SLOVENSKI STANDARD
SIST EN 60601-2-25:1998/A1:2002

01-februar-2002

Medicinska električna oprema - 2-25. del: Posebne varnostne zahteve za elektrokardiografe - Dopolnilo A1 (IEC 60601-2-25:1993/A1:1999)

Medical electrical equipment - Part 2-25: Particular requirements for the safety of electrocardiographs (IEC 60601-2-25:1993/A1:1999)

Medizinische elektrische Geräte - Teil 2-25: Besondere Festlegungen für die Sicherheit von Elektrokardiographen (IEC 60601-2-25:1993/A1:1999)

Appareils électromédicaux - Partie 2-25: Règles particulières de sécurité des électrocardiographes (CEI 60601-2-25:1993/A1:1999)

Ta slovenski standard je istoveten z: **EN 60601-2-25:1995/A1:1999**

ICS:

11.040.55	Diagnostična oprema	Diagnostic equipment

SIST EN 60601-2-25:1998/A1:2002 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-25/A1

June 1999

ICS 11.040.99

English version

Medical electrical equipment
Part 2-25: Particular requirements for the safety of electrocardiographs
(IEC 60601-2-25:1993/A1:1999)

Appareils électromédicaux
Partie 2-25: Règles particulières de sécurité des électrocardiographes
(CEI 60601-2-25:1993/A1:1999)

Medizinische elektrische Geräte
Teil 2-25: Besondere Festlegungen für die Sicherheit von Elektrokardiographen
(IEC 60601-2-25:1993/A1:1999)

This amendment A1 modifies the European Standard EN 60601-2-25:1995; it was approved by CENELEC on 1999-05-01. 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

Ref. No. EN 60601-2-25:1995/A1:1999 E

Foreword

The text of document 62D/309/FDIS, future amendment 1 to IEC 60601-2-25, 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 60601-2-25:1995 on 1999-05-01.

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) 2000-03-01
- latest date by which the national standards conflicting with the amendment have to be withdrawn (dow) 2002-05-01

Annexes designated "normative" are part of the body of the standard.
Annexes designated "informative" are given for information only.
In this standard, annex ZA is normative and annex AA is informative.
Annex ZA has been added by CENELEC.

Endorsement notice

The text of amendment 1:1999 to the International Standard IEC 60601-2-25:1993 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

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
Addition to annex ZA of EN 60601-1:1990/A2:1995:				
IEC 60601-2-2	1998[1)]	Medical electrical equipment Part 2-2: Particular requirements for the safety of high frequency surgical equipment	-	-
IEC 61000-4-3 (mod)	1995	Electromagnetic compatibility (EMC) Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test	EN 61000-4-3	1996
IEC 61000-4-6	1996	Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields	EN 61000-4-6	1996
IEC 61000-4-8	1993	Part 4-8: Testing and measurement techniques - Power frequency magnetic field immunity test	EN 61000-4-8	1993
CISPR 11 (mod)	1997	Industrial, scientific and medical (ISM) radio-frequency equipment - Radio disturbance characteristics - Limits and methods of measurement	EN 55011	1998

1) IEC 60601-2-2:1991 is harmonized as EN 60601-2-2:1993.

INTERNATIONAL STANDARD

IEC 60601-2-25

1993

AMENDMENT 1
1999-05

Amendment 1

Medical electrical equipment –

Part 2-25: Particular requirements for the safety of electrocardiographs

Amendement 1

Appareils électromédicaux –

Partie 2-25:
Règles particulières de sécurité
pour les électrocardiographes

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Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

PRICE CODE M

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/309/FDIS	62D/314/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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Page 3

CONTENTS

Replacement:

SECTION ONE – GENERAL

Page 11

1.3 Particular Standards

Replace the first paragraph of the Addition by the following:

This Particular Standard refers to IEC 60601-1 (1988): *Medical electrical equipment – Part 1: General requirements for safety* as amended by its amendment 1 (1991) and amendment 2 (1995). The General Standard takes into account IEC 60601-1-2 (1993), *Medical electrical equipment – Part 1 General requirements for safety – 2. Collateral Standard: Electromagnetic compatibility – Requirements and tests.*

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6 Identification, marking and documents

This clause of the Particular Standard applies except as follows:

6.1 Marking on the outside

Replace the existing title by the following:

Marking on the outside of EQUIPMENT or EQUIPMENT parts

Delete 6.1 l) and text.

6.8.2 Instructions for use

aa) Advice shall be given on the following:

In 1) replace the defined term TYPE B ELECTROCARDIOGRAPHS *by* TYPE B APPLIED PARTS.

In 3) replace the defined term TYPE BF OR CF ELECTROCARDIOGRAPHS *by* TYPE BF OR CF APPLIED PARTS.

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Addition:

13) Where relevant, a statement that the EQUIPMENT is protected against malfunction caused by electrosurgery.

17 Separation

Replacement:

This clause of the Particular Standard applies, except as follows:

17 h) second dash of the General Standard does not apply because it is covered by 51.101 and 51.102

Delete 17.101 and text.

Page 21

19.3 Allowable values

Delete 19.3 Item a), Additional item: 1) and Table 101, as they are covered by the General Standard.

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SECTION FIVE – PROTECTION AGAINST HAZARD
FROM UNWANTED OR EXCESSIVE RADIATION

36 Electromagnetic compatibility

Replacement:

IEC 60601-1-2 applies, except as follows:

36.201.1.1

Replacement:

The EQUIPMENT shall comply with the requirements of CISPR 11, group 1, class A or B depending on the environment of intended use.