भारतीय मानक

Indian Standard

IS 13450 (Part 2/Sec 35) : 2023
IEC 60601-2-35 : 2020

(*Superseding IS/ISO 80601-2-35 : 2009*)

चिकित्सीय विद्युत् उपकरण

भाग 2 बुनियादी सुरक्षा और आवश्यक कार्य निष्पादन के लिए विशेष आवश्यकताएँ

अनुभाग 35 कंबल, पैड या गद्दे का उपयोग करने वाले एवं चिकित्सयी उपयोग हेतु हीटिंग उपकरण

Medical Electrical Equipment

Part 2 Particular Requirements for Basic Safety and Essential Performance

Section 35 Heating Devices Using Blankets, Pads or Mattresses and Intended for Heating in Medical Use

ICS 11.040.01; 11.140

भारतीय मानक ब्यूरो
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NATIONAL FOREWORD

This Indian Standard (Part 2/Sec 35) which is identical with IEC 60601-2-35 : 2020 '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' issued by the International Electrotechnical Commission (IEC) was adopted by the Bureau of Indian Standards on the recommendation of the Electromedical, Diagnostic Imaging and Radiotherapy Equipment Sectional Committee and approval of the Medical Equipment and Hospital Planning Division Council.

This Indian standard was originally published in 2020 as IS/ISO 80601-2-35 : 2009, which was an adoption of ISO 80601-2-35 : 2009 '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'. Consequent upon the withdrawal of ISO 80601-2-35 : 2009 and publication of IEC 60601-2-35 : 2020, this adoption has been taken up in IS 13450 series under dual numbering to align it with the latest IEC Standard IEC 60601-2-35 : 2020. On publication of this standard, IS/ISO 80601-2-35 : 2009 shall be treated as withdrawn.

The text of IEC standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are however not identical to those used in the Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appear referring to this standard, theyshould be read as 'Indian Standard'.
b) Comma (,) has been used as a decimal marker while in Indian Standards, the currentpractice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards which are to be substituted in their places are listed below along with their degree of equivalence for the editions indicated:

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
IEC 60601-1 : 2005 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance IEC 60601-1 : 2005/AMD 1 : 2012	IS 13450 (Part 1) : 2018/IEC 60601-1 : 2012 Medical electrical equipment: Part 1 General requirements for basic safety and essential performance (*second revision*)	Identical
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	IS 13450 (Part 1/Sec 2) : 2018/IEC 60601-1-2 : 2014 Medical electrical equipment: Part 1 General requirements for basic safety and essential performance, Section 2 Collateral standard: Electromagnetic disturbances — Requirements and tests	Identical
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	IS 13450 (Part 1/Sec 10) : 2019/IEC 60601-1-10 : 2007 (Ed 1.1) Medical electrical equipment: Part 1 Particular requirements for the basic safety and essential performance, Section 10 Collateral standard: Requirements for the development of physiologic closed-loop controllers	Identical

(*Continued on third cover*)

CONTENTS

INTRODUCTION

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

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.

Indian Standard

MEDICAL ELECTRICAL EQUIPMENT

PART 2 PARTICULAR REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE

SECTION 35 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.

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

[2] Figures in square brackets refer to the Bibliography.

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.

IEC 60601-1-2:2014, IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012, and IEC 60601-1-10:2007 and IEC 60601-1-10:2007/AMD1:2013 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 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 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.

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

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

Replacement:

IEC 60384-14:2013, *Fixed capacitors for use in electronic equipment – Part 14: Sectional specification – Fixed capacitors for electromagneticinterference 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*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions specified in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, and the following apply.

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

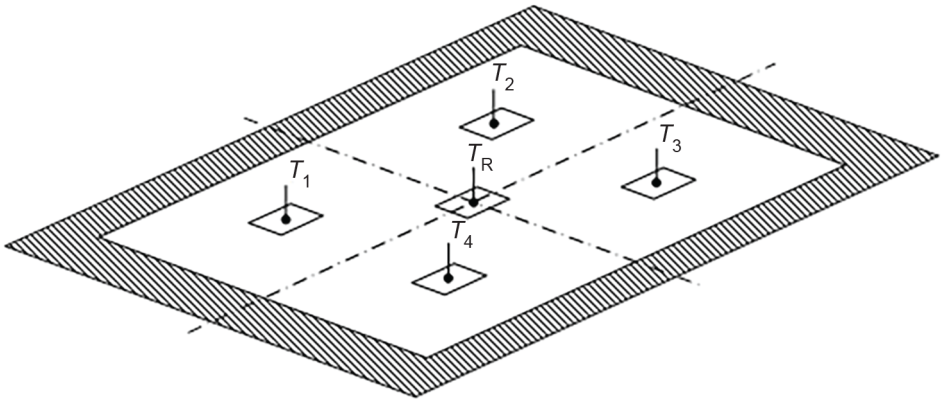
201.3.201.2
BLANKET
<FORCED AIR DEVICES> APPLIED PART of HEATING DEVICE intended to be used with a CONTROLLER to transfer thermal energy to all or part of the body of a PATIENT

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.



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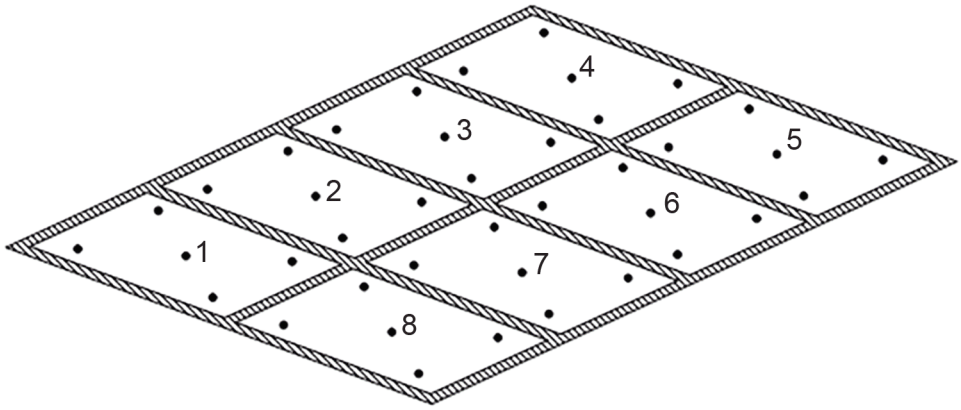
Key

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

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

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.

