SLOVENSKI STANDARD
SIST EN 60601-2-50:2009

01-julij-2009

Nadomeġļ a:
SIST EN 60601-2-50:2002

Medicinska elektriļ na oprema - 2-50. del: Posebne zahteve za osnovno varnost in bistvene lastnosti za otroġko fototerapevtsko opremo (IEC 60601-2-50:2009)

Medical electrical equipment - Part 2-50: Particular requirements for basic safety and essential performance of infant phototherapy equipment (IEC 60601-2-50:2009)

Medizinische elektrische Geräte - Teil 2-50: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Säuglings-Phototherapiegeräten (IEC 60601-2-50:2009)

Appareils électromédicaux - Partie 2-50: Exigences particulières de sécurité de base et de performances essentielles des appareils de photothérapie pour nouveau-nés (CEI 60601-2-50:2009)

Ta slovenski standard je istoveten z: **EN 60601-2-50:200X**

ICS:

11.040.60	Terapevtska oprema	Therapy equipment

SIST EN 60601-2-50:2009 **en,fr**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-50

May 2009

ICS 11.040.60

Supersedes EN 60601-2-50:2002

English version

Medical electrical equipment - Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment

(IEC 60601-2-50:2009)

Appareils électromédicaux -
Partie 2-50: Exigences particulières
pour la sécurité de base
et les performances essentielles
des appareils de photothérapie
pour nouveau-nés
(CEI 60601-2-50:2009)

Medizinische elektrische Geräte -
Teil 2-50: Besondere Festlegungen
für die Sicherheit einschließlich
der wesentlichen Leistungsmerkmale
von Säuglings-Phototherapiegeräten
(IEC 60601-2-50:2009)

SIST EN 60601-2-50:2009

This European Standard was approved by CENELEC on 2009-05-01. 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: Avenue Marnix 17, B - 1000 Brussels

Ref. No. EN 60601-2-50:2009 E

Foreword

The text of document 62D/736A/FDIS, future edition 2 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 2009-05-01.

This European Standard supersedes EN 60601-2-50:2002.

Specific technical changes from EN 60601-2-50:2002 include:

– requiring graphical representation of the spectral irradiance in the instructions for use (this was previously optional; see 201.7.9.2.5 b));

– requirements for support and mounting brackets for ACCESSORIES (see 201.9.8.101);

– requiring restoration of any preset values upon interruption and restoration of the power supply, if applicable (see 201.11.8); and

– corrections to the first four exposure limits (ELs) listed in Table AA.1.

Minor changes from EN 60601-2-50:2002 include replacing the figure containing the eye protection symbol with a reference to this same symbol in IEC 60878 (see 201.7.2.101), defining an INFANT (see 201.3.202) and clarifying the titles for subclauses 201.5.4.102 and 201.5.4.103.

The main purpose, however, is to provide consistency with the general standard EN 60601-1:2006. This EN 60601-2-50:2009 further provides consistency with the four other particular standards related to pediatric equipment for which the committee is responsible.

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) 2010-02-01

– latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2012-05-01

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 MDD (93/42/EEC). See Annex ZZ.

In this standard, the following print types are used:

– Requirements and definitions: roman type.

– *Test specifications: italic type.*

– Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

– “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);

– “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

Annexes ZA and ZZ have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-2-50:2009 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 60335-2-27	NOTE	Harmonized as EN 60335-2-27:1997 (not modified).
IEC 60601-2-19	NOTE	Harmonized as EN 60601-2-19:2009 (not modified).
IEC 60601-2-21	NOTE	Harmonized as EN 60601-2-21:2009 (not modified).
ISO 3743-1	NOTE	Harmonized as EN ISO 3743-1:1995 (not modified).

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.

Annex ZA of EN 60601-1:2006 applies, except as follows:

Publication	Year	Title	EN/HD	Year
Replace *the reference to IEC 60601-1-2 by:*				
IEC 60601-1-2 (mod)	2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2	2007

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 Directive concerned.

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

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IEC 60601-2-50

Edition 2.0 2009-03

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

Appareils électromédicaux –
Partie 2-50: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de photothérapie pour nouveau-nés

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy 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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9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

International standard IEC 60601-2-50 has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces the first edition published in 2000. This edition constitutes a technical revision.

Specific technical changes from the previous edition of this particular standard include:

– requiring graphical representation of the spectral irradiance in the instructions for use (this was previously optional; see 201.7.9.2.5 b));
– requirements for support and mounting brackets for ACCESSORIES (see 201.9.8.101);
– requiring restoration of any preset values upon interruption and restoration of the power supply, if applicable (see 201.11.8); and
– corrections to the first four exposure limits (ELs) listed in Table AA.1.

Minor changes from the previous edition of this particular standard include replacing the figure containing the eye protection symbol with a reference to this same symbol in IEC 60878 (see 201.7.2.101), defining an INFANT (see 201.3.202) and clarifying the titles for subclauses 201.5.4.102 and 201.5.4.103.

The main purpose of this new edition, however, is to provide consistency with the third edition of the general standard. This edition further provides consistency with the four other particular standards related to pediatric equipment for which the committee is responsible.

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

FDIS	Report on voting
62D/736A/FDIS	62D/765/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.

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

In this standard, the following print types are used:

– Requirements and definitions: roman type.
– *Test specifications: italic type.*
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– “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment*, can be found on the IEC website.