SLOVENSKI STANDARD

SIST EN 60601-2-2:2002

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Medical electrical equipment - Part 2-2: Particular requirements for the safety of high frequency surgical equipment (IEC 60601-2-2:1998)

ICS 11.040.30

Referenčna številka
SIST EN 60601-2-2:2002(en)

EUROPEAN STANDARD

NORME EUROPÉENNE

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EN 60601-2-2

November 2000

ICS 11.040.30

Supersedes EN 60601-2-2:1993

English version

Medical electrical equipment
Part 2-2: Particular requirements for the safety of high frequency surgical equipment
(IEC 60601-2-2:1998)

Appareils électromédicaux
Partie 2-2: Règles particulières de sécurité pour des appareils d'électrochirurgie à courant haute fréquence
(CEI 60601-2-2:1998)

Medizinische elektrische Geräte
Teil 2-2: Besondere Festlegungen für die Sicherheit von Hochfrequenz-Chirurgiegeräten
(IEC 60601-2-2:1998)

This European Standard was approved by CENELEC on 2000-08-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard 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 European Standard 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/291/FDIS, future edition 3 of IEC 60601-2-2, 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 EN 60601-2-2 on 2000-08-01.

This European Standard supersedes EN 60601-2-2:1993.

The following dates were fixed:

- latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2001-05-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2003-08-01

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 annexes AA and ZB are informative.
Annexes ZA and ZB have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-2-2:1998 was approved by CENELEC as a 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 60601-1-2	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 60601-2-18	1996	Part 2: Particular requirements for the safety of endoscopic equipment	EN 60601-2-18	1996

Annex ZB
(informative)

Other international publications mentioned in this standard with the references of the relevant European publications

Publication	Year	Title	EN/HD	Year
Addition to annex ZB of EN 60601-1:1990/A2:1995:				
IEC 60601-2-34	1994	Medical electrical equipment Part 2: Particular requirements for the safety of direct blood pressure monitoring equipment	EN 60601-2-34	1995
CISPR 11 (mod)	1997	Industrial, scientific and medical (ISM) radio-frequency equipment - Radio disturbance characteristics - Limits and methods of measurement	EN 55011	1998

INTERNATIONAL STANDARD

IEC 60601-2-2

Third edition
1998-09

Medical electrical equipment –

Part 2-2: Particular requirements for the safety of high frequency surgical equipment

Appareils électromédicaux –

Partie 2-2:
Règles particulières de sécurité pour appareils d'électrochirurgie à courant haute fréquence

Reference number
IEC 60601-2-2:1998(E)

Numbering

As from 1 January 1997 all IEC publications are issued with a designation in the 60000 series.

Consolidated publications

Consolidated versions of some IEC publications including amendments are available. For example, edition numbers 1.0, 1.1 and 1.2 refer, respectively, to the base publication, the base publication incorporating amendment 1 and the base publication incorporating amendments 1 and 2.

Validity of this publication

The technical content of IEC publications is kept under constant review by the IEC, thus ensuring that the content reflects current technology.

Information relating to the date of the reconfirmation of the publication is available in the IEC catalogue.

Information on the subjects under consideration and work in progress undertaken by the technical committee which has prepared this publication, as well as the list of publications issued, is to be found at the following IEC sources:

- **IEC web site***
- **Catalogue of IEC publications**
  Published yearly with regular updates
  (On-line catalogue)*
- **IEC Bulletin**
  Available both at the IEC web site* and as a printed periodical

Terminology, graphical and letter symbols

For general terminology, readers are referred to IEC 60050: *International Electrotechnical Vocabulary* (IEV).

For graphical symbols, and letter symbols and signs approved by the IEC for general use, readers are referred to publications IEC 60027: *Letter symbols to be used in electrical technology*, IEC 60417: *Graphical symbols for use on equipment. Index, survey and compilation of the single sheets* and IEC 60617: *Graphical symbols for diagrams.*

* IEC web site http: //www.iec.ch.

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Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

PRICE CODE S

For price, see current catalogue

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SECTION EIGHT – ACCURACY OF OPERATING DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT

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SECTION TEN – CONSTRUCTIONAL REQUIREMENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-2: Particular requirements for the safety of high frequency surgical equipment

FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, the IEC publishes International Standards. Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
2) The formal decisions or agreements of the IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested National Committees.
3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical reports or guides and they are accepted by the National Committees in that sense.
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6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 60601-2-2 has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This third edition of IEC 60601-2-2 cancels and replaces the second edition published in 1991, and constitutes a technical revision.

The text of this Particular Standard is based on the following documents:

FDIS	Report on voting
62D/291/FDIS	62D/297/RVD

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

Annex AA is for information only.

In this Particular Standard the following print types are used:

- requirements, compliance with which can be tested, and definitions: in roman type;
- notes, explanations, advice, introductions, general statements, exceptions and references: in smaller type;
- *test specifications: in italic type;*
- TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD OR THIS PARTICULAR STANDARD: SMALL CAPITALS.