SLOVENSKI STANDARD
SIST EN 60601-2-50:2009/A1:2017

01-februar-2017

Medicinska električna oprema - 2-50. del: Posebne zahteve za osnovno varnost in bistvene lastnosti za otroško fototerapevtsko opremo - Dopolnilo A1 (IEC 60601-2-50:2009/A1:2016)

Medical electrical equipment - Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment (IEC 60601-2-50:2009/A1:2016)

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

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

Ta slovenski standard je istoveten z: **EN 60601-2-50:2009/A1:2016**

ICS:

11.040.60	Terapevtska oprema	Therapy equipment

SIST EN 60601-2-50:2009/A1:2017 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

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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/A1:2016)

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Medizinische elektrische Geräte - Teil 2-50: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Säuglings-Phototherapiegeräten (IEC 60601-2-50:2009/A1:2016)

This amendment A1 modifies the European Standard EN 60601-2-50:2009; it was approved by CENELEC on 2016-06-03. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this amendment 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 CEN-CENELEC Management Centre or to any CENELEC member.

This amendment 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 CEN-CENELEC Management Centre has the same status as the official versions.

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

European foreword

The text of document 62D/1327/FDIS, future IEC 60601-2-50:2009/A1, prepared by SC 62D "Electromedical equipment", of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-2-50:2009/A1:2016.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2017-06-16
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2019-12-16

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive 93/42/EEC, see informative Annex ZZ, included in EN 60601-2-50:2009/A11:2011.

Endorsement notice

The text of the International Standard IEC 60601-2-50:2009/A1:2016 was approved by CENELEC as a European Standard without any modification.

In the Bibliography of EN 60601-2-50:2009, replace the existing reference to ISO 3743-1 by the following:

IEC 61672-1	NOTE	Harmonized as EN 61672-1.

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 When an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

Publication	Year	Title	EN/HD	Year
In Annex ZA of EN 60601-2-50:2009, replace the existing reference to IEC 60601-1-2:2007 as follows:				
IEC 60601-1-2	-	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests	EN 60601-1-2	2015

IEC 60601-2-50

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INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

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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FOREWORD

This amendment has been prepared by subcommittee 62D: Electromedical equipment of IEC technical committee 62: Electrical equipment in medical practice.

The text of this amendment is based on the following documents:

FDIS	Report on voting
62D/1327/FDIS	62D/1348/RVD

Full information on the voting for the approval of this amendment can be found in the report on voting indicated in the above table.

The committee has decided that the contents of this amendment and the base publication will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

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

INTRODUCTION

Replace, in the second paragraph, “IEC 60601-1:2005” *by* “IEC 60601-1”.

201.1 Scope, object and related standards

Replace, in footnote 1), “IEC 60601-1:2005” *by* “IEC 60601-1”.

201.1.3 Collateral standards

Replace, in footnote 2), “IEC 60601-1-10:2007” *by* “IEC 60601-1-10”.

201.2 Normative references

Replace “IEC 60601-1-2:2007” *by* “IEC 60601-1-2”.

201.3 Terms and definitions

Replace, in the first paragraph, “IEC 60601-1:2005” *by* “IEC 60601-1”.

201.9.6.2 * Acoustic energy

Replace the existing fourth paragraph by the following new paragraph:

With the microphone of a sound level meter complying with the requirements of IEC 61672-1 placed in the position of the PATIENT, the measured sound level shall not exceed the specified values. The background level shall be at least 10 dB(A) below the measuring value of the INFANT PHOTOTHERAPY EQUIPMENT.

202 ELECTROMAGNETIC COMPATIBILITY

Replace, in the first paragraph, "IEC 60601-1-2:2007" *by* "IEC 60601-1-2".

202.6.2.3 Radiated RF electromagnetic fields

Replace the number, title and entire text by the following new subclause number, title and text:

202.8.9 IMMUNITY TEST LEVELS

Addition:

For radiated radio-frequency electromagnetic fields, the INFANT PHOTOTHERAPY EQUIPMENT and/or system shall

– continue to perform its intended function as specified by the MANUFACTURER at a level up to 3 V/m for the frequency range of the collateral standard for EMC.

NOTE INFANT PHOTOTHERAPY EQUIPMENT is not considered to be used in a HOME HEALTHCARE ENVIRONMENT.

Annex AA
(informative)

Particular guidance and rationale

Rationale for particular clauses and subclauses

Subclause 201.11.1 – Excessive temperatures in ME EQUIPMENT

Add, after the existing text, the following new text:

The temperatures in ME EQUIPMENT may rise when combined with other heat sources such as phototherapy blankets or pads. Hence, it is important to specifically consider the impact of such additional heat sources in the RISK MANAGEMENT.

Subclause 202.6.2.3.1 – Requirements

Delete the number, title and entire text.

Bibliography

Replace the existing reference [8] by the following new reference:

[8] IEC 61672-1, *Electroacoustics – Sound level meters – Part 1: Specifications*