SLOVENSKI STANDARD
SIST EN 60601-2-2:2008

01-oktober-2008

Nadomeġļ a:

SIST EN 60601-2-2:2002

Medicinska elektriļ na oprema - 2-2. del: Posebne zahteve za varnost visokofrekvenļ ne kirurġke opreme (IEC 60601-2-2:2006)

Medical electrical equipment - Part 2-2: Particular requirements for the safety of high frequency surgical equipment (IEC 60601-2-2:2006)

Medizinische elektrische Geräte - Teil 2-2: Besondere Festlegungen für die Sicherheit von Hochfrequenz-Chirurgiegeräten (IEC 60601-2-2:2006)

Appareils électromédicaux - Partie 2-2: Exigences particulieres pour la sécurité des appareils d'électrochirurgie à courant haute fréquence (IEC 60601-2-2:2006)

Ta slovenski standard je istoveten z: EN 60601-2-2:2007

ICS:

11.040.30	Operacijski instrumenti in materiali	Surgical instruments and materials

SIST EN 60601-2-2:2008 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-2

March 2007

ICS 11.040.30

Supersedes EN 60601-2-2:2000

English version

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

(IEC 60601-2-2:2006)

Appareils électromédicaux - Partie 2-2: Exigences particulières pour la sécurité des appareils d'électrochirurgie à courant haute fréquence (CEI 60601-2-2:2006)

Medizinische elektrische Geräte - Teil 2-2: Besondere Festlegungen für die Sicherheit von Hochfrequenz-Chirurgiegeräten (IEC 60601-2-2:2006)

This European Standard was approved by CENELEC on 2006-10-01. 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, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the 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 60601-2-2:2007 E

Foreword

The text of document 62D/548/FDIS, future edition 4 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 2006-10-01.

This European Standard supersedes EN 60601-2-2:2000.

Significant revisions in EN 60601-2-2:2007 refer mainly to the following:

– revision of requirements and compliance testing for HF SURGICAL ACCESSORIES to make them independent of specific HF surgical generators;

– revision and expansion of Clause 2 definitions;

– addition of thermal, electrical and adhesive requirements testing for NEUTRAL ELECTRODES;

– revision of dielectric strength requirements for HF SURGICAL ACCESSORIES;

– accommodation of HF surgical generators that don't require continuous operation of the SWITCH SENSOR;

– addition of Annex BB to provide EMD information about HF SURGICAL EQUIPMENT.

This Particular Standard amends and supplements EN 60601-1:1990, *Medical Electrical Equipment – Part 1: General requirements for safety*, and its amendments, hereinafter referred to as the General Standard. The requirements of this Particular Standard take priority over those of the General Standard.

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) 2007-10-01

– latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2009-10-01

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 and headings of items: in italic type;*

– TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD OR THIS PARTICULAR STANDARD: SMALL CAPITALS.

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive 93/42/EEC (MDD). See Annex ZZ.

Annexes ZA and ZZ have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-2-2:2006 was approved by CENELEC as a European Standard without any modification.

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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
IEC 60601-1-2	2001	Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2	2001
IEC 60601-2-2	1998	Medical electrical equipment - Part 2-2: Particular requirements for the safety of high frequency surgical equipment	EN 60601-2-2	2000
IEC 60601-2-4	2005	Medical electrical equipment - Part 2-4: Particular requirements for the safety of cardiac defibrillators	-	-
IEC 60601-2-18 A1	1996 2000	Medical electrical equipment - Part 2-18: Particular requirements for the safety of endoscopic equipment	EN 60601-2-18 A1	1996 2000
IEC 60601-2-34	2000	Medical electrical equipment - Part 2-34: Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment	EN 60601-2-34	2000
IEC 61000-4-3	2006	Electromagnetic compatibility (EMC) - Part 4-3 : Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test	EN 61000-4-3	2006
IEC 61000-4-6 + A1	2003 2004	Electromagnetic compatibility (EMC) - Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields	EN 61000-4-6	200X[1)]
CISPR 11 (mod)	2003	Industrial scientific and medical (ISM) radio-frequency equipment - Electromagnetic disturbance characteristics - Limits and methods of measurement	EN 55011	2007[2)]

[1)] To be ratified; will also include A2:2006 to IEC 61000-4-6.
[2)] EN 55011 includes A1:2004 to CISPR 11.