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:

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 60601-1:2005, Table D.2, safety sign 10) shall accompany the "no FREE HOSING" safety sign shown in Annex D of this particular standard:

   "CAUTION! HOSE NOZZLE SHALL be connected to a compatible forced air BLANKET or thermal injury may occur."

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

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).

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 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;

– 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.

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;

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:

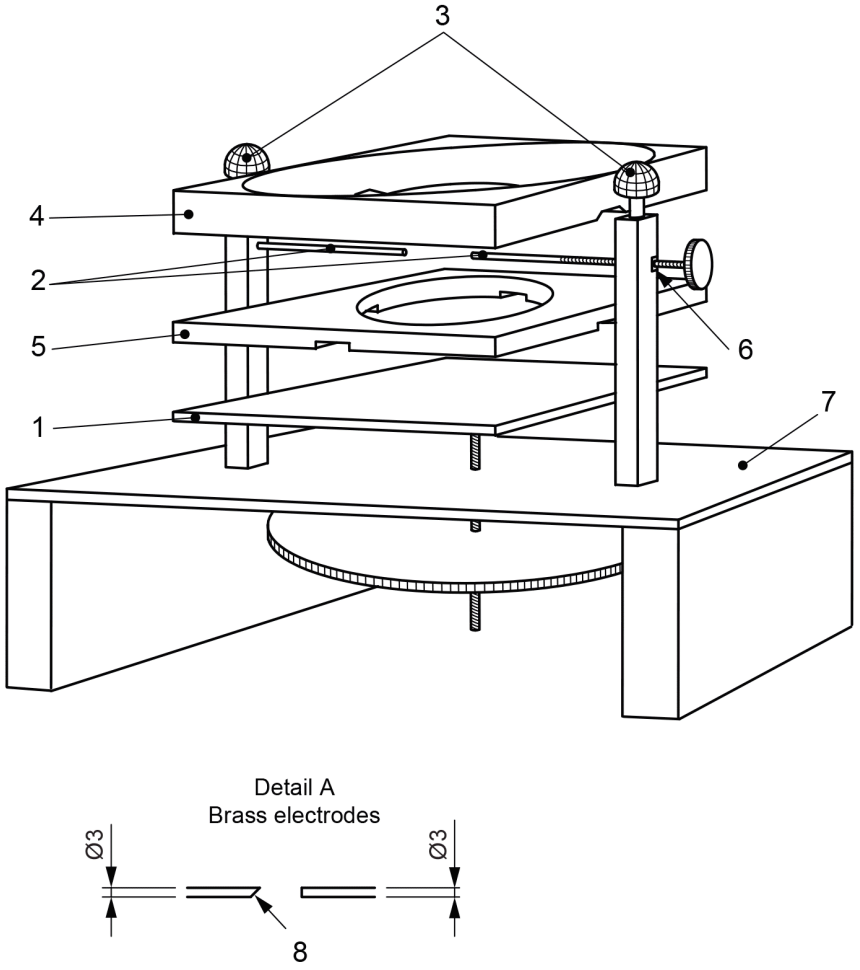
201.8.8.4.101 Mechanical and thermal resistance to damage of the ENCLOSURE of the flexible part of HEATING DEVICES

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.

Dimensions in millimetres



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)

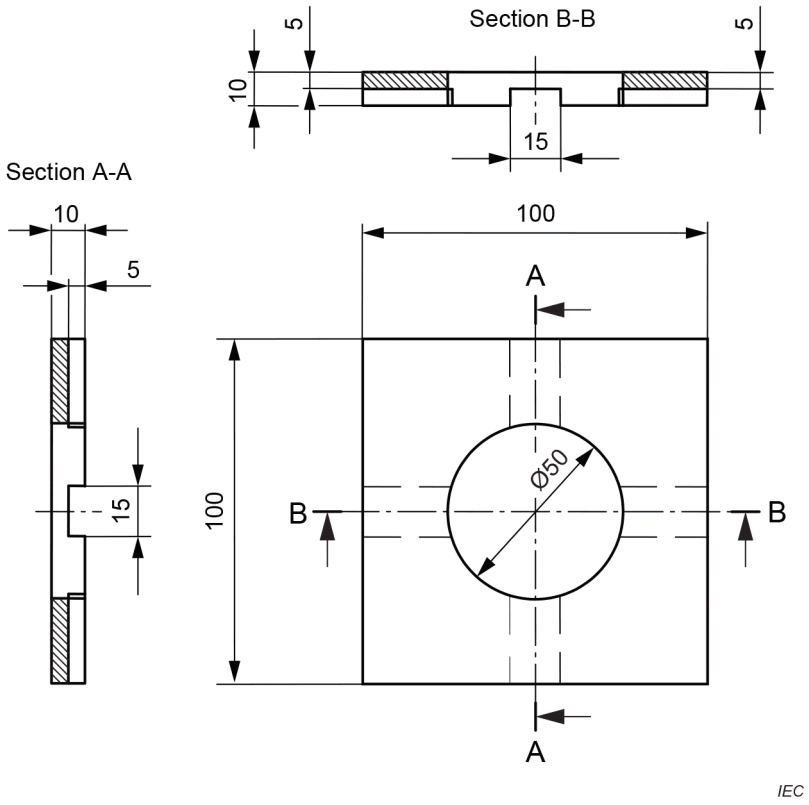
6 back stop

7 base plate

8 angle of tip 45°

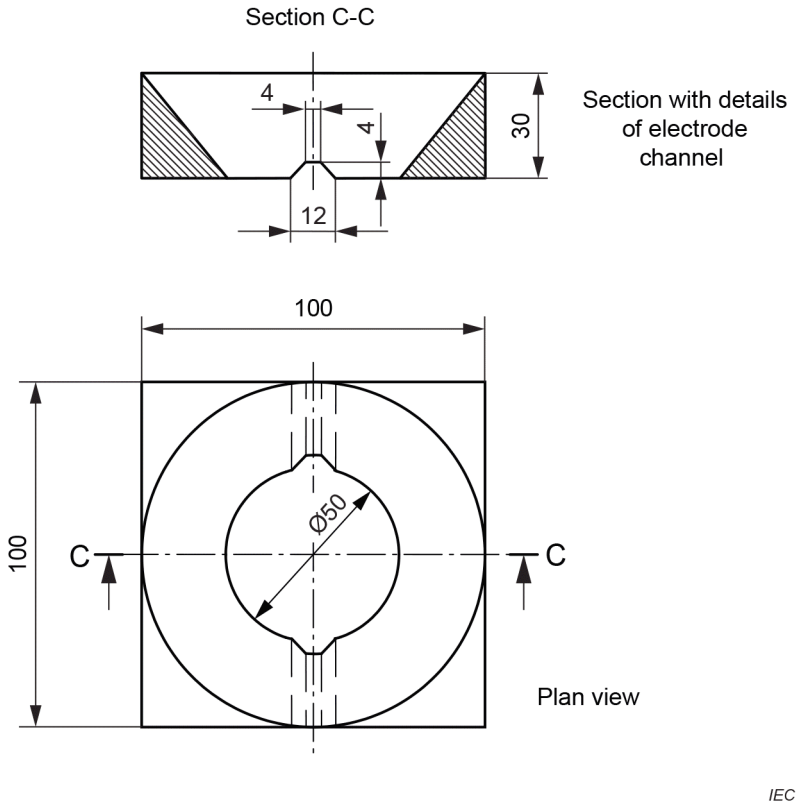
a) Detail A: apparatus
(see 201.8.8.4.101)

