

BSI Standards Publication

Medical electrical equipment

Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads or mattresses and intended for heating in medical use

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Full document details: BS EN IEC 60601-2-35:2021+A1:2024

National foreword

This British Standard is the UK implementation of EN IEC 60601-2-35:2021+A1:2024. It is identical to IEC 60601-2-35:2020, incoporatingg amendment 1:2023. It supersedes BS EN IEC 60601-2-35:2021, which is withdrawn.

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 to Technical Committee CH/62/4, Electromedical equipment.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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Published by BSI Standards Limited 2024

ISBN 978 0 539 16771 9

ICS 11.040.01; 11.140

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This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 August 2021.

Amendments/corrigenda issued since publication

Date	Text affected
31 January 2024	Implementation of IEC amendment 1:2023 with CENELEC endorsement A1:2024

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 60601-2-35:2021+A1

January 2024

ICS 11.140; 11.040.01

Supersedes EN 80601-2-35:2009 and all of its amendments and corrigenda (if any)

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 60601-2-35:2020)

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 60601-2-35:2020)

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 60601-2-35:2020)

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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Ref. No. EN IEC 60601-2-35:2021 E

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European foreword

The text of document 62D/1765/FDIS, future edition 2 of IEC 60601-2-35, prepared by SC 62D "Electromedical equipment" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 60601-2-35:2021.

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) 2022-01-16
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2024-07-16

This document supersedes EN 80601-2-35:2009 and all of its amendments and corrigenda (if any).

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

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Endorsement notice

The text of the International Standard IEC 60601-2-35:2020 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:

IEC 60601-2-19:2020	NOTE	Harmonized as EN IEC 60601-2-19:2021 (not modified)
IEC 60601-2-20:2020	NOTE	Harmonized as EN IEC 60601-2-20:2020 (not modified)
IEC 60601-2-21:2020	NOTE	Harmonized as EN IEC 60601-2-21:2020 (not modified)
IEC 60335-2-53	NOTE	Harmonized as EN 60335-2-53
IEC 60529:1989	NOTE	Harmonized as EN 60529:1991 (not modified)
IEC 60529:1989/A1:1999	NOTE	Harmonized as EN 60529:1991/A1:2000 (not modified)
IEC 60529:1989/A2:2013	NOTE	Harmonized as EN 60529:1991/A2:2013 (not modified)
ISO 2439:2008	NOTE	Harmonized as EN ISO 2439:2008 (not modified)

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European foreword to Amendment 1

The text of document 62D/2088/FDIS, future IEC 60601-2-35/AMD1, prepared by SC 62D "Electromedical equipment" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 60601-2-35:2021/A1:2024.

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)	2024-10-25
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2027-01-25

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Endorsement notice

The text of the International Standard IEC 60601-2-35:2020/AMD1:2023 was approved by CENELEC as a European Standard without any modification.

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Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 1 Where 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.

The Annex ZA of EN 60601-1:2006/A1:2013 applies with the following additions:

Publication	Year	Title	EN/HD	Year
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
-	-		+ corrigendum Mar. 2010	
+ A1	2012		+ A1	2013
-	-		+ A12	2014
+ A2	2020		+ A2	2021
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
+ A1	2013		+ A1	2015
+ A2	2020		+ A2	2021

The Annex ZA of EN 60601-1:2006/A1:2013 applies with the following replacements:

IEC 60384-14	2013	Fixed capacitors for use in electronic equipment - Part 14: Sectional specification - Fixed capacitors for electromagnetic interference suppression and connection to the supply mains	EN 60384-14	2013
+ A1	2016		+ A1	2016
IEC 60601-1-2	2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	EN 60601-1-2	2015
+ A1	2020		+A1	2021

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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International Standard IEC 60601-2-35 has been prepared by IEC technical committee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces IEC 80601-2-35 published in 2009 and Amendment 1:2016.

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

FDIS	Report on voting
62D/1765/FDIS	62D/1777/RVD

Full information on the voting for the approval of this International Standard can be found in the report on voting indicated in the above table.

