



BSI Standards Publication

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

National foreword

This British Standard is the UK implementation of EN 80601-2-35:2009+A1:2016. It is identical to IEC 80601-2-35:2009, incorporating amendment 1:2016. It supersedes BS EN 80601-2-35:2009+A11:2011, which will be withdrawn on 16 December 2019.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to IEC text carry the number of the IEC amendment. For example, text altered by IEC amendment 1 is indicated by **A1** ~~A1~~.

The UK participation in its preparation was entrusted by Technical Committee CH/62, Electrical Equipment in Medical Practice, to Subcommittee CH/62/4, Electromedical equipment.

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

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Amendments/corrigenda issued since publication

Date	Text affected
29 February 2012	Implementation of CENELEC amendment A11:2011: Annex ZZ updated
31 January 2017	Implementation of IEC amendment 1:2016 with CENELEC endorsement A1:2016. Annex ZA amended

**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

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). |
-

Foreword to amendment A11

This document (EN 80601-2-35:2009/A11:2011) has been prepared by CLC/TC 62 “Electrical equipment in medical practice”.

The following dates are fixed:

- latest date by which this document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2012-10-01
- latest date by which the national standards conflicting with this document have to be withdrawn (dow) 2014-10-01

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

Foreword to amendment A1

The text of document 62D/1328/FDIS, future IEC 80601-2-35:2009/A1, 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 approved by CENELEC as EN 80601-2-35:2009/A1:2016.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2017-06-16
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2019-12-16

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

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive 93/42/EEC, see informative Annex ZZ, included in EN 80601-2-35:2009/A1:2011.

Endorsement notice

The text of the International Standard IEC 80601-2-35:2009/A1:2016 was approved by CENELEC as a European Standard without any modification.

In the Bibliography of EN 80601-2-35:2009, replace the existing references [10], [11] and [12] by the following:

[10] IEC 60601-2-19	NOTE	Harmonized as EN 60601-2-19.
[11] IEC 60601-2-20	NOTE	Harmonized as EN 60601-2-20.
[12] IEC 60601-2-21	NOTE	Harmonized as EN 60601-2-21.

Annex ZA (normative)

Normative references to international publications with their corresponding European publications

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 When 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.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
<i>Amendment:</i>				
IEC 60601-1-2	-	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	2015
IEC 60601-1-8	-	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 + corr. Mar. + A1 + A1/AC	2007 2010 2013 2014
ISO 14971	2007	Medical devices - Application of risk management to medical devices	EN ISO 14971	2007
<i>Addition:</i>				
IEC 60601-1-10	-	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 + A1	2008 2015
ISO 2439	2008	Flexible cellular polymeric materials - Determination of hardness (indentation technique)	EN ISO 2439	2008

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 except as follows

- Essential Requirement 6a
- Essential Requirement 7.1
- Essential Requirement 7.4
- Essential Requirement 7.5 paragraph 2 & 3
- Essential Requirement 13.6 (q)

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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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  *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 standard¹⁾ 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, *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:

▣_{A1} IEC 60601-1-2 ▣_{A1}, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*

▣_{A1} IEC 60601-1-8 ▣_{A1}, *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:

▣_{A1} IEC 60601-1-10 ▣_{A1}, *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)*

▣_{A1} *Text deleted* ▣_{A1}

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 ▣_{A1} IEC 60601-1 ▣_{A1}, 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

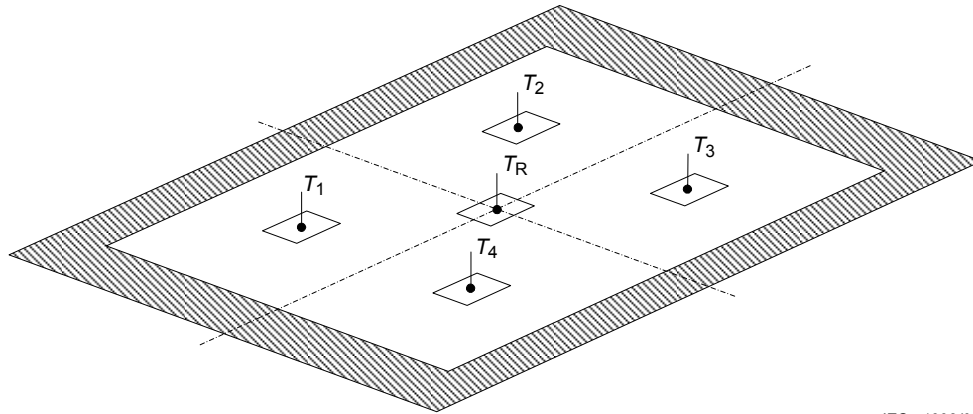
conditions achieved when a HEATING DEVICE is supported and covered as specified in Annex EE

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.



