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SVENSK STANDARD SS-EN 60601-2-46

Handläggande organ	Fastställd	Utgåva	Sida	Ingår i
Svenska Elektriska Kommissionen, SEK	1999-01-29	1	1 (1+18)	SEK Översikt 62
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Elektrisk utrustning för medicinskt bruk – Säkerhet – Del 2-46: Särskilda fordringar på operationsbord

Medical electrical equipment – Part 2-46: Particular requirements for the safety of operating tables

Som svensk standard gäller europastandarden EN 60601-2-46:1998. Den svenska standarden innehåller den officiella engelska språkversionen av EN 60601-2-46:1998.

Nationellt förord

Europastandarden EN 60601-2-46:1998

består av:

– **europastandardens ikraftsättningsdokument,** utarbetat inom CENELEC

– **IEC 60601-2-46, First edition, 1998 - Medical electrical equipment - Part 2-46: Particular requirements for the safety of operating tables**

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.

ICS 11.140

Standarder kan beställas hos SIS som även lämnar allmänna upplysningar om svensk och utländsk standard.
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Prisgrupp Q

Tryckt i mars 1999

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-46

August 1998

ICS 11.140

Descriptors: Medical electrical equipment, operating tables, safety requirements, protection against electric shock, protection against mechanical hazard, radiation protection, fire protection, environmental conditions

English version

Medical electrical equipment Part 2-46: Particular requirements for the safety of operating tables (IEC 60601-2-46:1998)

Appareils électromédicaux
Partie 2-46: Règles particulières de sécurité pour les tables d'opération
(CEI 60601-2-46:1998)

Medizinische elektrische Geräte
Teil 2-46: Besondere Festlegungen für die Sicherheit von Operationstischen
(IEC 60601-2-46:1998)

This European Standard was approved by CENELEC on 1998-08-01. 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.

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CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

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Ref. No. EN 60601-2-46:1998 E

Foreword

The text of document 62D/276/FDIS, future edition 1 of IEC 60601-2-46, 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 60601-2-46 on 1998-08-01.

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) 1999-05-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2001-05-01

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 the International Standard IEC 60601-2-46:1998 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 60601-2-2	1991	Medical electrical equipment Part 2: Particular requirements for the safety of high frequency surgical equipment	EN 60601-2-2	1993

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Clause Page

MEDICAL ELECTRICAL EQUIPMENT –
Part 2-46: Particular requirements for the safety of operating tables

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 safety requirements for OPERATING TABLES, as defined in 2.12.101, whether or not having electrical parts, including TRANSPORTERS, as defined in 2.12.104, used for the transportation of the table top to or from the base or pedestal of an OPERATING TABLE with detachable table top.

This Particular Standard does not apply to

- dental patient chairs;
- examination chairs and couches;
- patient-supporting systems of diagnostic and therapeutic devices;
- operating table heating blankets;
- patient transfer equipment;
- delivery tables and beds;
- hospital beds;
- field tables.

1.3 Particular Standards

Addition:

This Particular Standard refers to IEC 60601-1 (1988*): Medical electrical equipment – Part 1: General requirements for safety* as amended by its amendments 1 (1991) and 2 (1995).

For brevity, part 1 is referred to in this Particular Standard either as the "General Standard" or as the "General Requirements(s)".

The numbering of sections, clauses and subclauses of this Particular Standard corresponds to 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.

The term "this Standard" is used to make reference to the General Standard and this Particular Standard taken together.

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

The requirements of this Particular Standard take priority over those of the General Standard.

An asterisk (*) beside a clause or subclause number indicates that some explanatory notes are given in the "General guidance and rationale" section at the end of this Particular Standard.