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

In this document, 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 document, 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 document are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

In this document, 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 document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;
– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;
– "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 60601 International Standard, published under the general title *Medical electrical equipment*, can be found on the IEC website.

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The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

NOTE The attention of users of this document is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committees that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication.

IMPORTANT – The "colour inside" logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this publication using a colour printer.

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INTRODUCTION

The minimum safety requirements specified in this particular standard are considered to provide for a practical degree of safety in the operation for HEATING DEVICES using BLANKETS, PADS or MATTRESSES and intended for heating in medical use.

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

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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

201.1 Scope, object and related standards

Clause 1 of the general standard[1] applies, except as follows:

201.1.1 * Scope

Replacement:

This part of 60601 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 document.

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 be applicable to a specifically defined type of ME EQUIPMENT, as is the case with FORCED AIR DEVICES, then 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.

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

NOTE See also 4.2 of the general standard.

This document does not apply to:

– HEATING DEVICES intended for physiotherapy;
– INFANT RADIANT WARMERS; for information, see IEC 60601-2-21 [1][2];
– INFANT INCUBATORS; for information, see IEC 60601-2-19 [2];
– INFANT TRANSPORT INCUBATORS, for information, see IEC 60601-2-20 [3];
– cooling devices.

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1 A1 The general standard is IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.* A1

2 Figures in square brackets refer to the Bibliography.

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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 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.

〈A1〉 IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020, IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012, and IEC 60601-1-8:2006/AMD2:2020, IEC 60601-1-10:2007, IEC 60601-1-10:2007/AMD1:2013 and IEC 60601-1-10:2007/AMD2:2020 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. 〈A1〉

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, 〈A1〉 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 〈A1〉 are 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 document corresponds to that of the general standard with the prefix "201" (e.g. 201.1 in this document 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 document addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this document addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of the general standard and applicable collateral standards 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.

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Subclauses, figures or tables 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 3.147, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables 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 document" 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:

Addition:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012
▌A1⟩ IEC 60601-1:2005/AMD2:2020 ⟨A1▐

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*
IEC 60601-1-10:2007/AMD1:2013
▌A1⟩ IEC 60601-1-10:2007/AMD2:2020 ⟨A1▐

Replacement:

IEC 60384-14:2013, *Fixed capacitors for use in electronic equipment – Part 14: Sectional specification – Fixed capacitors for electromagnetic interference suppression and connection to the supply mains*
IEC 60384-14:2013/AMD1:2016

IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests*
▌A1⟩ IEC 60601-1-2:2014/AMD1:2020 ⟨A1▐

201.3 Terms and definitions

For the purposes of this document, the terms and definitions specified in ▌A1⟩ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 ⟨A1▐, and the following apply.

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ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

NOTE An index of defined terms used in this document is found beginning on page 69.

Addition:

201.3.201.1
BLANKET
<other than FORCED AIR DEVICES> APPLIED PART of HEATING DEVICE, which can be folded, for use under or over a PATIENT

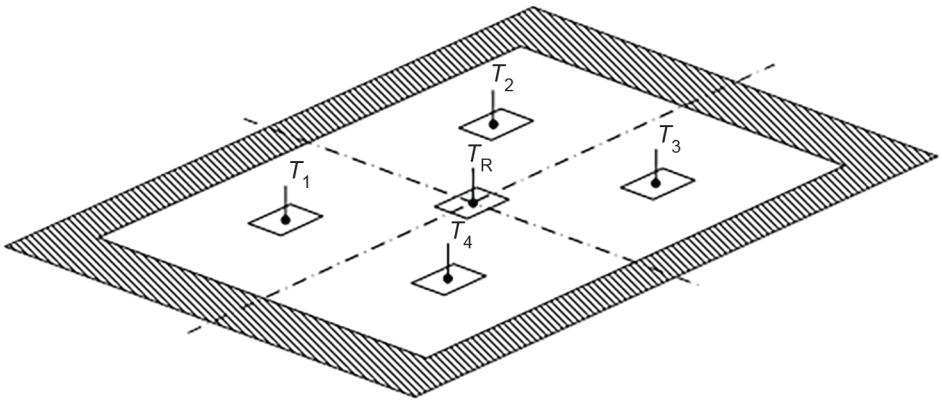
201.3.201.2
BLANKET
<FORCED AIR DEVICES> APPLIED PART of HEATING DEVICE intended to be used with a CONTROLLER to transfer thermal energy to all or part of the body of a PATIENT

