SLOVENSKI STANDARD
SIST EN IEC 60601-2-50:2021/oprA1:2023

01-januar-2023

Medicinska električna oprema - 2-50. del: Posebne zahteve za osnovno varnost in bistvene lastnosti za otroško fototerapevtsko opremo - Dopolnilo A1

Medical electrical equipment - Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment - Amendment 1

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

Amendement 1 - 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 IEC 60601-2-50:2021/prA1:2022**

ICS:

11.040.60	Terapevtska oprema	Therapy equipment

SIST EN IEC 60601-2-50:2021/oprA1:2023 **en**

62D/1981/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER:	
IEC 60601-2-50/AMD1 ED3	
DATE OF CIRCULATION:	CLOSING DATE FOR VOTING:
2022-11-04	**2023-01-27**
SUPERSEDES DOCUMENTS:	
62D/1872/CD, 62D/1964/CC	

IEC SC 62D : ELECTROMEDICAL EQUIPMENT

SECRETARIAT:	SECRETARY:
United States of America	Ms Ladan Bulookbashi
OF INTEREST TO THE FOLLOWING COMMITTEES:	PROPOSED HORIZONTAL STANDARD: ☐
	Other TC/SCs are requested to indicate their interest, if any, in this CDV to the secretary.

FUNCTIONS CONCERNED:

☐ EMC ☐ ENVIRONMENT ☐ QUALITY ASSURANCE ☒ SAFETY

☒ SUBMITTED FOR CENELEC PARALLEL VOTING	☐ NOT SUBMITTED FOR CENELEC PARALLEL VOTING
Attention IEC-CENELEC parallel voting The attention of IEC National Committees, members of CENELEC, is drawn to the fact that this Committee Draft for Vote (CDV) is submitted for parallel voting. The CENELEC members are invited to vote through the CENELEC online voting system.	

This document is still under study and subject to change. It should not be used for reference purposes.

Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

TITLE:

Amendment 1 - Medical electrical equipment - Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment

PROPOSED STABILITY DATE: 2028

NOTE FROM TC/SC OFFICERS:

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:

Draft	Report on voting
62D/XX/FDIS	62D/XX/RVD

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

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

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

NOTE The attention of users of this document is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC or ISO publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for mandatory implementation nationally not earlier than 3 years from the date of publication.

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

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INTRODUCTION to Amendment 1

At the October 2019 meeting of IEC SC 62D in Shanghai, China, the subcommittee discussed the need for administrative/technical changes to most 62D standards after completion of the amendment projects within the IEC 60601-1 series. Those projects were all completed and the amendments published in 2020.

The full list of IEC SC 62D documents that will be amended or revised may be found within the IEC document 62D/1792/DC. The results and comments on the DC may be found within 62D1808/INF. The review report for this amendment is 62D/1814/RR.

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201.1 Scope, object and related standards

Replace the existing footnote 1 with the following text:

The general standard is IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

201.1.3 * Collateral standards

Add an asterisk (*) at the beginning of the subclause title.

*Replace, in the existing second paragraph, "*IEC 60601-1-2:2014 applies*" with "*IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 apply*".*

201.1.4 * Particular standards

*Replace, in the existing third paragraph, "*IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012*" with "*IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020*".*

201.2 Normative references

Replace the existing references to IEC 60601-1 and IEC 60601-1-2 with the following new references:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
Amendment 1:2012
Amendment 2:2020

IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests*
Amendment 1:2020

201.3 Terms and definitions

Replace, in the existing first paragraph, "IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012" with "IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020".

Delete term and definition 201.3.76

201.3.202
INFANT

Add, after the existing first paragraph, the following note:

Note 1 to entry: INFANT includes premature/pre-born baby and neonate baby/newborn baby.

Table 201.101 – List of symbols, abbreviations and acronyms

Replace the existing 16th row of this table with:

Abbreviation	Term
IR – C	C region of infrared radiation (with wavelengths between 3 μm and 1 mm)

201.4.3 * ESSENTIAL PERFORMANCE

Replace the existing instruction "Replacement:" with "Addition:"

201.12.1.102 * Measuring principles

Add an asterisk (*) at the beginning of the subclause title.

202 * Electromagnetic disturbances – Requirements and tests

Replace the existing text of this clause with:

IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 applies.

Note 1 to entry: INFANT PHOTOTHERAPY EQUIPMENT is not considered suitable for use in a HOME HEALTHCARE ENVIRONMENT.

Annex AA
(informative)

Particular guidance and rationale

Add, after the rationale of Subclause 201.1.1, the following new rationale:

Subclause 201.1.3 – Collateral standards

New technologies with wide spectrum wavelength (UV/IR) cameras can detect/monitor the colour of the skin and also measure the body temperature. Such technologies could in a near future enable physiological closed loop controllers. Given the latter, the IEC 60601-1-10 [18] standard applies.

Subclause 201.9.8.3.1 – General

Replace, in the existing text, "shall" with "needs to".

Subclause 201.10.6 – Infrared radiation

Replace the existing last paragraph with the following text:

The IR-A region is mainly associated as being potentially hazardous to the retina, whilst the IR-B region has potential to damage the crystalline lens leading to a cataract as well as some absorption in the cornea. The IR-C region is almost completely absorbed by the cornea (the outermost layer of the eye) with a resulting potential for burn.

Subclause 201.11.1 – Excessive temperatures in ME EQUIPMENT

Replace, in the existing first paragraph, "IEC 60601-2-21:2021" with "IEC 60601-2-21:2020".

Add, after the rationale of Subclause 201.11.2, the following new rationale:

Subclause 201.12.1.102 – Measuring principles

A radiometer whose lens has a limited spectral sensitivity to the INFANT PHOTOTHERAPY EQUIPMENT needs to be calibrated to measure, and with the response limited to, the source spectrum of the lamps within the INFANT PHOTOTHERAPY EQUIPMENT.

Bibliography