IEC 1992/09

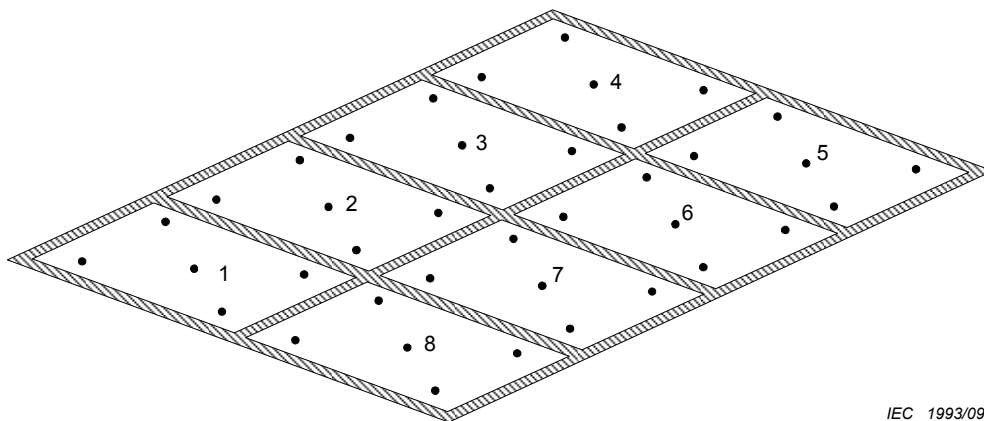
Key

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)



IEC 1993/09

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).

201.5 General requirements for testing ME EQUIPMENT

Clause 5 of the general standard applies.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies, except as follows:

201.6.2 Protection against electric shock

Amendment:

Replace the last paragraph with the following:

HEATING DEVICES shall have TYPE BF APPLIED PARTS OR TYPE CF APPLIED PARTS.

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of the general standard applies, except as follows:

201.7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts

201.7.2.1 Minimum requirements for marking on ME EQUIPMENT and on interchangeable parts

Addition:

201.7.2.1.101 *Additional minimum requirements for marking on ME EQUIPMENT and on interchangeable parts

201.7.2.1.101.1 HEATING DEVICES (other than for FORCED AIR DEVICES)

A HEATING DEVICE shall be marked as follows:

- a) to indicate how it is intended to be positioned in NORMAL USE, whether:
 - over the PATIENT;
 - under the PATIENT;
 - directly in contact with the PATIENT;
 - separated from the PATIENT by an intermediate layer, or layers (for example by a water-bed, other type of mattress, or bedclothes);
 - it has to be used flat (that is without creases), or whether it can be wrapped around the PATIENT;
- b) to warn against possible HAZARDOUS SITUATIONS from penetration by sharp objects;
- c) to warn against possible HAZARDOUS SITUATIONS from folding or methods of storage, other than those specified by the MANUFACTURER;
- d) to warn against the possibility of a HAZARDOUS SITUATION if a partial covering is caused by pillows or other items having good thermal insulation being laid over part of the HEATING DEVICE;
- e) to specify, in the case of liquid-filled MATTRESSES intended to be used above a PAD, the minimum amount of liquid to which the MATTRESS should be filled, and a warning that if this minimum amount is not present a PATIENT could suffer a burn;
- f) to specify, in the case of a HEATING DEVICE supplied or controlled by an external unit, that the HEATING DEVICE shall only be used with the external unit specified by the MANUFACTURER of the HEATING DEVICE.