Dimensions in millimetres



b) Detail B: lower member of mask

Dimensions in millimetres



Mass approximately 100 g. If necessary, the height may be reduced or mass added, care being taken not to provide a low-resistance path between the electrodes.

c) Detail C: upper member of mask

Figure 201.103 – Apparatus for the spark ignition test

One of the electrodes is fixed in position while the other electrode is movable, thus allowing the sample to be inserted. The tip of the fixed electrode has an angle of 45° to its major axis. The electrode is positioned so that the point farthest from the brass pillar is at the top and at a distance of approximately 3 mm from the centre of the platform. The movable electrode has a tip at right angles to its major axis.

The lower member of a two-part hardwood mask, as shown in detail B of Figure 201.103 b), is placed on the adjustable platform in the position indicated.

The test apparatus, together with the upper member of the mask, is placed in a heating cabinet having a door with an inspection window and where air is circulated by natural convection.

While in the heating cabinet, the electrodes are connected in series with an adjustable non-inductive resistor to a supply having a sinusoidal RATED output voltage of 10 kV and a characteristic such that the output voltage does not decrease by more than 100 V when a current of 1 mA is flowing.

The temperature of the heating cabinet is raised to 65 °C ± 2 °C. The electrodes are then short-circuited and the resistor adjusted so that a current of 1 mA flows. The supply is then disconnected and the six samples are placed in the cabinet, which is maintained at the temperature specified for a period of 3 h.

Without removing the apparatus from the heating cabinet, the movable electrode is withdrawn and one end of one sample drawn over the fixed electrode so that the electrode is situated centrally in the space normally occupied by the heating elements. The sample is adjusted so that its end is approximately level with the edge of the adjustable platform. The movable electrode is then inserted into the other end of the element space and is fixed so that the distance between the electrodes is 6,0 mm ± 0,1 mm. The sample is then smoothed out, care being taken to ensure that material is not looped or caught between the electrodes. The upper member of the mask, as shown in detail C of Figure 201.103 c) is then placed in position. The door of the heating cabinet is then closed for a further period of 5 min in order to stabilize the temperature.

The supply is then switched on and sparks are allowed to pass between the electrodes for a period of 2 min. If the sample ignites, the time from the instant of switching on until the flame reaches the inner edge of the mask is recorded, any ignition of fibres lasting not more than 3 s being ignored. If the sample does not ignite, a time of 120 s is recorded.

The sample is then removed and repositioned between the electrodes with the other surface uppermost so that the opposite end is subjected to the test.

The above test is then repeated on the other five samples.

If any time recorded is less than 30 s, the complete test is repeated on a second set of six samples. In this case, no sample shall have a recorded time less than 30 s.

The average of the 12 values recorded is calculated. All values differing by more than 30 s from the average are ignored and, if necessary, the average of the remaining values is recalculated. The average shall be not less than 80 s.

201.8.8.4.102 Unheated areas

Sections of the surface of a HEATING DEVICE between separately controlled heating areas which do not have heating elements within those sections and which do not exceed the requirements of 201.12.4.101, shall not exceed 20 mm in width, and their total area in proportion to the total area within the outer boundary of the heated area shall not exceed:

a) 2 % for HEATING DEVICES whose longest side does not exceed 700 mm; or

b) 10 % for HEATING DEVICES whose longest side is greater than 700 mm.

HEATING DEVICES having the length of the longest side not exceeding 700 mm shall have no unheated border surrounding the heated area or areas.

Compliance is checked by inspection.

201.8.11.1 Isolation from the SUPPLY MAINS

Addition:

201.8.11.1.101 * Isolation from the SUPPLY MAINS

Where mains isolation is achieved by means other than a mains isolating switch, means shall be provided to indicate that the SUPPLY MAINS has been interrupted.

Where disconnection of any part of the ME EQUIPMENT without the use of a TOOL can cause a HAZARD or malfunction, means shall be supplied to give a clear indication that the ME EQUIPMENT is incapable of NORMAL USE.

NOTE A disconnected device is not regarded as providing clear indication.

Compliance is checked by inspection and disconnection of any connection without the use of a TOOL.

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 of the general standard applies, except as follows:

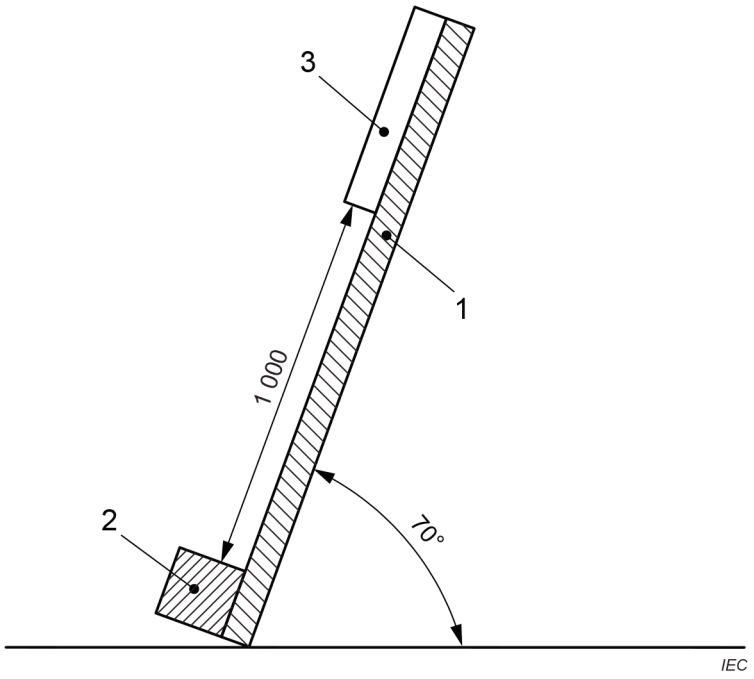
201.9.1 MECHANICAL HAZARDS of ME EQUIPMENT

Addition:

201.9.1.101 PADS

PADS are subjected to a test on a ramp as shown in Figure 201.104. The ramp is constructed of plywood or other smooth material, their POWER SUPPLY CORDS having been cut off at a distance of 100 mm from the point where the POWER SUPPLY CORD enters the PAD. The ramp is set at an angle of 70° to the horizontal.

