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Medical electrical equipment - Part 2-35: Particular requirements for basic safety and essential performance of blankets, pads and mattresses, intended for heating in medical use (IEC 80601-2-35:2009)

ITeH STANDARD PREVIEW
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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 80601-2-35:2009)

SIST EN 80601-2-35:2010
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Appareils électromédicaux - Partie 2-35: Exigences particulières pour la sécurité de base et les performances essentielles des couvertures, coussins et matelas chauffants destinés au réchauffage des patients en usage médical (CEI 80601-2-35:2009)

Ta slovenski standard je istoveten z: EN 80601-2-35:2009

ICS:

11.140 Oprema bolnišnic Hospital equipment

SIST EN 80601-2-35:2010 en,fr

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 80601-2-35

December 2009

ICS 11.140

Supersedes EN 60601-2-35:1996

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 80601-2-35:2009)**

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
(CEI 80601-2-35:2009)

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 80601-2-35:2009)

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This European Standard was approved by CENELEC on 2009-11-01. 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.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

This European Standard 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 Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

CENELEC

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

Central Secretariat: Avenue Marnix 17, B - 1000 Brussels

Foreword

The text of document 62D/784A/FDIS, future edition 2 of IEC 80601-2-35, prepared by SC 62D, Electromedical equipment, of IEC TC 62, Electrical equipment in medical practice, and SC 1, Breathing attachments and anaesthetic machines, of ISO TC 121: Anaesthetic and respiratory equipment, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 80601-2-35 on 2009-11-01.

This European Standard supersedes EN 60601-2-35:1996.

This new edition provides consistency with EN 60601-1:2006, as well as with the four other particular standards related to paediatric equipment for which the committee is responsible.

The following dates were fixed:

- latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2010-08-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2012-11-01

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive MDD (93/42/EEC). See Annex ZZ.

In this standard, the following print types are used:

- Requirements and definitions: roman type.
- *Test specifications: italic type.* [SIST EN 80601-2-35:2010](https://standards.iteh.ai/catalog/standards/sist/8d868709-dd19-46ae-8fcc-94475731a106/en-80601-2-35:2010)
<https://standards.iteh.ai/catalog/standards/sist/8d868709-dd19-46ae-8fcc-94475731a106/en-80601-2-35:2010>
- 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 standard, 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 standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

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

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

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- “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.

Annexes ZA and ZZ have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 80601-2-35:2009 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:

- | | | | |
|------|----------------|------|--|
| [10] | IEC 60601-2-19 | NOTE | Harmonized as EN 60601-2-19:2009 (not modified). |
| [11] | IEC 60601-2-20 | NOTE | Harmonized as EN 60601-2-20:2009 (not modified). |
| [12] | IEC 60601-2-21 | NOTE | Harmonized as EN 60601-2-21:2009 (not modified). |
| [19] | IEC 60335-2-53 | NOTE | Harmonized as EN 60335-2-53:2003 (not modified). |

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Annex ZA (normative)

Normative references to international publications with their corresponding European publications

The following referenced documents are indispensable for the application 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 When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
<i>Amendment:</i>				
IEC 60601-1-2 (mod)	2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2	2007
IEC 60601-1-8	2006	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	EN 60601-1-8	2007
ISO 14971	2007	Medical devices - Application of risk management to medical devices	EN ISO 14971	2007
<i>Addition:</i>				
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
ISO 2439	2008	Flexible cellular polymeric materials - Determination of hardness (indentation technique)	EN ISO 2439	2008
ISO 3743-1	1994	Acoustics - Determination of sound power levels of noise sources - Engineering methods for small, movable sources in reverberant fields - Part 1: Comparison method for hard-walled test rooms	EN ISO 3743-1	2009

Annex ZZ (informative)

Coverage of Essential Requirements of EC Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers all relevant essential requirements as given in Annex I of the EC Directive 93/42/EEC.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

WARNING: Other requirements and other EC Directives may be applicable to the products falling within the scope of this standard.

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IEC 80601-2-35

Edition 2.0 2009-10

INTERNATIONAL STANDARD

NORME INTERNATIONALE



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

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Appareils électromédicaux –
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essentiels des dispositifs de réchauffage utilisant des couvertures, des
coussins ou des matelas chauffants et destinés au réchauffage des patients en
usage médical

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

PRICE CODE
CODE PRIX

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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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International Standard IEC 80601-2-35 has been prepared by IEC technical committee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice, and subcommittee 1: Breathing attachments and anaesthetic machines, of ISO technical committee 121: Anaesthetic and respiratory equipment.

This second edition cancels and replaces the first edition published in 1996. This edition constitutes a technical revision.

This new edition provides consistency with the third edition of IEC 60601-1, as well as with the four other particular standards related to paediatric equipment for which the committee is responsible.

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

FDIS	Report on voting
62D/784A/FDIS	62D/804/RVD

Full information on the voting for the approval of this particular standard can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by 15 P-members out of 15 having cast a vote.

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

In this standard, 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.

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- “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.);
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- “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 IEC 60601 series, published under the general title: *Medical electrical equipment* can be found on the IEC website.

The committee has decided that the contents of this particular standard will remain unchanged until the maintenance result date indicated on the IEC web site 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.

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.

This particular standard amends and supplements IEC 60601-1 (third edition, 2005) *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*, hereinafter referred to as the general standard. The text of this particular standard relating to forced air warmers is based on ASTM F2196-02, *Standard specification for circulating liquid and forced air patient temperature management devices*.

The requirements are followed by specifications for the relevant tests.

A "general guidance and rationale" section giving some explanatory notes, where appropriate, about the more important requirements is included in Annex AA.

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

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