

STN	Zdravotnícke elektrické prístroje Časť 2-35: Osobitné požiadavky na základnú bezpečnosť a nevyhnutné prevádzkové vlastnosti prikrývok, podušiek a matracov určených na vyhrievanie na zdravotnícke používanie Zmena A1	STN EN IEC 60601-2-35/A1 36 4800
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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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 03/24

STN EN IEC 60601-2-35 z októbra 2021 sa bez tejto zmeny A1 môže používať do 25. 1. 2027.

Obsahuje: EN IEC 60601-2-35:2021/A1:2024, IEC 60601-2-35:2020/AMD1:2023

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Úrad pre normalizáciu, metrológiu a skúšobníctvo Slovenskej republiky, 2024
Slovenská technická norma a technická normalizačná informácia je chránená zákonom č. 60/2018 Z. z. o technickej normalizácii v znení neskorších predpisov.

EUROPEAN STANDARD

EN IEC 60601-2-35:2021/A1

NORME EUROPÉENNE

EUROPÄISCHE NORM

January 2024

ICS 11.040.01; 11.140

English Version

**Medical electrical equipment - Part 2-35: Particular requirements
for the basic safety and essential performance of heating
devices using blankets, pads or mattresses and intended for
heating in medical use
(IEC 60601-2-35:2020/AMD1:2023)**

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 et destinés au réchauffage des patients en usage médical
(IEC 60601-2-35:2020/AMD1:2023)

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
(IEC 60601-2-35:2020/AMD1:2023)

This amendment A1 modifies the European Standard EN IEC 60601-2-35:2021; it was approved by CENELEC on 2024-01-25. 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: Rue de la Science 23, B-1040 Brussels

EN IEC 60601-2-35:2021/A1:2024 (E)**European foreword**

The text of document 62D/2088/FDIS, future IEC 60601-2-35/AMD1, 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 IEC 60601-2-35:2021/A1:2024.

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) 2024-10-25
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2027-01-25

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Any feedback and questions on this document should be directed to the users' national committee. A complete listing of these bodies can be found on the CENELEC website.

Endorsement notice

The text of the International Standard IEC 60601-2-35:2020/AMD1:2023 was approved by CENELEC as a European Standard without any modification.

EN IEC 60601-2-35:2021/A1:2024 (E)**Annex ZA**
(normative)**Normative references to international publications
with their corresponding European publications**

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 1 Where 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.cencenelec.eu.

The Annex ZA of EN IEC 60601-2-35:2021 applies with the following changes:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
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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	EN 60601-1	2006
-	-		+ corrigendum Mar. 2010	
+ A1	2012		+ A1	2013
-	-		+ A12	2014
+ A2	2020		+ A2	2021
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	EN 60601-1-2	2015
+ A1	2020		+ A1	2021
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	EN 60601-1-10	2008
+ A1	2013		+ A1	2015
+ A2	2020		+ A2	2021



IEC 60601-2-35

Edition 2.0 2023-12

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

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

**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 et destinés au réchauffage des
patients en usage médical**

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IEC 60601-2-35

Edition 2.0 2023-12

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

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ELECTROTECHNIQUE
INTERNATIONALE

ICS 11.040, 11.140.01

ISBN 978-2-8322-8001-0

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –**Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads or mattresses and intended for heating in medical use****AMENDMENT 1****FOREWORD**

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Amendment 1 to IEC 60601-2-35:2020 has been prepared by subcommittee 62D: Particular medical equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems.

IEC 60601-2-35:2020/AMD1:2023

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

Draft	Report on voting
62D/2088/FDIS	62D/2108/RVD

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

The language used for the development of this Amendment is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications/.

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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 can be found within the IEC document 62D/1792/DC. The results and comments on the DC can be found within 62D/1808/INF. The review report for this amendment is 62D/1815/RR.

koniec náhľadu – text ďalej pokračuje v platenej verzii STN