201.7.2.1.101.2 CONTROLLERS

A CONTROLLER for FORCED AIR DEVICES shall be marked as follows:

- a)  The HOSE shall be marked within 15 cm of the NOZZLE to caution that the NOZZLE needs to be connected to a BLANKET. The following statement and the safety sign ISO 7010-M002 (see IEC 60601-1, Table D.2, safety sign 10) shall accompany the “NO FREE HOSE” safety sign of IEC 60878, shown in Annex D of this particular standard: 
- b) A caution that allowing the HOSE to contact the PATIENT can lead to thermal injury, if appropriate.
- c) A warning against using the device distal to arterial cross clamping and that non-observance can lead to thermal injury.

201.7.2.1.101.3 * Temperature sensors

A temperature sensor which is designed to be attached to or inserted into a PATIENT shall have its intended use identified clearly and unambiguously on or adjacent to the sensor.

201.7.2.1.101.4 APPLIED PARTS (for other than FORCED AIR DEVICES) with a large unheated border

For an APPLIED PART having an unheated border wider than 30 mm around the heated area, and where the requirements of 201.12.4.101 are not satisfied, the outer boundary of the heated area shall be marked on both sides of the APPLIED PART.

201.7.4.2 Control devices

Addition:

201.7.4.2.101 Additional requirements for control devices

(See also 201.12).

Where provided, on ME EQUIPMENT other than FORCED AIR DEVICES, a control for setting the CONTACT SURFACE TEMPERATURE of a HEATING DEVICE shall indicate the temperature in intervals not greater than 1 °C (see also 201.12.1.101).

For FORCED AIR DEVICES, each heated temperature control position shall be marked in degrees C. Such marking shall be CLEARLY LEGIBLE.

201.7.9.2.2 Warning and safety notices

Addition:

201.7.9.2.2.101 Additional requirements for warning and safety notices

The instructions for use shall additionally contain the following:

- a) a strong recommendation that the surface of the HEATING DEVICE should be checked for freedom from mechanical damage prior to each application;
- b) an indication for the use of parts of HEATING DEVICES which are intended to be used together;
- c) statements, details and warnings on the use of the HEATING DEVICE in combination with other heat sources, if applicable;
- d) a warning statement that the use of materials of good thermal conductivity, such as water, gel and similar substances, with the HEATING DEVICE not switched on can decrease the temperature of the body of a PATIENT;

- e) a warning statement regarding the RISK of electrical shock, burns or electromagnetic interference with use of HF surgical instruments or endocardial catheters while a HEATING DEVICE is in use, if applicable;
- f) a statement that the OPERATOR should monitor the temperature of the PATIENT at regular intervals;
- g) a statement that means for drainage of liquid from a liquid-filled HEATING DEVICE is required (see also 201.11.6.5.101);
- h) a warning that a means for retaining a PATIENT either on or under a HEATING DEVICE may need to be used and that the means for retaining a PATIENT should not block the fluid pathways of the HEATING DEVICE;
- i) a warning that warming transdermal medications (patches) can increase drug delivery, resulting in possible HARM to the PATIENT;
- j) a statement that the HEATING DEVICE contains an ALARM SYSTEM with an interruption of power supply/SUPPLY MAINS ALARM CONDITION;
- k) The instructions for use for CONTROLLERS for FORCED AIR DEVICES shall include the following additional warning statements:
 - a caution that the HOSE, if allowed to contact the PATIENT, can lead to thermal injury, if appropriate;
 - a description of system operating modes and PATIENT conditions where the HEATING DEVICE can be safely used;
 - a statement that the OPERATOR should monitor the temperature of the PATIENT at regular intervals;
 - *a statement that the HOSE NOZZLE needs to be connected to a BLANKET. The following statement shall accompany the “NO FREE HOSING” safety sign (11) of IEC 60878 shown in Annex D:
“CAUTION! Hose nozzle must be connected to a compatible forced air BLANKET or thermal injury may occur.”

201.7.9.2.9 Operating instructions

Addition:

201.7.9.2.9.101 Additional requirements for start-up PROCEDURE

The instructions for use shall include a method for testing the function of the ALARM SYSTEM for each of the ALARM CONDITIONS specified in this standard, if not performed automatically during start up.

