SLOVENSKI STANDARD
SIST EN 60601-1-1:1995/A1:1998

01-september-1998

Medical electrical equipment - Part 1: General requirements for safety - 1. collateral standard: Safety requirements for medical electrical systems - Amendment A1 (IEC 60601-1-1:1992/A1:1995)

Medical electrical equipment -- Part 1: General requirements for safety -- 1. Collateral standard: Safety requirements for medical electrical systems

Medizinische elektrische Geräte -- Teil 1: Allgemeine Festlegungen für die Sicherheit -- 1. Ergänzungsnorm: Festlegungen für die Sicherheit von medizinischen elektrischen Systemen

Appareils électromédicaux -- Partie 1: Règles générales de sécurité -- 1. Norme collatérale: Règles de sécurité pour systèmes électromédicaux

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Ta slovenski standard je istoveten z: **EN 60601-1-1:1993/A1:1996**

ICS:

11.040.01	Medicinska oprema na splošno	Medical equipment in general

SIST EN 60601-1-1:1995/A1:1998 **en**

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-1-1/A1

January 1996

UDC 615.841:614.8:620.1
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Descriptors: Medical electrical equipment, medical electrical systems, definitions, requirements, testing, construction, safety, symbols

English version

Medical electrical equipment
Part 1: General requirements for safety
1. Collateral standard: Safety requirements for medical electrical systems
(IEC 601-1-1:1992/A1:1995)

Appareils électromédicaux
Partie 1: Règles générales de sécurité
1. Norme collatérale: Règles de sécurité pour systèmes électromédicaux
(CEI 601-1-1:1992/A1:1995)

Medizinische elektrische Geräte
Teil 1: Allgemeine Anforderungen an die Sicherheit
1. Ergänzungsnorm: Sicherheitsanforderungen an Medizinische elektrische Systeme
(IEC 601-1-1:1992/A1:1995)

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This amendment A1 modifies the European Standard EN 60601-1-1:1993; it was approved by CENELEC on 1995-11-28. 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.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

REPUBLIKA SLOVENIJA
MINISTRSTVO ZA ZNANOST IN TEHNOLOGIJO
Urad RS za standardizacijo in meroslovje
LJUBLJANA
SIST.....EN 60601-1-1/A1
PREVZET PO METODI RAZGLASITVE
-09- 1998

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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Foreword

The text of document 62A/184/DIS, future amendment 1 to IEC 601-1-1:1992, 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 A1 to EN 60601-1-1:1993 on 1995-11-28.

The following dates were 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) 1996-09-01
- latest date by which the national standards conflicting with the amendment have to be withdrawn (dow) 1996-09-01

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 annex FFF is informative.
Annex ZA has been added by CENELEC.

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Endorsement notice

The text of amendment 1:1995 to the International Standard IEC 601-1-1:1992 was approved by CENELEC as an amendment to the European Standard without any modification.

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Annex ZA (normative)

Normative references to international publications with their corresponding European publications

Addition:

Publication	Year	Title	EN/HD	Year
IEC 83 A1	1975 1979	Plugs and socket-outlets for domestic and similar general use Standards	-	-
IEC 884-1	1994	Plugs and socket-outlets for household and similar purposes Part 1: General requirements	-	-
IEC 989	1991	Separating transformers, autotransformers, variable transformers and reactors	-	-

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NORME INTERNATIONALE
INTERNATIONAL STANDARD

CEI
IEC
601-1-1

1992

AMENDEMENT 1
AMENDMENT 1

1995-10

Amendement 1

Appareils électromédicaux

Première partie:
Règles générales de sécurité

1. Norme collatérale: Règles de sécurité pour systèmes électromédicaux

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Amendment 1

Medical electrical equipment

Part 1:
General requirement for safety

1. Collateral standard: Safety requirements for medical electrical systems

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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/184/DIS	62A/196/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.

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CONTENTS

Add, after 2.205, the title of the following new subclause:

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Add on page 5, after 56.3.201, the titles of the following new subclauses:

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Add the following two annexes:

Page 9

INTRODUCTION

Add the following new paragraph:

Requirements for programmable electronic medical systems will also have to be taken into account as soon as the document under consideration* is finalized.

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* Document in preparation by TC 62 – IEC 601-1-4 currently at the Committee Draft for voting stage under reference 62 (Secretariat) 73.

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Section 1

1 Scope and object

*1.201 *Scope*

Replace the text of this subclause by the following:

This standard applies to the safety of MEDICAL ELECTRICAL SYSTEMS, as defined in 2.203. It describes the safety requirements necessary to provide protection for the PATIENT, the OPERATOR and surroundings.

NOTE – It is presumed that the party assembling or modifying the MEDICAL ELECTRICAL SYSTEMS will take the necessary steps to assure compliance with this standard.

