SVENSK STANDARD SS-EN 80601-2-35

Fastställd	Utgåva	Sida	Ansvarig kommitté
2010-06-21	1	1 (1+68)	SEK TK 62

Elektrisk utrustning för medicinskt bruk – Säkerhet och väsentliga prestanda – Del 2-35: Särskilda fordringar på värmefiltar, värmedynor och värmemadrasser

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

Som svensk standard gäller europastandarden EN 80601-2-35:2009. Den svenska standarden innehåller den officiella engelska språkversionen av EN 80601-2-35:2009.

Nationellt förord

Europastandarden EN 80601-2-35:2009

består av:

– **europastandardens ikraftsättningsdokument,** utarbetat inom CENELEC
– **IEC 80601-2-35, Second edition, 2009 - 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**

utarbetad inom International Electrotechnical Commission, IEC.

Standarden ska användas tillsammans med SS-EN 60601-1, utgåva 2, 2006.

Tidigare fastställd svensk standard SS-EN 60601-2-35, utgåva 1, 1997, gäller ej fr o m 2012-11-01.

ICS 11.140

Denna standard är fastställd av SEK Svensk Elstandard,
som också kan lämna upplysningar om **sakinnehållet** i standarden.
Postadress: SEK, Box 1284, 164 29 KISTA
Telefon: 08 - 444 14 00. *Telefax*: 08 - 444 14 30
E-post: sek@elstandard.se. *Internet*: www.elstandard.se

Standarder underlättar utvecklingen och höjer elsäkerheten

Det finns många fördelar med att ha gemensamma tekniska regler för bl a säkerhet, prestanda, dokumentation, utförande och skötsel av elprodukter, elanläggningar och metoder. Genom att utforma sådana standarder blir säkerhetskraven tydliga och utvecklingskostnaderna rimliga samtidigt som marknadens acceptans för produkten eller tjänsten ökar.

Många standarder inom elområdet beskriver tekniska lösningar och metoder som åstadkommer den elsäkerhet som föreskrivs av svenska myndigheter och av EU.

SEK är Sveriges röst i standardiseringsarbetet inom elområdet

SEK Svensk Elstandard svarar för standardiseringen inom elområdet i Sverige och samordnar svensk medverkan i internationell och europeisk standardisering. SEK är en ideell organisation med frivilligt deltagande från svenska myndigheter, företag och organisationer som vill medverka till och påverka utformningen av tekniska regler inom elektrotekniken.

SEK samordnar svenska intressenters medverkan i SEKs tekniska kommittéer och stödjer svenska experters medverkan i internationella och europeiska projekt.

Stora delar av arbetet sker internationellt

Utformningen av standarder sker i allt väsentligt i internationellt och europeiskt samarbete. SEK är svensk nationalkommitté av International Electrotechnical Commission (IEC) och Comité Européen de Normalisation Electrotechnique (CENELEC).

Standardiseringsarbetet inom SEK är organiserat i referensgrupper bestående av ett antal tekniska kommittéer som speglar hur arbetet inom IEC och CENELEC är organiserat.

Arbetet i de tekniska kommittéerna är öppet för alla svenska organisationer, företag, institutioner, myndigheter och statliga verk. Den årliga avgiften för deltagandet och intäkter från försäljning finansierar SEKs standardiseringsverksamhet och medlemsavgift till IEC och CENELEC.

Var med och påverka!

Den som deltar i SEKs tekniska kommittéarbete har möjlighet att påverka framtida standarder och får tidig tillgång till information och dokumentation om utvecklingen inom sitt teknikområde. Arbetet och kontakterna med kollegor, kunder och konkurrenter kan gynnsamt påverka enskilda företags affärsutveckling och bidrar till deltagarnas egen kompetensutveckling.

Du som vill dra nytta av dessa möjligheter är välkommen att kontakta SEKs kansli för mer information.

SEK Svensk Elstandard
Box 1284
164 29 Kista
Tel 08-444 14 00
www.elstandard.se

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)

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

SEK Svensk Elstandard

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

CONTENTS

INTRODUCTION 7
201.1 Scope, object and related standards 8
201.2 Normative references 10
201.3 Terms and definitions 10
201.4 General requirements 13
201.5 General requirements for testing ME EQUIPMENT 14
201.6 Classification of ME EQUIPMENT and ME SYSTEMS 14
201.7 ME EQUIPMENT identification, marking and documents 14
201.8 Protection against electrical HAZARDS from ME EQUIPMENT 17
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS 22
201.10 Protection against unwanted and excessive radiation HAZARDS 24
201.11 Protection against excessive temperatures and other HAZARDS 24
201.12 Accuracy of controls and instruments and protection against hazardous outputs 27
201.13 HAZARDOUS SITUATIONS and fault conditions 32
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) 37
201.15 Construction of ME EQUIPMENT 37
201.16 ME SYSTEMS 41
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS 41
202 Electromagnetic compatibility – Requirements and tests 42
208 General requirements, tests and guidance for ALARM SYSTEMS in MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS 42
210 * Requirements for the development of physiologic closed-loop controllers 42
Annex D (informative) Symbols on marking 43
Annex AA (informative) Particular guidance and rationale 44
Annex BB (normative) Determination of the LAGGING MATERIAL 55
Annex CC (normative) *Determination of heat transfer towards the PATIENT 56
Annex DD (normative) *Determination of heat transfer away from the PATIENT 58
Annex EE (normative) Conditions of adequate heat discharge 59
Annex FF (normative) Test procedure for maximum CONTACT SURFACE TEMPERATURE for FORCED AIR DEVICES 60
Annex GG (normative) Test procedure for maximum CONTACT SURFACE TEMPERATURE for FORCED AIR DEVICES under SINGLE FAULT CONDITION 62
Annex HH (normative) Safety test procedure for average CONTACT SURFACE TEMPERATURE for FORCED AIR DEVICES 63
Bibliography 65
Index of defined terms used in this particular standard 66

Figure 201.101 – Positioning of temperature sensors on the contact surface of the heated area of a HEATING DEVICE (see 201.12.4.101 and 201.12.4.105) 11
Figure 201.102 – Example of the positioning of temperature sensors on the contact surface of the heated areas of a HEATING DEVICE having more than one separately heated area 11

Figure 201.103 a) – Apparatus for the spark ignition test – Detail A: The apparatus (see 201.8.8.4.101)..... 19
Figure 201.103 b) – Apparatus for the spark ignition test – Detail B: Lower member of mask..... 20
Figure 201.103 c) – Apparatus for the spark ignition test – Detail C: Upper member of mask..... 20
Figure 201.103 – Apparatus for the spark ignition test..... 20
Figure 201.104 – Ramp for the impact test on PADS..... 23
Figure 201.105 – Partial covering conditions..... 25
Figure 201.106 – Method of folding BLANKETS..... 34
Figure 201.107 – Examples of folds..... 36
Figure 201.108 – Positions of a BLANKET for the RUCK-RESISTANCE test..... 41
Figure HH.1 – Sensor locations – Average CONTACT SURFACE TEMPERATURE..... 64

Table 201.101 – *Additional ESSENTIAL PERFORMANCE requirements..... 13
Table 201.102 – Temperature limits in dependency to time..... 38

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*