Dimensions in millimetres



Key

1 smooth ramp

2 stop block

3 PAD under test

Figure 201.104 – Ramp for the impact test on PADS

A stop block, strong enough to withstand the impact of the PAD, is fixed at the lower end of the ramp. The ramp and stop block are at least as wide as the longest dimension of the PAD under test.

The PAD is placed on the ramp, 1 m above the stop block (measured along the ramp) and with the lower edge of the PAD parallel to the stop block. The PAD is allowed to slide down the ramp so that its lower edge impacts against the stop block. This test is repeated 100 times for each of the four edges of the PAD.

After the test, any damage sustained that results in unacceptable RISK, as determined by inspection of the RISK MANAGEMENT FILE, constitutes a failure.

201.9.1.102 * Bonded construction

If separation could cause a HAZARDOUS SITUATION, HEATING DEVICES using bonded construction shall have sufficient strength and/or rigidity to withstand such rough handling as can be experienced in NORMAL USE, without separation of the layers which are bonded.

NOTE Bonded means welded or glued.

Compliance for ME EQUIPMENT other than FORCED AIR DEVICES is checked by cutting six samples of the bonded material, each having dimensions of 100 mm × 130 mm, from the flexible part. Three of the samples are cut in the direction of the runs of the heating elements and the other three samples are cut perpendicular to this direction.

From the sides measuring 100 mm, a strip of the ENCLOSURE material having a width of 25 mm is removed from one face at one end of each sample. Another similar strip is removed from the opposite face and at the opposite end of the sample. Any heating element situated under the removed strips is cut away.

A clamp is attached along the full length of each single layer.

The sample is then suspended by one of the clamps and a mass of 1,25 kg is suspended from the other clamp. The test is carried out for 1 h at an ambient temperature of 20 °C, and then for 1 h at a temperature of 60 °C. The test is repeated on six samples taken from the flexible part of a new HEATING DEVICE.

201.9.8 MECHANICAL HAZARDS associated with support systems

201.9.8.3.1 * General

Amendment:

The normal load for an INFANT is reduced to 10 kg (see 201.3.210).

Addition:

For ME EQUIPMENT intended for use with INFANTS and having an integral MATTRESS, suitable barriers shall be provided to prevent the INFANT from falling off the MATTRESS. Barriers intended to be opened or removed to allow access to the INFANT shall latch in their closed positions and shall remain locked under the test conditions.

Compliance is checked by inspection and the following test: Apply to all the barriers (other than those secured with the use of a TOOL) an outward horizontal force of 20 N to the centre of each barrier for 5 s. The barriers shall remain closed.

Additional subclause:

201.9.8.101 Supports and mounting brackets for ACCESSORIES

Supports and mounting brackets for ACCESSORIES shall be suitable and of adequate strength for their purpose.

Compliance is checked by inspection and by the following test:

A gradually increasing force is applied so as to act vertically through the centre of the supports and mounting brackets, for example an accessory shelf in the extended position with a MANUFACTURER's recommended load. The force is increased from zero in 5 s to 10 s intervals, until it equals three times the recommended load and is sustained for a period of 1 min. There shall be no evidence of damage to the item(s) under test.

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of the general standard applies.

201.11 Protection against excessive temperatures and other HAZARDS

Clause 11 of the general standard applies, except as follows:

201.11.1.2.1 APPLIED PARTS intended to supply heat to a PATIENT

Addition:

201.11.1.2.1.101 Requirements for HEATING DEVICES other than FORCED AIR DEVICES

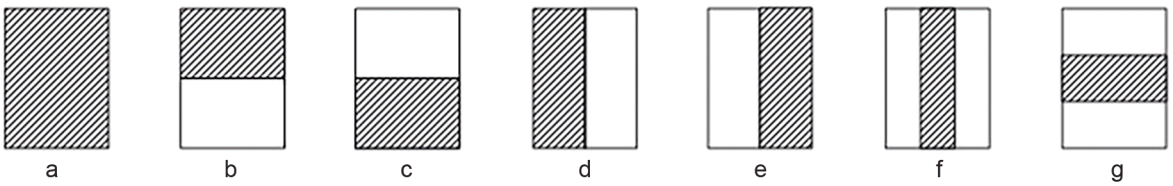
201.11.1.2.1.101.1 Maximum CONTACT SURFACE TEMPERATURE in NORMAL CONDITION

APPLIED PARTS of ME EQUIPMENT intended to supply heat to a PATIENT shall not have a CONTACT SURFACE TEMPERATURE exceeding 40 °C in NORMAL CONDITION.

Compliance is checked under CONDITIONS OF ADEQUATE HEAT DISCHARGE by measurement using temperature sensors conductively attached to copper plates 65 mm × 65 mm × 0,5 mm. The plates are positioned in locations in contact with the APPLIED PART and below the LAGGING MATERIAL where maximum temperatures are expected.

The leads of the temperature sensors are positioned so as to avoid any additional heat discharge.

Tests are repeated with the HEATING DEVICE partially covered in turn as shown in Figure 201.105, except that the partial covering condition illustrated in "g" of that figure is used only for PADS whose longest side is less than 1 m in length. Any part of a copper plate which would not be covered by insulation in a partial covering situation is separately covered by lagging.



The partial covering condition marked "g" is considered relevant for PADS which can be positioned across the width of a bed, and can only have, for example, part of one leg of a PATIENT across the heated area.

Figure 201.105 – Partial covering conditions

201.11.1.2.1.101.2 Sensor

Any sensor whose position can be changed without the use of a TOOL shall not be used to control the maximum temperature which the HEATING DEVICE can attain.

Compliance is checked by inspection.

