SVENSK STANDARD SS-EN 60601-2-2

Fastställd	Utgåva	Sida	Ansvarig kommitté
2007-05-21	3	1 (1+86)	SEK TK 62

Elektrisk utrustning för medicinskt bruk – Säkerhet – Del 2-2: Särskilda fordringar på kirurgiska diatermiapparater

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

Som svensk standard gäller europastandarden EN 60601-2-2:2007. Den svenska standarden innehåller den officiella engelska språkversionen av EN 60601-2-2:2007.

Nationellt förord

Europastandarden EN 60601-2-2:2007

består av:

– **europastandardens ikraftsättningsdokument,** utarbetat inom CENELEC
– **IEC 60601-2-2, Fourth edition, 2006 - Medical electrical equipment - Part 2-2: Particular requirements for the safety of high frequency surgical equipment**

utarbetad inom International Electrotechnical Commission, IEC.

Standarden skall användas tillsammans med SS-EN 60601-1, Elektromedicinsk utrustning – Säkerhet – Del 1: Allmänna fordringar, och dess separat utgivna ändringar och tillägg.

Till SS-EN 60601-1 utges en serie tilläggsstandarder som anger allmänna fordringar på säkerhet som är tillämpliga på:

– en grupp av elektrisk utrustning för medicinskt bruk, t ex radiologisk utrustning
– särskilda egenskaper hos all elektrisk utrustning för medicinskt bruk, ej särskilt behandlade i SS-EN 60601-1, t ex elektromagnetisk kompatibilitet.

Tidigare fastställd svensk standard SS-EN 60601-2-2, utgåva 2, 2001, gäller ej fr o m 2009-10-01.

ICS 11.040.30

Denna standard är fastställd av SEK Svensk Elstandard,
som också kan lämna upplysningar om **sakinnehållet** i standarden.
Postadress: SEK, Box 1284, 164 29 KISTA
Telefon: 08 - 444 14 00. *Telefax*: 08 - 444 14 30
E-post: sek@elstandard.se. *Internet*: www.elstandard.se

Standarder underlättar utvecklingen och höjer elsäkerheten

Det finns många fördelar med att ha gemensamma tekniska regler för bl a säkerhet, prestanda, dokumentation, utförande och skötsel av elprodukter, elanläggningar och metoder. Genom att utforma sådana standarder blir säkerhetskraven tydliga och utvecklingskostnaderna rimliga samtidigt som marknadens acceptans för produkten eller tjänsten ökar.

Många standarder inom elområdet beskriver tekniska lösningar och metoder som åstadkommer den elsäkerhet som föreskrivs av svenska myndigheter och av EU.

SEK är Sveriges röst i standardiseringsarbetet inom elområdet

SEK Svensk Elstandard svarar för standardiseringen inom elområdet i Sverige och samordnar svensk medverkan i internationell och europeisk standardisering. SEK är en ideell organisation med frivilligt deltagande från svenska myndigheter, företag och organisationer som vill medverka till och påverka utformningen av tekniska regler inom elektrotekniken.

SEK samordnar svenska intressenters medverkan i SEKs tekniska kommittéer och stödjer svenska experters medverkan i internationella och europeiska projekt.

Stora delar av arbetet sker internationellt

Utformningen av standarder sker i allt väsentligt i internationellt och europeiskt samarbete. SEK är svensk nationalkommitté av International Electrotechnical Commission (IEC) och Comité Européen de Normalisation Electrotechnique (CENELEC).

Standardiseringsarbetet inom SEK är organiserat i referensgrupper bestående av ett antal tekniska kommittéer som speglar hur arbetet inom IEC och CENELEC är organiserat.

Arbetet i de tekniska kommittéerna är öppet för alla svenska organisationer, företag, institutioner, myndigheter och statliga verk. Den årliga avgiften för deltagandet och intäkter från försäljning finansierar SEKs standardiseringsverksamhet och medlemsavgift till IEC och CENELEC.

Var med och påverka!

Den som deltar i SEKs tekniska kommittéarbete har möjlighet att påverka framtida standarder och får tidig tillgång till information och dokumentation om utvecklingen inom sitt teknikområde. Arbetet och kontakterna med kollegor, kunder och konkurrenter kan gynnsamt påverka enskilda företags affärsutveckling och bidrar till deltagarnas egen kompetensutveckling.

Du som vill dra nytta av dessa möjligheter är välkommen att kontakta SEKs kansli för mer information.

SEK Svensk Elstandard
Box 1284
164 29 Kista
Tel 08-444 14 00
www.elstandard se

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)

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	-	-

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

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)

IEC 60601-1-4:1996, *Medical electrical equipment – Part 1: General requirements for safety – 4. Collateral Standard: Programmable electrical medical systems*
Amendment 1 (1999)

For brevity, IEC 60601-1 is referred to, in this Particular Standard, either as the “General Standard” or as the “General Requirement(s)”, IEC 60601-1-1, IEC 60601-1-2, and IEC 60601-1-4 as the Collateral Standard(s).

The term "this Standard" covers the Particular Standard used together with the General Standard and any Collateral Standards.

The numbering of sections, clauses and subclauses of this Particular Standard corresponds with that of the General Standard. The changes to the text of the General Standard are specified by the use of the following words:

“Replacement” means that the clause or subclause of the General Standard is replaced completely by the text of this Particular Standard.

“Addition” means that the text of this Particular Standard is additional to the requirements of the General Standard.

“Amendment” means that the clause or subclause of the General Standard is amended as indicated by the text of this Particular Standard.

Subclauses or figures which are additional to those of the General Standard are numbered starting from 101, additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Clauses and subclauses for which there is a rationale are marked with an asterisk *. These rationales can be found in an informative Annex AA. Annex AA should be used in determining the relevance of the requirements addressed but should never be used to establish additional test requirements.

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause of the General Standard or Collateral Standards applies without modification. Where it is intended that any part of the General Standard or Collateral Standards, although possibly relevant, is not to be applied, a statement to that effect is given in this Particular Standard.

A requirement of this Particular Standard, replacing or modifying requirements of the General Standard or Collateral Standards, takes precedence over the corresponding General Requirement(s).