201.7.9.2.9.102 Additional requirements for operating instructions

The following shall appear in the instructions for use:

- a) the approximate time required for the CONTACT SURFACE TEMPERATURE to heat up from $23 \pm 2^{\circ}\text{C}$ to 37°C , when operated under CONDITIONS OF ADEQUATE HEAT DISCHARGE as specified in Annex EE;
- b) a description of how and when to verify the functionality of the ALARM SYSTEM.

201.7.9.2.9.103 Additional requirements for operating instructions for BLANKETS

The instructions for use for BLANKETS shall contain the following:

- a) a description of system operating modes and PATIENT conditions where the system can be safely used;
- b) a statement that the OPERATOR should monitor the temperature of the PATIENT at regular intervals;

- c) an indication of how the BLANKET is to be positioned during NORMAL USE, e.g.:
 - i) over the PATIENT,
 - ii) under the PATIENT,
 - iii) directly in contact with the PATIENT,
 - iv) separated from the PATIENT by an intermediate layer, or layers, of material,
 - v) whether it has to be used flat (without creases),
 - vi) whether it can be wrapped around the PATIENT.
- d) *a statement identifying which CONTROLLER(S) can be used safely with the BLANKET. The description shall include, as applicable, the CONTROLLER model number, revision level, product version, options or any other element that could affect the safety of the combination;
- e) *a warning against using the device distal to arterial cross clamping;

NOTE BLANKETS can be used proximal to the clamped artery without any additional RISK.
- f) a warning describing the possible HAZARD of using the device with ischemic limbs.

201.7.9.2.9.104 Additional requirements for operating instructions for temperature sensors

The instructions for use for temperature sensors required for temperature control, which are designed to be attached to, or inserted into, a PATIENT shall have their intended use identified.

201.7.9.2.13 Maintenance

Addition:

201.7.9.2.13.101 Additional requirements for maintenance

The following shall appear in the documentation:

- particulars of any necessary calibration procedure(s);
- information as to how to confirm that the independent THERMAL CUT-OUT is operational.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of the general standard applies, except as follows:

201.8.1 *Fundamental rule of protection against electric shock

- b) SINGLE FAULT CONDITION includes:

Addition:

- contact between a PATIENT and the heat-transfer fluid caused by a leak from a fluid-filled MATTRESS;
- *perforation of a liquid-filled MATTRESS heated by circulation of liquid from a remote unit;
- perforation of the ENCLOSURE of a HEATING DEVICE separated from the SUPPLY MAINS by a transformer (see 15.5 of the general standard).

201.8.5.1.2 MEANS OF PATIENT PROTECTION (MOPP)

Addition:

201.8.5.1.2.101 * Additional requirements for MEANS OF PATIENT PROTECTION (MOPP)

[A1] The electrical circuit within the APPLIED PART shall be isolated from earth by at least one MOPP and from MAINS by at least two MOPP. Where a transformer is used to achieve this isolation, it need not meet 15.5.3. **[A1]**

Compliance is checked by inspection of the HEATING DEVICES and examination of the circuit diagram.

201.8.7.4.7 Measurement of the PATIENT LEAKAGE CURRENT

Addition:

201.8.7.4.7.101 Additional requirements for measurement of the PATIENT LEAKAGE CURRENT

An APPLIED PART consisting of a surface of insulating material is tested using metal foil as mentioned in 8.7.4.7 of the general standard.

- a) for an APPLIED PART large enough for a PATIENT not to be in contact with the whole surface of the APPLIED PART, foil of area 100 cm × 30 cm shall be used; or
- b) for an APPLIED PART whose area is less than 100 cm × 30 cm, the whole APPLIED PART shall be covered by foil.
- c) For a liquid-filled MATTRESS heated by circulation of liquid from a remote unit the liquid is replaced by isotonic saline (0,9 g sodium chloride per liter of water). The PATIENT LEAKAGE CURRENT is measured using an electrode 5 mm × 5 mm positioned in the saline in contact with the surface which provides heat to the liquid;

201.8.8 Insulation

Amendment:

This subclause of the general standard does not apply to BLANKETS for FORCED AIR DEVICES that do not contain active electrically conductive wires.