201.11.1.2.1.101.3 Maximum CONTACT SURFACE TEMPERATURE in SINGLE FAULT CONDITION

The surface temperature of a HEATING DEVICE shall not exceed 41 °C in SINGLE FAULT CONDITION.

Compliance is checked under the conditions of 201.12.1.101 by repeating the tests for NORMAL CONDITION (see 201.11.1.2.1), but with the higher temperature limit specified here. One fault is applied at a time, and then the steady surface temperature reached is measured in each case.

201.11.1.2.1.102 Requirements for FORCED AIR DEVICES

201.11.1.2.1.102.1 * Maximum CONTACT SURFACE TEMPERATURE in NORMAL CONDITION

When tested according to the methods described in Annexes FF and HH, the maximum CONTACT SURFACE TEMPERATURE shall not exceed 48,0 °C and the average CONTACT SURFACE TEMPERATURE shall not exceed 46,0 °C.

201.11.1.2.1.102.2 Sensor

Any sensor whose position can be changed without the use of a TOOL shall not be used to control the maximum temperature which the CONTROLLER can attain.

201.11.1.2.1.102.3 * Maximum CONTACT SURFACE TEMPERATURE in SINGLE FAULT CONDITION

The FORCED AIR DEVICE shall be equipped with a THERMAL CUT-OUT to eliminate the RISK of excessive CONTACT SURFACE TEMPERATURE. The THERMAL CUT-OUT shall activate within 10 min after the occurrence of the SINGLE FAULT CONDITION described in Annex GG or when the CONTACT SURFACE TEMPERATURE exceeds 56 °C.

The FORCED AIR DEVICE shall be equipped with an ALARM SYSTEM that includes at least a LOW PRIORITY TECHNICAL ALARM CONDITION that indicates when the THERMAL CUT-OUT has activated.

Consideration shall be given to lower limits or different RISK CONTROL measures for FORCED AIR DEVICES intended for INFANTS.

201.11.2 * Fire prevention

Addition:

NOTE See rationale.

201.11.6.3 Spillage on ME EQUIPMENT and ME SYSTEMS

Replacement:

ME EQUIPMENT requiring the use of liquids in NORMAL USE shall be so constructed that spillage does not wet parts which can cause an unacceptable RISK.

Compliance is checked by the following test:

The ME EQUIPMENT is positioned as in NORMAL USE. A quantity of 200 ml of isotonic saline (9 g sodium chloride per litre of water) is poured steadily on an arbitrary point on the top surface of the ME EQUIPMENT from a height not exceeding 5 cm for approximately 15 s (see also 5.4 of the general standard).

After the test, the ME EQUIPMENT shall comply with the requirements of this document for NORMAL CONDITION.

201.11.6.5 Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS

Addition:

201.11.6.5.101 Leakage

Means for drainage of liquid leaking from a liquid-filled HEATING DEVICE shall be provided (see 201.7.9.2.2.101 g)).

Compliance is checked by inspection.

201.11.6.5.102 * Ingress of liquids

Electrically-heated APPLIED PARTS of the ME EQUIPMENT using 50 V RMS or less shall be at least to IPX2. ME EQUIPMENT using higher voltages shall be to IPX7.

NOTE See also Clause 4 of IEC 60529:1989 and IEC 60529:1989/AMD2:2013.

The ENCLOSURE of any HEATING DEVICE shall provide the degree of protection against moisture in accordance with the classification of the HEATING DEVICE.

201.11.8 Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT

Addition:

201.11.8.101 * Interruption of power supply/SUPPLY MAINS ALARM CONDITION

Except for LOW HEAT TRANSFER HEATING DEVICES (see Annexes CC and DD) and FORCED AIR DEVICES, the HEATING DEVICE shall be equipped with an ALARM SYSTEM that includes at least a MEDIUM PRIORITY TECHNICAL ALARM CONDITION during any period of interruption of the SUPPLY MAINS to the HEATING DEVICE, or for 10 min, whichever is shorter (see also rationale).

Compliance is checked by disconnection from the SUPPLY MAINS with the HEATING DEVICE switched on.

201.11.8.102 * Preset values after restoration of power supply/SUPPLY MAINS

For ME EQUIPMENT other than FORCED AIR DEVICES, the equipment shall be designed so that interruption and restoration of the power supply/SUPPLY MAINS up to 10 min does not change the control temperature or other preset values.

For FORCED AIR DEVICES, if the equipment is designed to resume operation after interruption and restoration of the power supply/SUPPLY MAINS up to 10 min, it shall not supply heat at any temperature higher or lower than the OPERATOR-selected temperature setting prior to interruption of the power supply/SUPPLY MAINS.

Compliance is checked by switching the SUPPLY MAINS off and then switching it on again within 10 min, and inspecting the ME EQUIPMENT.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

Clause 12 of the general standard applies, except as follows:

201.12.1 Accuracy of controls and instruments

Addition:

201.12.1.101 Additional requirements for accuracy of controls and instruments

201.12.1.101.1 Range of temperature control

For ME EQUIPMENT other than FORCED AIR DEVICES, the range of the temperature control setting shall be at least from 35 °C to 38 °C, but not exceeding 41 °C.

Compliance is checked by inspection.

For ME EQUIPMENT other than FORCED AIR DEVICES, HEATING DEVICES with HIGH HEAT TRANSFER to the PATIENT (see Annexes CC and DD) shall have the indicators specified in 201.12.1.101.2.

201.12.1.101.2 Control setting and display indications

There shall be:

a) an indication of the temperature control setting;

b) for ME EQUIPMENT other than FORCED AIR DEVICES, a display showing the CONTACT SURFACE TEMPERATURE (see also 201.12.3.103); and

c) * for FORCED AIR DEVICES, the temperature control setting shall be marked in "degrees C" or "˚C". Methods of confirming the referenced output shall be provided in the ACCOMPANYING DOCUMENTS.

Compliance is checked by inspection.

201.12.1.101.3 * Weighing scale for INFANTS

If a weighing scale is supplied as an integral part of the ME EQUIPMENT or as an ACCESSORY specifically for use with the ME EQUIPMENT, the value displayed on the scale shall not differ from the test load by more than the MANUFACTURER's specifications in the ACCOMPANYING DOCUMENTS when operating the ME EQUIPMENT with horizontal MATTRESS orientation. Each value measured shall remain latched on the scale display at the conclusion of any individual measurement cycle and be retained until discarded by the OPERATOR. If the scale may be exposed to an OXYGEN RICH ENVIRONMENT in use, it shall comply with the requirements of 6.5 of the general standard.

