SLOVENSKI STANDARD

SIST EN 60601-2-50:2002

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

ICS 11.040.60

Referenčna številka
SIST EN 60601-2-50:2002(en)

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)

This European Standard was approved by CENELEC on 2000-09-01. 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, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and 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

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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.

Endorsement notice

The text of the International Standard IEC 60601-2-50:2000 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
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

INTERNATIONAL STANDARD

IEC 60601-2-50

First edition
2000-07

Medical electrical equipment –

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

Appareils électromédicaux –

Partie 2-50: Prescriptions particulières de sécurité des appareils de photothérapie infantile

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SECTION TEN – CONSTRUCTIONAL REQUIREMENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the 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, the IEC publishes International Standards. 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. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.

2) The formal decisions or agreements of the IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested National Committees.

3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical specifications, technical reports or guides and they are accepted by the National Committees in that sense.

4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.

5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.

6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. The 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.

The text of this Particular Standard is based on the following documents:

FDIS	Report on voting
62D/363/FDIS	62D/369/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 3.

Annex AA is for information only.

In this Particular 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 type;
– *test specifications: in italic type*;
– TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD IEC 60601-1 OR IN THIS PARTICULAR STANDARD: SMALL CAPITALS.

The committee has decided that the contents of this publication will remain unchanged until 2005. At this date, the publication will be

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

A bilingual version of this publication may be issued at a later date.

INTRODUCTION

This Particular Standard concerns the safety of INFANT PHOTOTHERAPY EQUIPMENT. The minimum requirements specified in this Particular Standard shall ensure a reasonable degree of safety during operation. This Particular Standard amends and supplements IEC 60601-1 (second edition 1988): *Medical electrical equipment – Part 1: General requirements for safety,* as amended by its amendment 1 (1991) and its amendment 2 (1995), hereinafter referred to as the General Standard. The requirements of this Particular Standard take priority over those of the General Standard.

A guidance and rationale for the requirements of this Particular Standard is included in annex AA.

It is considered that a knowledge of the reasons for these requirements will not only facilitate the proper application of the standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However, this annex does not form part of the requirements of this standard.

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