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

201.3.203.1
CONTACT SURFACE TEMPERATURE
<other than FORCED AIR DEVICES> temperature T_R at the reference point of the heated APPLIED PART

Note 1 to entry: See Figures 201.101 and 201.102.

Note 2 to entry: The CONTACT SURFACE TEMPERATURE for FORCED AIR DEVICES is measured by the test methods described in Annexes FF, GG and HH.



IEC

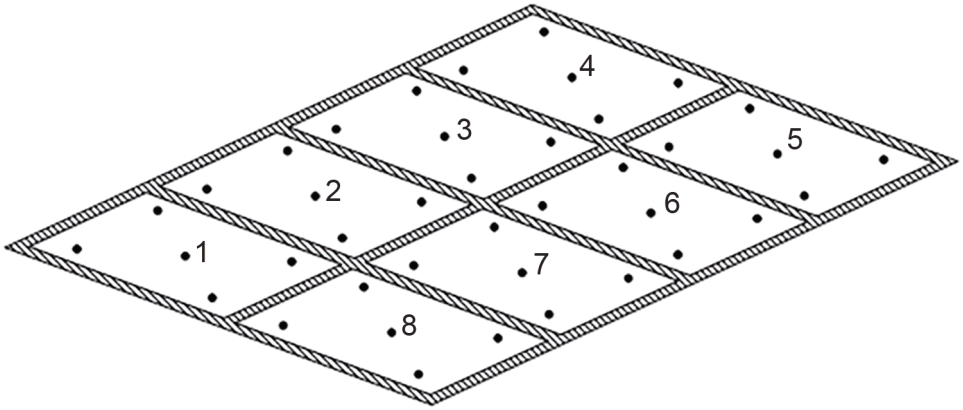
Key

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)

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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

201.3.203.2
CONTACT SURFACE TEMPERATURE
< FORCED AIR DEVICES> temperature resulting from the heat transferred to a target surface by the APPLIED PART

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

Note 1 to entry: 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

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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
polyurethane or polystyrene insulation material used in the test methods of this specification to assist in the determination of temperature

Note 1 to entry: 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
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.

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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 201.12.3.102

201.4.5 Alternative RISK CONTROL measures or test methods 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

Replacement of the last paragraph with the following new paragraph:

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:

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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) [A1] The HOSE shall be marked within 15 cm of the NOZZLE to caution that the NOZZLE needs to be connected to a BLANKET. The safety sign ISO 7010-M002 (see IEC 60601-1:2005, Table D.2, safety sign 10) shall accompany the "NO FREE HOSING" safety sign shown in Annex D of this particular standard. [A1]

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.

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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

NOTE 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).

〖A1〉 For FORCED AIR DEVICES, each heated temperature control position shall be marked in °C. Such marking shall be CLEARLY LEGIBLE. 〈A1〗

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 high frequency (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) for CONTROLLERS for FORCED AIR DEVICES, the following warning statements:

   – a caution that the HOSE, if allowed to contact the PATIENT, can lead to thermal injury, if appropriate;

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– 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 shown in Annex D:

"CAUTION! HOSE NOZZLE SHALL 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 document, 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 °C ± 2 °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, for example:

   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.

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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

Addition to item b):

– 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)

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.

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.

For a liquid-filled MATTRESS heated by circulation of liquid from a remote unit, the liquid is replaced by isotonic saline (9 g sodium chloride per litre 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;

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