NOTE It can be possible for the OPERATOR to verify and update the calibration of the device during use.

Compliance is checked by the following test:

Test load measurements shall be demonstrated using values of 500 g and 2 000 g (± 1 g). Tests shall be conducted with the ME EQUIPMENT operating with a MATTRESS temperature of 36 °C ± 0,2 °C.

The accuracy of measurement is verified with the test loads positioned in locations as shown in Figure 201.101. Place the test load on four different positions on the horizontal MATTRESS at the centres of each of four rectangles formed by bisecting the length and width of the MATTRESS as shown in Figure 201.101. Place the test load on the fifth position on the midpoint of the MATTRESS.

201.12.3 ALARM SYSTEMS

Addition:

201.12.3.101 Overtemperature ALARM CONDITION

Except for FORCED AIR DEVICES, the HEATING DEVICE shall be equipped with an ALARM SYSTEM that includes at least a MEDIUM PRIORITY TECHNICAL ALARM CONDITION that indicates when either THERMAL CUT-OUT operates. The ALARM SYSTEM shall also include at least a MEDIUM PRIORITY TECHNICAL ALARM CONDITION that indicates when the HEATING DEVICE is switched off after the THERMAL CUT-OUT has operated, and is then switched on again before the fault condition has been corrected.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS and functional testing.

201.12.3.102 * CONTACT SURFACE TEMPERATURE variation ALARM CONDITION

Except for FORCED AIR DEVICES, HEATING DEVICES with HIGH HEAT TRANSFER to the PATIENT (see Annexes CC and DD) shall be equipped with an ALARM SYSTEM that includes at least a MEDIUM PRIORITY TECHNICAL ALARM CONDITION if the average value of the CONTACT SURFACE TEMPERATURE differs from the control setting by more than either:

a) ± 1 °C in the case of HEATING DEVICES having HIGH HEAT TRANSFER both inwards toward and outwards from the PATIENT; or

b) +1 °C in the case of HEATING DEVICES having HIGH HEAT TRANSFER inwards toward the PATIENT but LOW HEAT TRANSFER outwards from the PATIENT.

A HEATING DEVICE having HIGH HEAT TRANSFER in both directions may be equipped with an AUDIO PAUSE for up to 4 h duration while the HEATING DEVICE is being heated from COLD CONDITION to the set temperature.

Compliance is checked by inspection and functional testing.

201.12.3.103 Visual and auditory ALARM SIGNALS

While visual ALARM SIGNALS shall be designed with separate visual indicators, auditory ALARM SIGNALS may be combined.

Compliance is checked by inspection and operation of the ME EQUIPMENT.

201.12.3.104 Disconnection or short-circuiting of sensors ALARM CONDITION

The HEATING DEVICE shall switch off automatically if the leads to either the temperature control sensors or the THERMAL CUT-OUT sensors are damaged or otherwise disconnected from the control unit.

The HEATING DEVICE shall be equipped with an ALARM SYSTEM that includes at least a MEDIUM PRIORITY TECHNICAL ALARM CONDITION for HIGH HEAT TRANSFER DEVICES and at least a LOW PRIORITY ALARM for LOW HEAT TRANSFER DEVICES and FORCED AIR DEVICES that indicates when leads to either the temperature control sensors or the THERMAL CUT-OUT sensors are damaged or otherwise disconnected from the control unit.

Compliance is checked by inspection and, if applicable, by the disconnection of the sensors one at a time.

201.12.4 Protection against hazardous output

Additional subclauses:

201.12.4.101 * Variation of temperature across the contact surface

Except for FORCED AIR DEVICES, the difference between the average value of the CONTACT SURFACE TEMPERATURE and the average values of each single measuring point (T_1 to T_4 in Figures 201.101 and 201.102) shall not exceed:

a) ±1 °C for HIGH HEAT TRANSFER HEATING DEVICES (see Annexes CC and DD); or

b) ±2,5 °C for LOW HEAT TRANSFER HEATING DEVICES (see Annexes CC and DD).

In the case of HEATING DEVICES having more than one separately controlled heating area (see Figure 201.102), the variation of temperature between T_R and the temperature at the other centre points and the other measuring points in each heated area shall not exceed the values given above.

For the purpose of isolation from environmental conditions and to simulate conditions unfavourable to the PATIENT, the test shall be made under CONDITIONS OF ADEQUATE HEAT DISCHARGE (see Annex EE).

Compliance is checked by inspection and the following test:

The HEATING DEVICE and its contact surface are tested in a draught-free room in which the ambient temperature is maintained at 23 °C ± 2 °C. Four temperature sensors conductively attached to copper plates 65 mm × 65 mm × 0,5 mm are placed on the contact surface at the midpoints of the four rectangles formed by bisecting the length and the width of the contact surface as shown in Figure 201.101. A fifth temperature sensor is placed at the midpoint of the contact surface.

Other measuring points within the heating area, in addition to those shown in Figure 201.101, should be used (for example as in Figure 201.102), except that no part of the measuring plates shall be positioned:

– *less than 30 mm from the outer edges of the HEATING DEVICE;*
– *over the supply cord entry position;*
– *over non-heated sections between separately controlled heated areas (see Figure 201.102).*

The temperature control is set so that the CONTACT SURFACE TEMPERATURE reaches 36 °C. Temperature readings are taken at least every 10 min for 60 min. From these, the values of the individual average temperatures at T_1 to T_4 are calculated and compared with the average values of the CONTACT SURFACE TEMPERATURE.

201.12.4.102 Variation of the CONTACT SURFACE TEMPERATURE

Except for FORCED AIR DEVICES, after a steady temperature has been reached, the CONTACT SURFACE TEMPERATURE shall not vary from the mean value by more than:

a) ±0,5 °C in the case of HIGH HEAT TRANSFER HEATING DEVICES; or

b) ±1 °C in the case of LOW HEAT TRANSFER HEATING DEVICES.

Compliance is checked by the following test:

Under the conditions specified in 201.12.4.101, the temperature control is set so that the CONTACT SURFACE TEMPERATURE reaches 36 °C. The temperature is then recorded for 1 h, using sufficiently sensitive apparatus (at least able to discriminate a variation of 0,1 °C).

201.12.4.103 Temperature overshoot when the temperature control is set to its maximum setting

Except for FORCED AIR DEVICES, the temperature overshoot of the CONTACT SURFACE TEMPERATURE shall not exceed 1 °C when the control is changed to its maximum temperature setting from a lower setting at which a steady temperature of 36 °C was first attained.