Publication	Year	Title	EN/HD	Year
CISPR 16-2-1	2003	Specification for radio disturbance and immunity measuring apparatus and methods - Part 2-1: Methods of measurement of disturbances and immunity - Conducted disturbance measurements	EN 55016-2-1	2004
ANSI/AAMI HF18	2001	Electrosurgical devices	-	-

Annex ZZ
(informative)

Coverage of Essential Requirements of EC Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers all relevant essential requirements as given in Annex I of the EC Directive 93/42/EEC.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directives concerned.

WARNING: Other requirements and other EC Directives may be applicable to the products falling within the scope of this standard.

NORME INTERNATIONALE

INTERNATIONAL STANDARD

CEI
IEC
60601-2-2

Quatrième édition
Fourth edition
2006-07

Appareils électromédicaux –

Partie 2-2: Exigences particulières pour la sécurité des appareils d'électrochirurgie à courant haute fréquence

Medical electrical equipment –

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

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Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

CODE PRIX
PRICE CODE XC

Pour prix, voir catalogue en vigueur
For price, see current catalogue

CONTENTS

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

SECTION NINE – ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS

SECTION TEN – CONSTRUCTIONAL REQUIREMENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of 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, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). 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. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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International Standard IEC 60601-2-2 has been prepared by sub-committee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This fourth edition of IEC 60601-2-2 cancels and replaces the third edition published in 1998, of which it constitutes a technical revision.

Significant revisions in this fourth edition refer mainly to the following:

– revision of requirements and compliance testing for HF SURGICAL ACCESSORIES to make them independent of specific HF surgical generators;
– revision and expansion of Cause 2 definitions;
– addition of thermal, electrical and adhesive requirements testing for NEUTRAL ELECTRODES;

– revision of dielectric strength requirements for HF SURGICAL ACCESSORIES;

– accommodation of HF surgical generators that don't require continuous operation of the SWITCH SENSOR;

– addition of Annex BB to provide EMD information about HF SURGICAL EQUIPMENT.

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

FDIS	Report on voting
62D/548/FDIS	62D/560/RVD

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

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

This Particular Standard amends and supplements IEC 60601-1:1998 (second edition) *Medical Electrical Equipment – Part 1: General requirements for safety*, modified by Amendment 1 and Amendment 2, hereinafter referred to as the General Standard. The requirements of this Particular Standard take priority over those of the General Standard.[1)]

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, headings of subclauses and headings of items: in italic type;*

– TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD OR THIS PARTICULAR STANDARD: SMALL CAPITALS.

The committee has decided that the contents of this publication will remain unchanged until the maintenance result date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

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

1) A third edition of IEC 60601-1 was published in 2005, incorporating significant structural modifications. Future editions of this Part 2-2 will be based on the latest edition of Part 1 and any amendments.

INTRODUCTION

This fourth edition represents an extensive revision of the previous edition. It is being released as a new edition to improve readability and usage. It was felt that the breadth of the technical changes, and the improved safety that they will provide, were too important to wait for the harmonization effort with the new edition of the General Standard.

MEDICAL ELECTRICAL EQUIPMENT –

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

SECTION ONE – GENERAL

The clauses and subclauses of this section of the General Standard apply except as follows:

1 Scope and object

This clause of the General Standard applies except as follows:

*1.1 Scope

Addition:

This Particular Standard specifies requirements for the safety of HIGH FREQUENCY SURGICAL EQUIPMENT and HF SURGICAL ACCESSORIES used in medical practice, as defined in 2.1.110 and hereinafter referred to as HF SURGICAL EQUIPMENT.

HF SURGICAL EQUIPMENT having a RATED OUTPUT POWER not exceeding 50 W (for example for micro-coagulation, or for use in dentistry or ophthalmology) is exempt from certain of the requirements of this Particular Standard. These exemptions are indicated in the relevant requirements.

1.2 Object

Replacement:

The object of this Particular Standard is to establish particular requirements for the safety of HF SURGICAL EQUIPMENT.

1.3 Particular Standards

Addition:

This Particular Standard amends and supplements a set of IEC publications consisting of

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

IEC 60601-1-1:2000, *Medical electrical equipment – Part 1-1: General requirements for safety – Collateral Standard: Safety requirements for medical electrical systems*

IEC 60601-1-2:2001, *Medical electrical equipment – Part 1-2: General requirements for safety – Collateral Standard: Electromagnetic compatibility – Requirements and tests*
Amendment 1 (2004)