IEC 80601-2-35

Edition 2.0 2009-10

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

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 chauffants et destinés au réchauffage des patients en usage médical

IEC 80601-2-35:2009

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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

FOREWORD

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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.

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.

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.

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

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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:

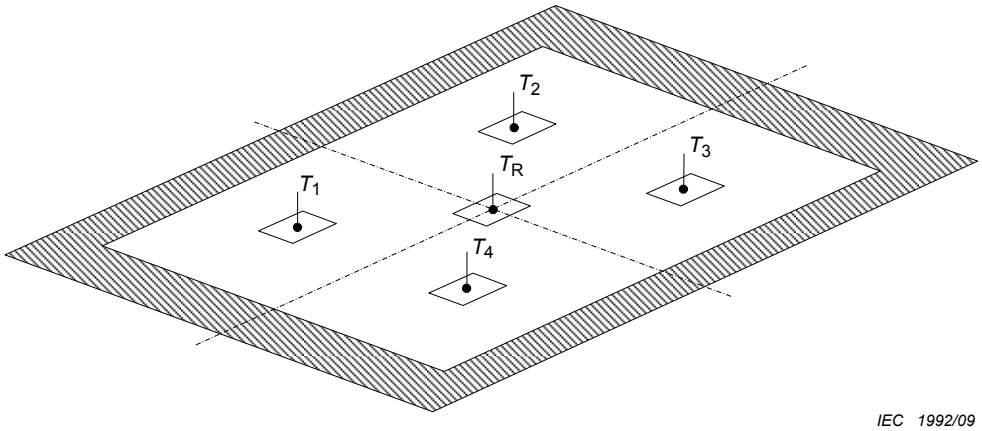
Addition:

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

201.3.203
CONTACT SURFACE TEMPERATURE
for FORCED AIR DEVICES, temperature resulting from the heat transferred to a target surface by the APPLIED PART; for other than FORCED AIR DEVICES temperature T_R at the reference point of the heated APPLIED PART (see Figures 201.101 and 201.102)

NOTE The CONTACT SURFACE TEMPERATURE for FORCED AIR DEVICES is measured by the test methods described in Annexes FF, GG and HH.

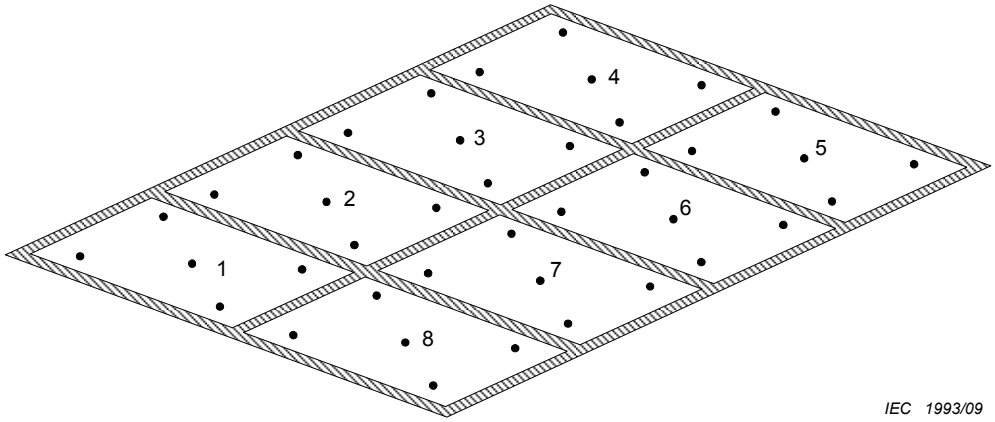


Key

T_R CONTACT SURFACE TEMPERATURE reference point on the contact surface

Some heating devices may have unheated areas shown in the following figures as:

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)



The temperature at the centre point of any one of the heated areas closest to the centre of the HEATING DEVICE (in the example shown above 2, 3, 6, or 7) is treated as T_R.

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

201.3.204
CONTROLLER
that part of a HEATING DEVICE intended to supply and control thermal energy to a BLANKET, PAD or MATTRESS

NOTE This includes the HOSE, if present.

201.3.205
FORCED AIR DEVICE
HEATING DEVICE that uses air as the heat transfer medium to warm a PATIENT and is comprised of a CONTROLLER and a BLANKET

201.3.206
FREE HOSING
hazardous practice or condition of using the CONTROLLER without a BLANKET

201.3.207
HEATING DEVICE
ME EQUIPMENT intended to supply heat to the whole or part of the body of a PATIENT by means of heated BLANKETS, PADS, or MATTRESSES

201.3.208
HIGH HEAT TRANSFER
thermal characteristic of a HEATING DEVICE as determined according to Annex CC or Annex DD

201.3.209
HOSE
component of the CONTROLLER that is the conduit for the heat transfer medium to and/or from the BLANKET, PAD or MATTRESS

201.3.210
INFANT
PATIENT up to the age of three months and with a weight less than 10 kg

201.3.211
LAGGING MATERIAL
open-cell polyurethane or polystyrene insulation material used in the test methods of this specification to assist in the determination of temperature.

NOTE Specifications for LAGGING MATERIAL are given in Annexes BB and FF.

201.3.212
LOW HEAT TRANSFER
thermal characteristic of a HEATING DEVICE as determined according to Annex CC or Annex DD

201.3.213
MATTRESS
APPLIED PART of a HEATING DEVICE, which provides resilient support to the whole body of a PATIENT

201.3.214
NOZZLE
end of the HOSE that connects to the BLANKET, PAD or MATTRESS

201.3.215
OVER-BLANKET
BLANKET designed to be used over a PATIENT

201.3.216
PAD
APPLIED PART of HEATING DEVICE, which can be bent but not folded

201.3.217
RUCK
an unintended fold in a normally even surface

201.3.218
RUCK-RESISTANT BLANKET
BLANKET having a construction such that RUCKING of the flexible part is unlikely

201.3.219
UNDER-BLANKET
BLANKET designed to be used under a PATIENT

201.4 General requirements

Clause 4 of the general standard applies except as follows:

201.4.3 ESSENTIAL PERFORMANCE

Addition:

201.4.3.101 Additional requirements for ESSENTIAL PERFORMANCE

Additional ESSENTIAL PERFORMANCE requirements are found in the subclauses listed in Table 201.101.

Table 201.101 – *Additional ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
ESSENTIAL PERFORMANCE requirement 1	201.12.4.104 or generation of a TECHNICAL ALARM CONDITION in compliance with 201.12.3.103

201.4.5 Equivalent safety for ME EQUIPMENT or ME SYSTEMS

Addition:

This particular standard specifies safety requirements for HEATING DEVICES using BLANKETS, PADS or MATTRESSES, but alternate methods of compliance with a specific clause or subclause by demonstrating equivalent safety will not be judged non-compliant if the MANUFACTURER has demonstrated in his RISK MANAGEMENT FILE that the RISKS presented by the HAZARDS are of an acceptable level when weighed against the benefits of treatment using the device.

Additional subclause:

201.4.101 Combination of equipment

For equipment which combines several heat sources, the safety requirements of other relevant particular standards shall be considered. Further, the safety requirements of this particular standard shall be fulfilled with the combination of the other equipment, which is approved by the MANUFACTURER as stated in the instructions for use according to Clause 16 of the general standard (ME SYSTEMS).