Compliance is checked by functional testing.

201.12.4.104 Accuracy of the control of the CONTACT SURFACE TEMPERATURE

Except for FORCED AIR DEVICES, the average value of the CONTACT SURFACE TEMPERATURE shall not differ from the value of the temperature indicated by the temperature control setting by more than ±1 °C but not exceeding 41 °C. See 201.11.1.2.1.101.

Compliance is checked by the following test:

Under the conditions specified in 201.11.1.2.1.101, the CONTACT SURFACE TEMPERATURE is measured with the temperature control set to 36 °C.

201.12.4.105 Temperature indicator

If provided, the indication of the CONTACT SURFACE TEMPERATURE shall be CLEARLY LEGIBLE.

Except for FORCED AIR DEVICES, within the range of the control setting, the temperature indication shall not differ from the CONTACT SURFACE TEMPERATURE by more than ±0,7 °C.

For FORCED AIR DEVICES:

a) If provided, the temperature indicator shall be CLEARLY LEGIBLE; and
b) If provided, an alpha-numeric temperature indicator shall be accurate to ±1 °C of the measured temperature. Methods of confirming the accuracy of the display shall be provided in the ACCOMPANYING DOCUMENTS.

Compliance is checked by inspection.

The range of indication shall be at least from 20 °C to 42 °C.

Except for FORCED AIR DEVICES, if the sensor of the temperature indicator is positioned at a point where the measured temperature is different from the temperature which would have been measured if the sensor had been at the centre of the HEATING DEVICE, that is, at the position T_R (see Figures 201.101 and 201.102), the indicator shall indicate the actual CONTACT SURFACE TEMPERATURE.

Compliance is checked by inspection and by measurement under the conditions specified in 201.12.4.101 (ensuring that any necessary calibration is correct).

201.12.4.106 * Avoidance of incorrect connection of parts

Except for the practice or condition of FREE HOSING, if omission of a part, or interchange of parts of a multi-part HEATING DEVICE, can cause an unacceptable RISK, the HEATING DEVICE shall be designed such that heat is supplied only if all parts of the HEATING DEVICE are correctly positioned.

For FORCED AIR DEVICES, adequate warning labels shall be provided on the CONTROLLER and particular attention shall be directed to caution statements against the practice of FREE HOSING in 201.7.2.1.101.2 a) and 201.7.9.2.2.101 k).

Compliance is checked by inspection.

201.12.4.107 * Inadvertent changing of control settings

In the case of HIGH HEAT TRANSFER HEATING DEVICES, the control shall be designed or guarded to prevent unintentional changing of the setting, for example by an interlocking device or an additional safety control.

Compliance is checked by inspection.

201.12.4.108 Maximum CONTACT SURFACE TEMPERATURE

For FORCED AIR DEVICES, the maximum CONTACT SURFACE TEMPERATURE, as determined using the test methods in Annex FF, shall be reported in the ACCOMPANYING DOCUMENTS.

Compliance is checked by inspection.

201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT

Clause 13 of the general standard applies, except as follows*:*

201.13.1 Specific HAZARDOUS SITUATIONS

201.13.1.2 Emissions, deformation of ENCLOSURE or exceeding maximum temperature

Addition:

201.13.1.2.101 Failure of components

201.13.1.2.101.1 * Electronic component failure in an APPLIED PART

For APPLIED PARTS incorporating electronic components, the following fault conditions shall be considered and, if necessary, applied one at a time. Consequential faults also shall be taken into consideration:

a) short-circuit of CREEPAGE DISTANCES and AIR CLEARANCES between live parts of different polarity, if these distances are less than the values specified in 8.9 of the general standard;

b) short-circuit of live parts of different polarity across insulation, which does not withstand the tests of 8.8.3 of the general standard;

c) open-circuit at the terminals of any component;

d) short-circuit of capacitors, unless they comply with IEC 60384-14;

e) short-circuit of any two terminals of an electronic component, other than integrated circuits;

f) failure of an integrated circuit. In this case the possible HAZARDOUS SITUATIONS of the HEATING DEVICE shall be assessed to ensure that safety does not rely on the correct functioning of such a component.

All possible output signals shall be considered under fault conditions within the integrated circuit. If it can be shown that a particular output signal is unlikely to occur, then the relevant fault shall not be considered.

NOTE Microprocessors are regarded as integrated circuits.

201.13.1.2.101.2 * Excessive temperature

Excessive temperatures may result with HEATING DEVICES incorporating heating elements or internal wiring consisting of stranded conductors, under abnormal or careless use, including that which could cause one or more strands of a heating element or internal conductor to break.

Any unsheathed core of a flexible cord within the APPLIED PART extending beyond 100 mm from the cord anchorage is considered to be internal wiring.

Compliance is checked as follows:

a) BLANKETS, other than RUCK-RESISTANT BLANKETS, by Tests 1 to 3;

b) PADS and RUCK-RESISTANT BLANKETS, by Test 4.

Unless otherwise specified, the HEATING DEVICE is supplied with a voltage resulting in the most unfavourable conditions, but within the following range:

– for inherently controlled HEATING DEVICES, 0,9 to 1,1 times RATED voltage;

– for other HEATING DEVICES, 0,85 to 1,24 times RATED input.

The tests are continued until steady conditions are established.

Ensure that the CONTACT SURFACE TEMPERATURE does not exceed 41 °C as specified in 201.11.1.2.1.101.3.

Compliance is checked under CONDITIONS OF ADEQUATE HEAT DISCHARGE. If, in any of the tests, a SELF-RESETTING THERMAL CUT-OUT, or a non-SELF-RESETTING THERMAL CUT-OUT operates, a heating element or an intentionally weak part ruptures, or if the current is otherwise interrupted before steady conditions are established without the possibility of automatic restoration, the heating period shall be ended. However, if the interruption is due to the rupture of a heating element or of an intentionally weak part, the test shall be repeated on a second sample. Open circuiting of a heating element or of an intentionally weak part in the second sample does not in itself entail a failure to comply. Both samples shall comply with the conditions specified in 13.1.2 of the general standard. Fuses, THERMAL CUT-OUTS, OVER-CURRENT RELEASES or the like, incorporated into the HEATING DEVICE, may be used to provide the necessary protection. If more than one of the tests is applicable for the same HEATING DEVICE, these tests may be performed consecutively. For Tests 1 to 3, the folds in the BLANKETS may be secured by stitching.