201.8.8.4 Insulation other than wire insulation

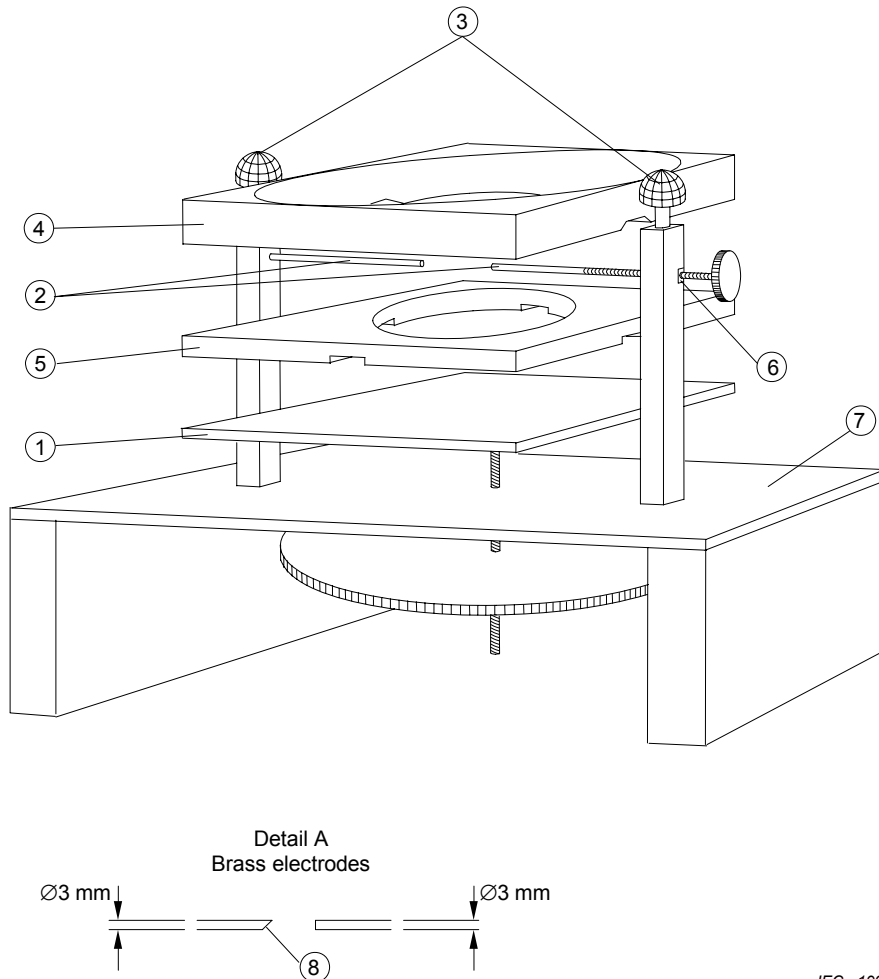
Additional subclauses:

201.8.8.4.101 Mechanical and thermal resistance to damage of the ENCLOSURE of the flexible part of HEATING DEVICES

For BLANKETS and PADS consisting of woven material surrounding an electrical heating element, the woven material is tested by the ball-pressure test according to 8.8.4.1 a) of the general standard and additionally by the following ignition test.

Six samples having dimensions of 100 mm × 200 mm are cut from the ENCLOSURE. They are selected from parts of the ENCLOSURE so that no two samples contain the same warp thread or the same weft thread or, if this is not possible, the samples are selected so that the same threads do not appear in more than two samples. Any pieces of heating elements and trimming are removed from the samples.

The test apparatus, as shown in Figure 201.103, has two brass electrodes 3 mm in diameter, which are supported by brass pillars, mounted on a base plate of insulating material so that their axes are aligned. The base plate also supports a platform of insulating material having dimensions of 100 mm × 100 mm, which is located centrally between the brass pillars. Provision shall be made for the height of the platform to be adjusted.



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Key

- 1 Adjustable insulation plate (to support mask)
- 2 Brass electrodes (see detail A)
- 3 Terminals
- 4 Upper member of mask (see detail C)
- 5 Lower part of mask (see detail B)
- 6 Back stop
- 7 Base plate
- 8 Angle of tip 45°

**Figure 201.103 a) – Apparatus for the spark ignition test –
Detail A: the apparatus
(see 201.8.8.4.101)**