions;

– general requirements are included for EQUIPMENT in which the APPLIED PART is marked as providing protection against the discharge voltage from a defibrillator and for which there is no Particular Standard;

– limits for the d.c. component of PATIENT LEAKAGE CURRENT are included to align with the requirement for PATIENT AUXILIARY CURRENT;

– clarification concerning the degree of protection against ingress of liquids by using IP Code, as detailed in the basic safety publication IEC 529 is an improvement;

– the term "not used", which was introduced in the second edition of IEC 601-1, is replaced, where applicable, by the wording "no general requirement" in order to avoid misunderstanding; this means that a Particular Standard may specify requirements if it is deemed necessary;

– references to existing IEC Collateral Standards 601-1-1, 601-1-2, 601-1-3 and future IEC 601-1-4 (see Appendix L), are included;

– additional requirements are included regarding the information which must be supplied by the manufacturer in order to improve the international acceptance of symbols and units and to provide more information about the intended use of the EQUIPMENT; the latter is becoming necessary due to the relation with performance safety aspects;

– some requirements and test methods have been aligned with other existing IEC standards;

– a number of accidents having being reported due to user error during the use of biopotential connectors (as electrodes having attached leads terminating in 2 mm exposed metal pin connectors), some additional requirements have been introduced to prevent the recurrence of such accidents whatever the type of equipment.

Page 3

CONTENTS

Replace clauses 44 and 48 respectively by the following:

Add figures 50 and 51 as follows:

SECTION ONE

Page 13

***1 Scope and object**

Add the following new subclause:

1.5 *Collateral Standards*

In the IEC 601 series, Collateral Standards specify general requirements for safety applicable to:

– a group of MEDICAL ELECTRICAL EQUIPMENT (e.g. radiological equipment);

– a specific characteristic of all MEDICAL ELECTRICAL EQUIPMENT not fully addressed in the General Standard (e.g. electromagnetic compatibility).

If a Collateral Standard applies to a Particular Standard, then the Particular Standard takes priority over the Collateral Standard.

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2 Terminology and definitions

Replace the existing definitions by the following:

*2.1.5 *APPLIED PART*

A part of the EQUIPMENT which in NORMAL USE:

– necessarily comes into physical contact with the PATIENT for the EQUIPMENT to perform its function; or

– can be brought into contact with the PATIENT; or

– needs to be touched by the PATIENT.

2.1.7 *F-TYPE ISOLATED (FLOATING) APPLIED PART*
(hereinafter referred to as *F-TYPE APPLIED PART)*

APPLIED PART isolated from other parts of the EQUIPMENT to such a degree that no current higher than the PATIENT LEAKAGE CURRENT allowable in SINGLE FAULT CONDITION flows if an unintended voltage originating from an external source is connected to the PATIENT, and thereby applied between the APPLIED PART and earth.

F-TYPE APPLIED PARTS are either TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS.

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*2.1.15 *PATIENT CIRCUIT*

Any electrical circuit which contains one or more PATIENT CONNECTIONS.

PATIENT CIRCUITS include all conductive parts which are not insulated from the PATIENT CONNECTIONS to the extent necessary to comply with the dielectric strength requirements (see clause 20) or which are not separated from the PATIENT CONNECTIONS to the extent necessary to comply with the CREEPAGE DISTANCE and AIR CLEARANCE requirements (see 57.10).

Add the following definitions:

*2.1.23 *PATIENT CONNECTION*

Every individual part of the APPLIED PART through which current can flow between the PATIENT and the EQUIPMENT in NORMAL CONDITION or SINGLE FAULT CONDITION.

*2.1.24 *TYPE B APPLIED PART*

APPLIED PART complying with the specified requirements of this Standard to provide protection against electric shock, particularly regarding allowable LEAKAGE CURRENT and marked with symbol 1, table DII, of Appendix D.

NOTE – TYPE B APPLIED PARTS are not suitable for DIRECT CARDIAC APPLICATION.

*2.1.25 *TYPE BF APPLIED PART*

F-TYPE APPLIED PART complying with the specified requirements of this Standard to provide a higher degree of protection against electric shock than that provided by TYPE B APPLIED PARTS and marked with symbol 2, table DII, of Appendix D.

NOTE – TYPE BF APPLIED PARTS are not suitable for DIRECT CARDIAC APPLICATION.

*2.1.26 *TYPE CF APPLIED PART*

F-TYPE APPLIED PART complying with the specified requirements of this Standard to provide a higher degree of protection against electric shock than that provided by TYPE BF APPLIED PARTS and marked with symbol 3, table DII, of Appendix D.

*2.1.27 *DEFIBRILLATION-PROOF APPLIED PART*

APPLIED PART having protection against the effects of a discharge of a cardiac defibrillator to the PATIENT.

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2.2.7 *DIRECT CARDIAC APPLICATION*

In the text replace "EQUIPMENT" *by* "APPLIED PART".

2.2.9 *DRIP-PROOF EQUIPMENT*

and

2.2.20 *SPLASH-PROOF EQUIPMENT:*

Delete these definitions and replace by:

2.2.9 Not used.

2.2.20 Not used.

These modifications invalidate the corresponding modifications of Amendment 1 to IEC 601-1 (page 7).

2.2.15 *MEDICAL ELECTRICAL EQUIPMENT*

Add a second paragraph to the definition:

The EQUIPMENT includes those ACCESSORIES as defined by the manufacturer which are necessary to enable the NORMAL USE of the EQUIPMENT.

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2.2.24 *TYPE B EQUIPMENT*

2.2.25 *TYPE BF EQUIPMENT*

2.2.26 *TYPE CF EQUIPMENT*

2.2.28 *WATERTIGHT EQUIPMENT*

Delete these definitions and replace by:

2.2.24 Not used.

2.2.25 Not used.

2.2.26 Not used.

2.2.28 Not used.

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2.6.4 *FUNCTIONAL EARTH TERMINAL*

Add an asterisk in front of the subclause number.

Page 29

2.9.13 *THERMOSTAT*

Replace the text of Amendment 1 (page 9) by the following:

A temperature sensing control, which is intended to keep a temperature between two particular values under normal operating conditions and which may have provision for setting by the OPERATOR.

Page 31

2.11.4 *PRESSURE (overpressure)*

In the text change "PRESSURE" *to* "Pressure".

Page 37

*3.6 (continued)

Replace the existing items e) to h), and the last paragraph of the subclause in the body of the standard, and item j) in Amendment 1 (page 9) by the following:

e) leakage of the ENCLOSURE of a FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE (see Section Six);

f) leakage of liquid (see subclause 44.4)

g) failure of an electrical component which might cause a SAFETY HAZARD (see Section Nine);

h) failure of mechanical parts which might cause a SAFETY HAZARD (see Section Four);

j) failure of temperature limiting devices (see Section Seven).