

SLOVENSKI STANDARD

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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 (IEC 60601-2-35:2020)

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 (IEC 60601-2-35:2020)

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)

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 patients en usage médical (IEC 60601-2-35:2020)

Ta slovenski standard je istoveten z: EN IEC 60601-2-35:2021

ICS:

11.140

Oprema bolnišnic

Hospital equipment

SIST EN IEC 60601-2-35:2021

en

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EUROPEAN STANDARD

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NORME EUROPÉENNE

EUROPÄISCHE NORM

July 2021

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Supersedes EN 80601-2-35:2009 and all of its
amendments and corrigenda (if any)

English Version

**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
(IEC 60601-2-35:2020)**

Appareils électromédicaux - Partie 2-35: Exigences
particulières pour la sécurité de base et les performances
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(IEC 60601-2-35:2020)

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)

This European Standard was approved by CENELEC on 2020-10-26. 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.

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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 (E)**European foreword**

The text of document 62D/1765/FDIS, future edition 2 of IEC 60601-2-35, 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.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical standard or by endorsement (dop) 2022-01-16
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2024-07-16

This document supersedes EN 80601-2-35:2009 and all of its amendments and corrigenda (if any).

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

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.

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

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

| | | |
|------------------------|------|---|
| IEC 60601-2-19:2020 | NOTE | Harmonized as EN IEC 60601-2-19:2021 (not modified) |
| IEC 60601-2-20:2020 | NOTE | Harmonized as EN IEC 60601-2-20:2020 (not modified) |
| IEC 60601-2-21:2020 | NOTE | Harmonized as EN IEC 60601-2-21:2020 (not modified) |
| IEC 60335-2-53 | NOTE | Harmonized as EN 60335-2-53 |
| IEC 60529:1989 | NOTE | Harmonized as EN 60529:1991 (not modified) |
| IEC 60529:1989/A1:1999 | NOTE | Harmonized as EN 60529:1991/A1:2000 (not modified) |
| IEC 60529:1989/A2:2013 | NOTE | Harmonized as EN 60529:1991/A2:2013 (not modified) |
| ISO 2439:2008 | NOTE | Harmonized as EN ISO 2439:2008 (not modified) |

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.cenelec.eu.

The Annex ZA of EN 60601-1:2006/A1:2013 applies with the following additions:

| <u>Publication</u> | <u>Year</u> | <u>Title</u> | <u>EN/HD</u> | <u>Year</u> |
|--------------------|-------------|--|--------------------|-------------|
| 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 |
| 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 |

The Annex ZA of EN 60601-1:2006/A1:2013 applies with the following replacements:

| | | | | |
|---------------|------|--|--------------|------|
| IEC 60384-14 | 2013 | Fixed capacitors for use in electronic equipment - Part 14: Sectional specification - Fixed capacitors for electromagnetic interference suppression and connection to the supply mains | EN 60384-14 | 2013 |
| + A1 | 2016 | | + A1 | 2016 |
| 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 |

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IEC 60601-2-35

Edition 2.0 2020-09

INTERNATIONAL STANDARD



iTeh STANDARD

**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**

SIST EN IEC 60601-2-35:2021

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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**

FOREWORD

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of 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, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). 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. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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- 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 60601-2-35 has been prepared by IEC technical committee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces IEC 80601-2-35 published in 2009 and Amendment 1:2016.

The text of this particular standard is based on the following documents:

| FDIS | Report on voting |
|---------------|------------------|
| 62D/1765/FDIS | 62D/1777/RVD |

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

This document has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this document, the following print types are used:

- requirements and definitions: roman type;
- *test specifications: italic type;*
- informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;
- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this document, the term

- "clause" means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
- "subclause" means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this document are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

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In this document, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

2021

The verbal forms used in this document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

- "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;
- "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;
- "may" is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the 60601 International Standard, published under the general title *Medical electrical equipment*, can be found on the IEC website.

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 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 committees that the content of this publication be adopted for 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 publication using a colour printer.

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INTRODUCTION

The minimum safety requirements specified in this particular standard are considered to provide for a practical degree of safety in the operation for HEATING DEVICES using BLANKETS, PADS or MATTRESSES and intended for heating in medical use.

While K (degree Kelvin) is the recognized unit and symbol for absolute temperature and temperature difference, °C has been used throughout this document because all measurements are commonly made using equipment marked with the Celsius temperature scale.

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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 or mattresses and intended for heating in medical use

201.1 Scope, object and related standards

Clause 1 of the general standard¹ applies, except as follows:

201.1.1 * Scope

Replacement:

This part of 60601 International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of HEATING DEVICES using BLANKETS, PADS or MATTRESSES in medical use, also referred to as ME EQUIPMENT. HEATING DEVICES intended to prewarm a bed are included in the scope of this document.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

If a clause or subclause is specifically intended to be applicable to a specifically defined type of ME EQUIPMENT, as is the case with FORCED AIR DEVICES, then the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this document are not covered by specific requirements in this document, except in 7.2.13 and 8.4.1 of the general standard.

NOTE See also 4.2 of the general standard.

This document does not apply to:

- HEATING DEVICES intended for physiotherapy;
- INFANT RADIANT WARMERS; for information, see IEC 60601-2-21 [1]²;
- INFANT INCUBATORS; for information, see IEC 60601-2-19 [2];
- INFANT TRANSPORT INCUBATORS, for information, see IEC 60601-2-20 [3];
- cooling devices.

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

² Figures in square brackets refer to the Bibliography.

201.1.2 Object*Replacement:*

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements, which minimize HAZARDS to PATIENTS, and OPERATORS for HEATING DEVICES using BLANKETS, PADS or MATTRESSES and intended for heating in medical use and to specify tests for demonstrating compliance with these requirements.

201.1.3 Collateral standards*Addition:*

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

IEC 60601-1-2:2014, IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012, and IEC 60601-1-10:2007 and IEC 60601-1-10:2007/AMD1:2013 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*Replacement:*

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 are referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this document corresponds to that of the general standard with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix "20x" where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this document addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this document addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of the general standard and applicable collateral standards are specified by the use of the following words:

"*Replacement*" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

"*Addition*" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

"*Amendment*" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.