SLOVENSKI STANDARD
SIST EN 60601-2-3:1995/A1:2002

01-februar-2002

Medicinska električna oprema - 2. del: Posebne varnostne zahteve za opremo za kratkovalovno terapijo (IEC 60601-2-3:1991/A1:1998)

Medical electrical equipment - Part 2: Particular requirements for the safety of short-wave therapy equipment

Medizinische elektrische Geräte - Teil 2: Besondere Festlegungen für die Sicherheit von Kurzwellen-Therapiegeräten

Appareils électromédicaux - Partie 2: Règles particulières de sécurité pour appareils de thérapie à ondes courtes

Ta slovenski standard je istoveten z: **EN 60601-2-3:1993/A1:1998**

ICS:

11.040.60	Terapevtska oprema	Therapy equipment

SIST EN 60601-2-3:1995/A1:2002 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-3/A1

November 1998

ICS 11.040.60
UDC 615.841:615.849.11:621.3.029.
55/.62:001.4:620.1:614.8

Descriptors: Medical electrical equipment, short-wave therapy, instructions for use, safety requirements, protection against electric shock, protection against mechanical hazard, radiation protection, fire protection, environmental conditions

English version

Medical electrical equipment
Part 2: Particular requirements for the safety of short-wave therapy equipment
(IEC 60601-2-3:1991/A1:1998)

Appareils électromédicaux
Partie 2: Règles particulières de sécurité pour appareils de thérapie à ondes courtes
(CEI 60601-2-3:1991/A1:1998)

Medizinische elektrische Geräte
Teil 2: Besondere Festlegungen für die Sicherheit von Kurzwellen-Therapiegeräten
(IEC 60601-2-3:1991/A1:1998)

This amendment A1 modifies the European Standard EN 60601-2-3:1993;it was approved by CENELEC on 1998-10-01. 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, 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

Foreword

The text of document 62D/292/FDIS, future amendment 1 to IEC 60601-2-3:1991, prepared by SC 62D, Electromedical equipment, 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 60601-2-3:1993 on 1998-10-01.

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) 1999-07-01
- latest date by which the national standards conflicting with the amendment have to be withdrawn (dow) 2001-07-01

Annexes designated "normative" are part of the body of the standard.
In this standard, annex ZA is normative.
Annex ZA has been added by CENELEC.

Endorsement notice

The text of amendment 1:1998 to the International Standard IEC 60601-2-3:1991 was approved by CENELEC as an amendment to the European Standard without any modification.

Annex ZA (normative)

Normative references to international publications with their corresponding European publications

Addition:

Publication	Year	Title	EN/HD	Year
IEC 60601-1-1	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 60601-1-2	1993	Medical electrical equipment Part 1: General requirements for safety 2. Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2 + corr. December	1993 1997
IEC 60601-1-4	1996	Medical electrical equipment Part 1: General requirements for safety 4. Collateral standard: Programmable electrical medical systems	EN 60601-1-4	1996

INTERNATIONAL STANDARD

IEC 60601-2-3

1991

AMENDMENT 1
1998-09

Amendment 1

Medical electrical equipment –

Part 2:
Particular requirements for the safety of short-wave therapy equipment

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IEC Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

PRICE CODE C

For price, see current catalogue

FOREWORD

This amendment has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

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

FDIS	Report on voting
62D/292/FDIS	62D/298/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 series of revisions to IEC 60601-2-3 (second edition, 1991) taking into account amendments 1 and 2 of the General Standard, which include reference to the collateral standards. The technical content remaining essentially unchanged.

NOTE – The page numbers referenced in this amendment are those in IEC 60601-2-3:1991.

Page 3

CONTENTS

Delete clauses 13 and 18 from the Contents.

Page 5

Replace "FIGURES 101 à 104" *by* "FIGURES 101 to 104"

Page 9

INTRODUCTION

Replace in the last sentence "...an * after..." *by* "...an asterisk (*) before...".

Page 11

1 Scope and object

Add, after the introductory sentence of this clause, the following subclause heading:

1.1 Scope

Replace, in the existing text of the first paragraph of the Addition, "Sub-clause 2.1" *by* "subclause 2.1.101".

Replace the second paragraph of the Addition by the following:

"LOW POWER EQUIPMENT as defined in subclause 2.2.101 is exempted from certain requirements of this standard".

Add the following subclause to the Particular Standard:

1.5 Collateral Standards

Addition:

The following Collateral Standards apply:

IEC 60601-1-1:1992, *Medical electrical equipment – Part 1: General requirements for safety – 1. Collateral Standard: Safety requirements for medical electrical systems*

IEC 60601-1-2:1993, *Medical electrical equipment – Part 1: General requirements for safety – 2. Collateral Standard: Electromagnetic compatibility – Requirements and tests*

IEC 60601-1-4:1996, *Medical electrical equipment – Part 1: General requirements for safety – 4. Collateral Standard: Programmable electrical medical systems*

2 Terminology and definitions

Add, after 2.1.103, the following new definition:

2.2.101 LOW POWER EQUIPMENT

EQUIPMENT having a RATED OUTPUT POWER not exceeding 10 W.

Page 13

4.11 Sequence

In the Amendment replace "temperature-rise test of Sub-clause 42.4" *by* "compliance test which follows subclause 42.3".

***5.2 Amendment:**

Replace "EQUIPMENT" *by* "APPLIED PART".

Page 15

6.1 Marking on the outside of EQUIPMENT

p) Output

In the text of the first dash of the Replacement, replace "power in watts" *by* "POWER in watts".