SVENSK STANDARD SS-EN 60601-2-50

Fastställd	Utgåva	Sida	Ingår i
2002-06-19	1	1 (1+27)	SEK Område 62

Svenska Elektriska Kommissionen, SEK

Elektrisk utrustning för medicinskt bruk – Säkerhet – Del 2: Särskilda fordringar på utrustning för fototerapi för spädbarn

Medical electrical equipment – Part 2-50: Particular requirements for the safety of infant phototherapy equipment

Som svensk standard gäller europastandarden EN 60601-2-50:2002. Den svenska standarden innehåller den officiella engelska språkversionen av EN 60601-2-50:2002.

Nationellt förord

Europastandarden EN 60601-2-50:2002

består av:

- **europastandardens ikraftsättningsdokument,** utarbetat inom CENELEC
- **IEC 60601-2-50, First edition, 2000 - Medical electrical equipment - Part 2-50: Particular requirements for the safety of infant phototherapy equipment**

  jämte

  Corrigendum 1, 2001 till IEC 60601-2-50:2000

  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 11.040.60

Denna standard är fastställd av Svenska Elektriska Kommissionen, SEK, 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@sekom.se. *Internet*: www.sekom.se

EUROPEAN STANDARD **EN 60601-2-50**

NORME EUROPÉENNE

EUROPÄISCHE NORM February 2002

ICS 11.040.60

English version

Medical electrical equipment
Part 2-50: Particular requirements for the safety of infant phototherapy equipment
(IEC 60601-2-50:2000 + corrigendum March 2001)

Appareils électromédicaux
Partie 2-50: Prescriptions particulières de sécurité des appareils de photothérapie infantile
(CEI 60601-2-50:2000 + corrigendum mars 2001)

Medizinische elektrische Geräte
Teil 2-50: Besondere Festlegungen für die Sicherheit von Säuglings-Phototherapiegeräten
(IEC 60601-2-50:2000 + Corrigendum März 2001)

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 60601-2-50:2002 E

Foreword

The text of document 62D/363/FDIS, future edition 1 of IEC 60601-2-50, 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 60601-2-50 on 2000-09-01.

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)	2002-08-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2003-09-01

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.

In this standard, the following print types are used:
– requirements, compliance with which can be tested, and definitions: roman type;
– notes, explanations, advice, introductions, general statements, exceptions and references: smaller roman type;
– *test specifications: italic type;*
– TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD EN 60601-1 OR THIS PARTICULAR STANDARD: SMALL CAPITALS.

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Endorsement notice

The text of the International Standard IEC 60601-2-50:2000 was approved by CENELEC as a European Standard without any modification.

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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
IEC 60050-845	1987	International Electrotechnical Vocabulary (IEV) Chapter 845: Lighting	-	-
IEC 60335-2-27	1995	Safety of household and similar electrical appliances Part 2-27: Particular requirements for appliances for skin exposure to ultraviolet and infrared radiation	EN 60335-2-27 + A11	1997 1997
IEC 60651 A1	1979 1993	Sound level meters	EN 60651 A1	1994 1994
ISO 3743-1	1994	Acoustics - Determination of sound power levels of noise sources using sound pressure - Engineering methods for small, movable sources in reverberant fields Part 1: Comparison method for hard-walled test rooms	-	-

Annex ZB
(informative)

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

Publication	Year	Title	EN/HD	Year
IEC 60601-2-19	1990	Medical electrical equipment Part 2: Particular requirements for the safety of baby incubators	EN 60601-2-19	1996
A1	1996		A1	1996
IEC 60601-2-20	1990	Part 2: Particular requirements for the safety of transport incubators		
+ A1	1996		EN 60601-2-20	1996
IEC 60601-2-21	1994	Part 2: Particular requirements for the safety of infant radiant warmers	EN 60601-2-21	1994
A1	1996		A1	1996
IEC 60601-2-35	1996	Part 2: Particular requirements for the safety of blankets, pads and mattresses, intended for heating in medical use	EN 60601-2-35	1996

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SECTION SEVEN – PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS

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 2-50: Particular requirements for the safety of infant phototherapy 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 applicable to INFANT PHOTOTHERAPY EQUIPMENT (as defined in 2.1.101) which by means of visible radiation serve to reduce bilirubin in the body of infants suffering from icterus in the first months of life.

1.2 Object

Replacement:

The object of this Particular Standard is to establish requirements for INFANT PHOTOTHERAPY EQUIPMENT which reduce the safety hazards to PATIENTS and operators as much as possible and to specify tests for demonstrating compliance with these requirements.

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 amendment 1 (1991) and its amendment 2 (1995).

For brevity, IEC 60601-1 is referred to in this Particular Standard either as the General Standard or as the General Requirement(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.