Elektrilised meditsiiniseadmed. Osa 2-35: Erinõuded meditsiinilises kasutuses soojendustekkide, -patjade ja –madratsite esmasele ohutusele ja olulistele toimimisnäitajatele

Medical electrical equipment - Part 2-35: Particular requirements for the basicsafety and essential performance of heating devices using blankets, pads andmattresses and intended for heating in medical use

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 80601-2-35:2010 sisaldab Euroopa standardi EN 80601-2-35:2009 ingliskeelset teksti.	This Estonian standard EVS-EN 80601-2-35:2010 consists of the English text of the European standard EN 80601-2-35:2009.
Standard on kinnitatud Eesti Standardikeskuse 28.02.2010 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 28.02.2010 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 11.12.2009.	Date of Availability of the European standard text 11.12.2009.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

ICS 11.140

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)

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

Ref. No. EN 80601-2-35:2009 E

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.*

– 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).

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.

Publication	Year	Title	EN/HD	Year
Amendment:				
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
Addition:				
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.

_____

CONTENTS

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.

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 standard[1)] applies, except as follows:

201.1.1 * Scope

Replacement:

This 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 International Standard.

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 apply to a specifically defined type of ME EQUIPMENT, as is the case with FORCED AIR DEVICES, then the clause or subclause is entitled as such. Clauses or subclauses that apply to all types of ME EQUIPMENT within the scope of this standard are not specifically entitled.

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

NOTE See also 4.2 of the general standard.

This particular standard does not apply to:

– HEATING DEVICES intended for physiotherapy;
– radiant warmers; for information, see IEC 60601-2-21 [12][2];
– incubators; for information, see IEC 60601-2-19 [10];
– transport incubators, for information, see IEC 60601-2-20 [11];
– cooling devices.

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

---

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

2) Figures in square brackets refer to the Bibliography.

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, IEC 60601-1-8 and IEC 60601-1-10 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 is 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 particular standard corresponds to that of the general standard with the prefix “201” (e.g. 201.1 in this standard 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 particular standard addresses the content of Clause 4 of the 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the 60601-1-3 collateral standard, etc.). The changes to the text of the general standard 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.

Subclauses or figures which are additional to those of the general standard are numbered starting from 201.101. However due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses or figures which are additional to those of a collateral standard are numbered starting from 20x, where “x” is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this standard" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

NOTE Informative references are listed in the Bibliography.

Clause 2 of the general standard applies, except as follows*:*

Amendment:

IEC 60601-1-2:2007, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*

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*

ISO 14971:2007, *Medical devices – Application of risk management to medical devices*

Addition:

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*

ISO 2439:2008, *Flexible cellular polymeric materials – Determination of hardness (indentation technique)*

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*

201.3 Terms and definitions

NOTE An index of defined terms used in this document is found beginning on page 66.

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, apply, except as follows:

Addition:

201.3.201
BLANKET
for FORCED AIR DEVICES, APPLIED PART of HEATING DEVICE intended to be used with a CONTROLLER to transfer thermal energy to all or part of the body of a PATIENT; for other than FORCED AIR DEVICES, APPLIED PART of HEATING DEVICE, which can be folded, for use under or over a PATIENT

201.3.202
CONDITIONS OF ADEQUATE HEAT DISCHARGE
conditions achieved when a HEATING DEVICE is supported and covered as specified in Annex EE