2 Terminology and definitions

*2.203 *MEDICAL ELECTRICAL SYSTEM (hereinafter referred to as a SYSTEM)*

Replace the text of this subclause by the following:

Combination of either more than one item of MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL EQUIPMENT and other non-medical electrical equipment having a specified function and inter-connected by:

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– COUPLING, and/or

– a MULTIPLE PORTABLE SOCKET-OUTLET.

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NOTE – The SYSTEM includes those accessories which are needed for operating the SYSTEM and are to be specified by the manufacturer.

(See also examples given in annexes BBB and FFF.)

*2.204 *PATIENT ENVIRONMENT*

Replace, first line, the word "area" *by* "volume", *and add, at the end of the paragraph,* "(see for illustration figure 201)".

Add the following new definition, taken and derived from IEC 884-1:

*2.206 *MULTIPLE PORTABLE SOCKET-OUTLET*

A combination of two or more socket-outlets intended to be connected to, or integral with, flexible cables or cords, and which can easily be moved from one place to another while connected to the supply.

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4 General requirements for tests

Add an asterisk in front of the 4.201 *subclause number.*

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Replace the text of the last dash of the compliance text of this subclause by the following:

– *Tests shall be carried out:*
  - *in NORMAL CONDITION unless otherwise specified in this standard, and*
  - *under operating conditions as specified by the manufacturer of the SYSTEM.*

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6 Identification, marking and documents

6.1.201 *Marking*

Replace, in the second line of the subclause, "table 1" *by* "table DI".

Add, before the compliance text, the following note:

NOTE – The party assembling or modifying the SYSTEM should calculate the power consumption of the SYSTEM, make sure that this consumption is consistent with the power that the MULTIPLE PORTABLE SOCKET-OUTLET(S) can support and document it.

*6.8.201 *ACCOMPANYING DOCUMENTS*

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Replace the title and the text of this subclause by the following:

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*6.8.201 *Accompanying documents*

A SYSTEM (including a modified SYSTEM) shall be accompanied by documents containing all the data necessary for safe and reliable use.

NOTE – It is the responsibility of the assembler of a SYSTEM (including a modified SYSTEM), that it is accompanied by documents containing all the data necessary for safe and reliable use.

These documents shall include:

a) The ACCOMPANYING DOCUMENTS for each item of MEDICAL ELECTRICAL EQUIPMENT (see 6.8 of IEC 601-1).

b) The accompanying documents for each item of non-medical electrical equipment.

c) The following information:

– instructions for cleaning and, where applicable, sterilizing and disinfecting each item of equipment forming part of the SYSTEM;

– additional safety measures which should be applied, during installation of the SYSTEM;

– which parts of the SYSTEM are suitable for use within the PATIENT ENVIRONMENT;

– additional measures which should be applied during preventive maintenance;

– a warning that MULTIPLE PORTABLE SOCKET-OUTLETS shall not be placed on the floor;

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– the maximum permitted load for any MULTIPLE PORTABLE SOCKET-OUTLET(S);

– an instruction that MULTIPLE PORTABLE SOCKET-OUTLETS provided with the SYSTEM shall only be used for powering equipment which forms part of the SYSTEM;

– an explanation of the risks of connecting a non-medical electrical equipment, which has been supplied as a part of the SYSTEM, directly to the wall outlet when the SYSTEM is supplied via a MULTIPLE PORTABLE SOCKET-OUTLET with a separating transformer;

– an explanation of the risks of connecting electrical equipment which has not been supplied as a part of the SYSTEM, to the MULTIPLE PORTABLE SOCKET-OUTLET.

Compliance is checked by inspection.

Page 17

Section 3

17 Separation

Replace the last three paragraphs of the compliance text by the following:

The test voltage is chosen from clause 20, table V, for BASIC INSULATION.

The reference voltage (U) is the highest RATED supply voltage or, for polyphase equipment, the phase to neutral supply voltage. For INTERNALLY POWERED EQUIPMENT, U is 250 V.

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19.201.1 *ENCLOSURE LEAKAGE CURRENT*

Add, after the second paragraph of this subclause, the following sentence:

If the SYSTEM includes a MULTIPLE PORTABLE SOCKET-OUTLET the ENCLOSURE LEAKAGE CURRENT shall also be measured from parts which are in NORMAL CONDITION protectively earthed.

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Section 10

Add, after 56.3.201, the following new subclauses:

57.2 *MAINS CONNECTORS, APPLIANCE INLETS and the like*

*57.2.201 *MULTIPLE PORTABLE SOCKET-OUTLET*

Connection of equipment used in medical practice to a MULTIPLE PORTABLE SOCKET-OUTLET shall only be possible by using a TOOL, or the MULTIPLE PORTABLE SOCKET-OUTLET shall be supplied via at least a separating transformer.