SLOVENSKI STANDARD
SIST EN IEC 60601-2-35:2021/oprA1:2023

01-januar-2023

Medicinska električna oprema - 2-35. del: Posebne zahteve za osnovno varnost in bistvene lastnosti za odeje, blazine in posteljne vložke, namenjene za ogrevanje pri medicinski uporabi - Dopolnilo A1

Medical electrical equipment - Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads and mattresses and intended for heating in medical use - Amendment 1

Medizinische elektrische Geräte - Teil 2-35: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Decken, Matten und Matratzen zur Erwärmung von Patienten in der medizinischen Anwendung

Appareils électromédicaux - Partie 2-35: Exigences particulières pour la sécurité de base et les performances essentielles des dispositifs de réchauffage utilisant des couvertures, des coussins ou des matelas chauffants et destinés au réchauffage des pati

Ta slovenski standard je istoveten z: **EN IEC 60601-2-35:2021/prA1:2022**

ICS:

11.140	Oprema bolnišnic	Hospital equipment

SIST EN IEC 60601-2-35:2021/oprA1:2023 **en**

62D/1982/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER: **IEC 60601-2-35/AMD1 ED2**	
DATE OF CIRCULATION: **2022-11-04**	CLOSING DATE FOR VOTING: **2023-01-27**
SUPERSEDES DOCUMENTS: **62D/1876/CD, 62D/1965/CC**	

IEC SC 62D : ELECTROMEDICAL EQUIPMENT	
SECRETARIAT: United States of America	SECRETARY: 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 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads and mattresses and intended for heating in medical use

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/1815/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

Replace the existing second paragraph with:

IEC 60601-1-2:2014 and IEC60601-1-2:2014/AMD1:2020, IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012, and IEC 60601-1-8:2006/AMD2:2020, IEC 60601-1-10:2007, IEC 60601-1-10:2007/AMD1:2013 and IEC 60601-1-10:2007/AMD2:2020 apply as modified in Articles 202, 208 and 210 respectively.

IEC 60601-1-3 does not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

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, IEC 60601-1-2 and IEC 60601-1-10 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

IEC 60601-1-10:2007, *Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers*
Amendment 1:2013
Amendment 2:2020

201.7.2.1.101.2 CONTROLLERS

Replace the existing list item a) with:

a) The HOSE shall be marked within 15 cm of the NOZZLE to caution that the NOZZLE needs to be connected to a BLANKET. The safety sign ISO 7010-M002 (see the general standard, Table D.2, safety sign 10) shall accompany the "NO FREE HOSING" safety sign shown in Annex D of this particular standard.

201.7.4.2.101 Additional requirements for control devices

Replace the existing last paragraph with:

For FORCED AIR DEVICES, each heated temperature control position shall be marked in °C. Such marking shall be CLEARLY LEGIBLE.

201.13.1.2.101.5 * Blockage of a fluid circulation system

Replace the existing second paragraph with:

Compliance is checked under CONDITIONS OF ADEQUATE HEAT DISCHARGE, by setting the temperature control to maximum until steady-state conditions are reached, blocking the circulation system between the fluid heater and the APPLIED PART for 10 s, then removing the blockage and measuring the surface temperature immediately above the fluid inlet.

201.15.4.102 Ruck-resistant BLANKETS

*Replace, in the subclause title, "*Ruck-resistant BLANKETS*" with "*RUCK-RESISTANT BLANKETS*".*

*Replace, in the existing first paragraph, "*RUCK-RESISTANCE*" with "*RUCK resistance*" and "*RUCKING*" with "*rucking*".*

Figure 201.108 – Positions of a BLANKET for the RUCK-RESISTANCE test

*Replace, in the existing figure caption, "*RUCK-RESISTANCE*" with "*RUCK resistance*".*

201.15.4.103 UNDER-BLANKETS

Replace, the existing first paragraph with:

UNDER-BLANKETS, other than RUCK-RESISTANT BLANKETS, FORCED AIR DEVICE BLANKETS, and circulating liquid BLANKETS, shall be provided with means to prevent rucking. The means used for this purpose shall be permanently attached, ensure that the BLANKET cannot RUCK in any direction, and not cause damage to the BLANKET in NORMAL USE. If tapes or similar means are provided for this purpose, they shall be so positioned and of such a length that the BLANKET can be readily and effectively secured to the maximum size of mattress for which it is intended. Pins shall not be used.

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: A HEATING DEVICE is not considered to be used in a HOME HEALTHCARE ENVIRONMENT.

AA.2 Rationale for particular clauses and subclauses

Subclause 201.7.9.2.2.101 k) Additional requirements for warning and safety notices

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

BB.1 LAGGING MATERIAL

Replace the existing second dash of the first paragraph with:

– thermal conductivity 0,03 W/(mK) -10%…0,04 W/(mK) + 10%.

BB.2 Test procedure

Replace the existing first paragraph with:

The heat source is connected to the supply and the temperature rise is measured. The thickness of the LAGGING MATERIAL is established when the following steady temperature rises are recorded: