SLOVENSKI STANDARD
SIST EN 60601-2-10:2002/A1:2002

01-junij-2002

Medicinska električna oprema - 2-10. del: Posebne varnostne zahteve za živčne in mišične stimulatorje - Dopolnilo A1 (IEC 60601-2-10:1987/A1:2001)

Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators (IEC 60601-2-10:1987/A1:2001)

Medizinische elektrische Geräte - Teil 2-10: Besondere Festlegungen für die Sicherheit von Geräten zur Stimulation von Nerven und Muskeln (IEC 60601-2-10:1987/A1:2001)

Appareils électromédicaux - Partie 2-10: Règles particulières de sécurité pour stimulateurs de nerfs et de muscles (CEI 60601-2-10:1987/A1:2001)

Ta slovenski standard je istoveten z: **EN 60601-2-10:2000/A1:2001**

ICS:

11.040.60	Terapevtska oprema	Therapy equipment

SIST EN 60601-2-10:2002/A1:2002 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-10/A1

November 2001

ICS 11.040.60

English version

Medical electrical equipment
Part 2-10: Particular requirements for the safety of nerve and muscle stimulators
(IEC 60601-2-10:1987/A1:2001)

Appareils électromédicaux
Partie 2-10: Règles particulières de sécurité pour stimulateurs de nerfs et de muscles
(CEI 60601-2-10:1987/A1:2001)

Medizinische elektrische Geräte
Teil 2-10: Besondere Festlegungen für die Sicherheit von Geräten zur Stimulation von Nerven und Muskeln
(IEC 60601-2-10:1987/A1:2001)

This amendment A1 modifies the European Standard EN 60601-2-10:2000; it was approved by CENELEC on 2001-11-01. 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, Malta, 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

Ref. No. EN 60601-2-10:2000/A1:2001 E

Foreword

The text of document 62D/413/FDIS, future amendment 1 to IEC 60601-2-10:1987, prepared by SC 62D [1)], 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 60601-2-10:2000 on 2001-11-01.

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) 2002-08-01
- latest date by which the national standards conflicting with the amendment have to be withdrawn (dow) 2004-11-01

Endorsement notice

The text of amendment 1:2001 to the International Standard IEC 60601-2-10:1987 was approved by CENELEC as an amendment to the European Standard without any modification.

1) The foreword of EN 60601-2-10:2000 mistakenly indicated SC 62C as the technical body that drafted the text of the International Standard.

INTERNATIONAL STANDARD

IEC 60601-2-10

1987

AMENDMENT 1
2001-09

Amendment 1

Medical electrical equipment –

Part 2-10:
Particular requirements for the safety of nerve and muscle stimulators

Amendement 1

Appareils électromédicaux –

Partie 2-10:
Règles particulières de sécurité pour stimulateurs de nerfs et de muscles

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International Electrotechnical Commission
Международная Электротехническая Комиссия

PRICE CODE J

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/413/FDIS	62D/420/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.

The committee has decided that the contents of the base publication and its amendments will remain unchanged until 2004. At this date, the publication will be

- reconfirmed;
- withdrawn;
- replaced by a revised edition, or
- amended.

The contents of the corrigendum of January 2002 have been included in this copy.

Page 5

PREFACE

Replace the final two paragraphs of the Preface with the following new text:

A rationale for the more important requirements, where appropriate, is given in annex AA. It is considered that a knowledge of the reasons for these requirements will not only facilitate the proper application of the Particular Standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However this annex does not form part of the requirements of this standard.

The clauses and subclauses which have corresponding rationale statements are marked with an asterisk (*) before their number.

The numbers of the following clauses should be preceded by an asterisk in the main body of the text:

1.1, 5.2, 5.6, 6.1, 6.8.2 aa), 14.6, 19, 20.2, 46.101, 50.1, 50.2, 51.101, 51.102, 50.103, 51.104, 57.3

SECTION ONE – GENERAL

Page 7

1 Scope and object

1.1 Scope

At the end of the 4th dashed item add: (partly covered by IEC 60601-2-31)

At the end of the 7th dashed item add: (covered by IEC 60601-2-40)

At the end of the 8th dashed item add: (covered by IEC 60601-2-40)

Add the following subclauses:

1.3 Particular Standards

Add the following new text:

This Particular Standard for NERVE AND MUSCLE STIMULATORS is to be read in conjunction with the following standard:

IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety*
Amendment 1 (1991)
Amendment 2 (1995)

The requirements of this Particular Standard take priority over the above-mentioned standard and its amendments, hereinafter referred to as the General Standard.

1.5 Collateral Standards

Add the following new text:

The following Collateral Standards apply:

IEC 60601-1-1:2000, *Medical electrical equipment – Part 1-1: General requirements for safety – 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*
Amendment 1 (1999)

Page 9

2.1.102 Pulse duration

Replace “waveform” *by* “WAVEFORM”.

2.1.103 Waveform

Replace "the APPLIED PART" *by* "a PATIENT CIRCUIT".

4 General requirements for tests

4.1 Item b)

Delete 4.1, Item b.

Add the following new text:

4.6 *Additional Item:*

aa) Where reference is made in test specifications to electrode cables and/or electrodes, those supplied or recommended by the manufacturer shall be used.

5 Classification

5.1 *Amendment:*

Delete subclause 5.1.

5.2 *Amendment:*

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

6 Identification, marking and documents

6.1 Marking on the outside

Replace the existing title with “**Marking on the outside of EQUIPMENT or EQUIPMENT parts**".

6.1 j) Power input

Replace "MAINS OPERATED" *by* "mains operated".

6.1 p) Output

Replace "Appendix D" *by* "Appendix D, Table DI".

Page 11

6.8 Accompanying documents

6.8.2 Instructions for use

Item aa) e):

Add the following new dashed item:

– Application of electrodes near the thorax may increase the risk of cardiac fibrillation.

7 Power input

Replace, on page 13, first line, the numbering of subclause "7.3" *by* "7.1".

Page 13

SECTION TWO – SAFETY REQUIREMENTS

Change title to "SECTION TWO — ENVIRONMENTAL CONDITIONS".

SECTION THREE – PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

14 Requirements related to classification

14.3 Class III equipment

Delete subclause 14.3.

14.4 *Item a)*

Delete subclause 14.4

14.6 *Replacement:*

In the text replace "STIMULATORS shall be TYPE BF or CF EQUIPMENT". *by* "THE APPLIED PARTS of STIMULATORS shall be TYPE BF or TYPE CF APPLIED PARTS".

20 Dielectric strength

20.3 Values of test voltages

In the text, on page 15, replace "EQUIPMENT with an INTERNAL ELECTRICAL POWER SOURCE" *by* "INTERNALLY POWERED EQUIPMENT".