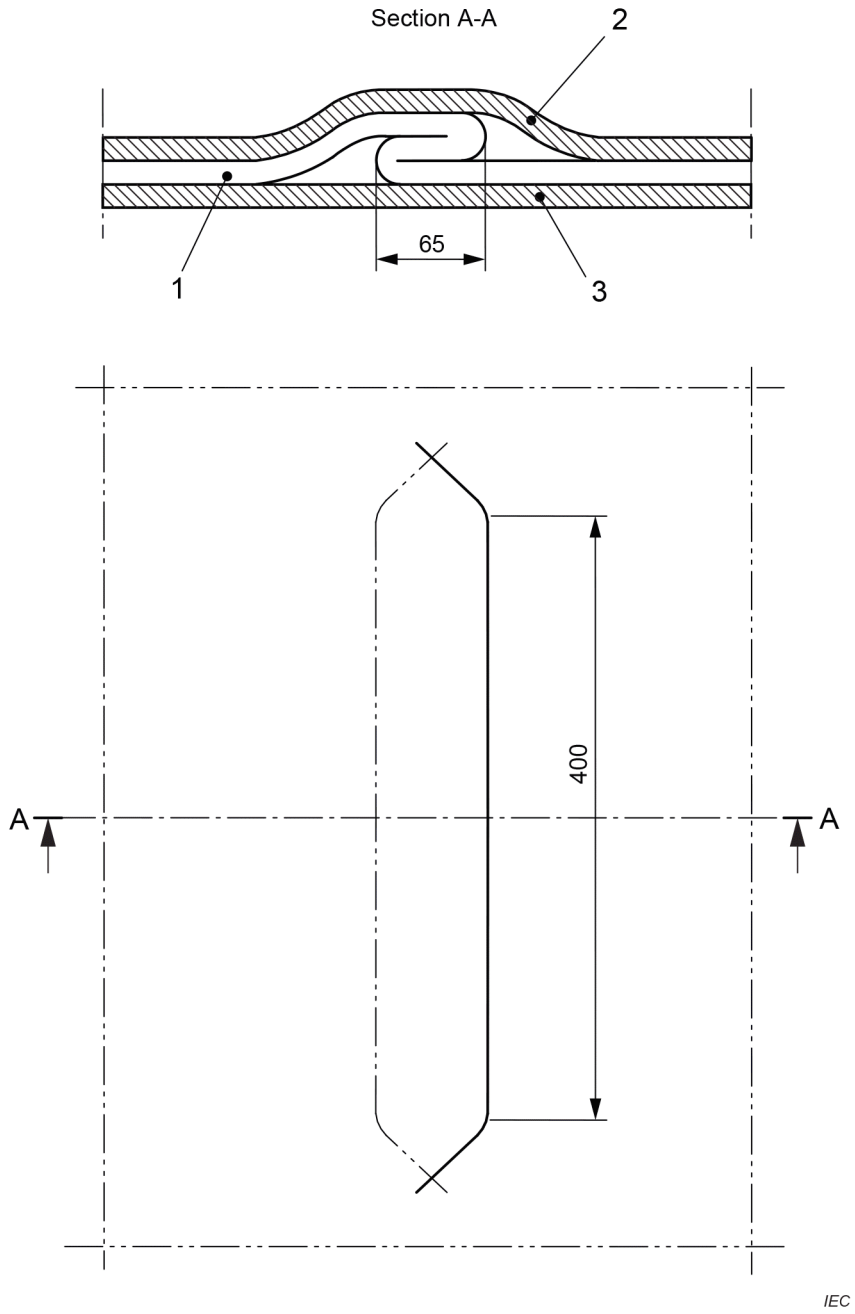
NOTE 1 Rupture of a heating element or of an intentionally weak part in the second sample does not in itself entail a rejection.

NOTE 2 An intentionally weak part is a part designed to fail under conditions of abnormal operation so as to prevent the occurrence of a condition which is unsafe within the meaning of this document. Such a part can be a replaceable component, such as a restrictor, capacitor or thermal fuse or part of a component to be replaced.

Test 1

BLANKETS, other than RUCK-RESISTANT BLANKETS, provided with THERMOSTATS or THERMAL CUT-OUTS are operated under the CONDITIONS OF ADEQUATE HEAT DISCHARGE specified in Annex EE, except that the BLANKET is folded with a three-thickness fold, 65 mm wide and 400 mm long at the most unfavourable place, as shown in Figure 201.106. The fold is perpendicular to the direction of the runs of the heating element and is fanned out at the ends. The upper sheet of LAGGING MATERIAL, having dimensions of 300 mm × 450 mm and a thickness d as specified in Annex BB, is placed on the folded BLANKET in the most unfavourable position.

Dimensions in millimetres



Key

1 sample

2 upper lagging sheet

3 lower lagging sheet

Figure 201.106 – Method of folding BLANKETS

For all BLANKETS other than RUCK-RESISTANT BLANKETS, this test is also carried out under the CONDITIONS OF ADEQUATE HEAT DISCHARGE specified in Annex EE.

Test 2

UNDER-BLANKETS, other than RUCK-RESISTANT BLANKETS, are operated under the CONDITIONS OF ADEQUATE HEAT DISCHARGE specified in Annex EE except that the BLANKET is folded with a five-fold thickness fold 100 mm wide and 400 mm long at the most unfavourable place. The fold is perpendicular to the direction of the runs of the heating element and is fanned out at the ends. The upper sheet of LAGGING MATERIAL, having dimensions of 300 mm × 450 mm and thickness d as specified in Annex BB, is placed on the folded BLANKET.

The HEATING DEVICE is supplied with a voltage or input at the upper limit of the range specified in this subclause.

Test 3

OVER-BLANKETS, other than RUCK-RESISTANT BLANKETS, are operated under the CONDITIONS OF ADEQUATE HEAT DISCHARGE specified in Annex EE except that the BLANKET is folded with a five-thickness fold with a width of 65 mm and a length of 400 mm. The fold is fanned out at the ends. The position and width of the folds are chosen so as to produce the most unfavourable result.

The test is made with the BLANKET covered or uncovered, whichever is more unfavourable.

The LAGGING MATERIAL has a thickness of approximately 0,2 d as specified in Annex BB.3. It has a length equal to the width of the BLANKET and a width equal to half the length of the heated area before the folds are made. It is applied with its length parallel to the shorter edge of the BLANKET in the most unfavourable position that allows the folds to be completely covered.

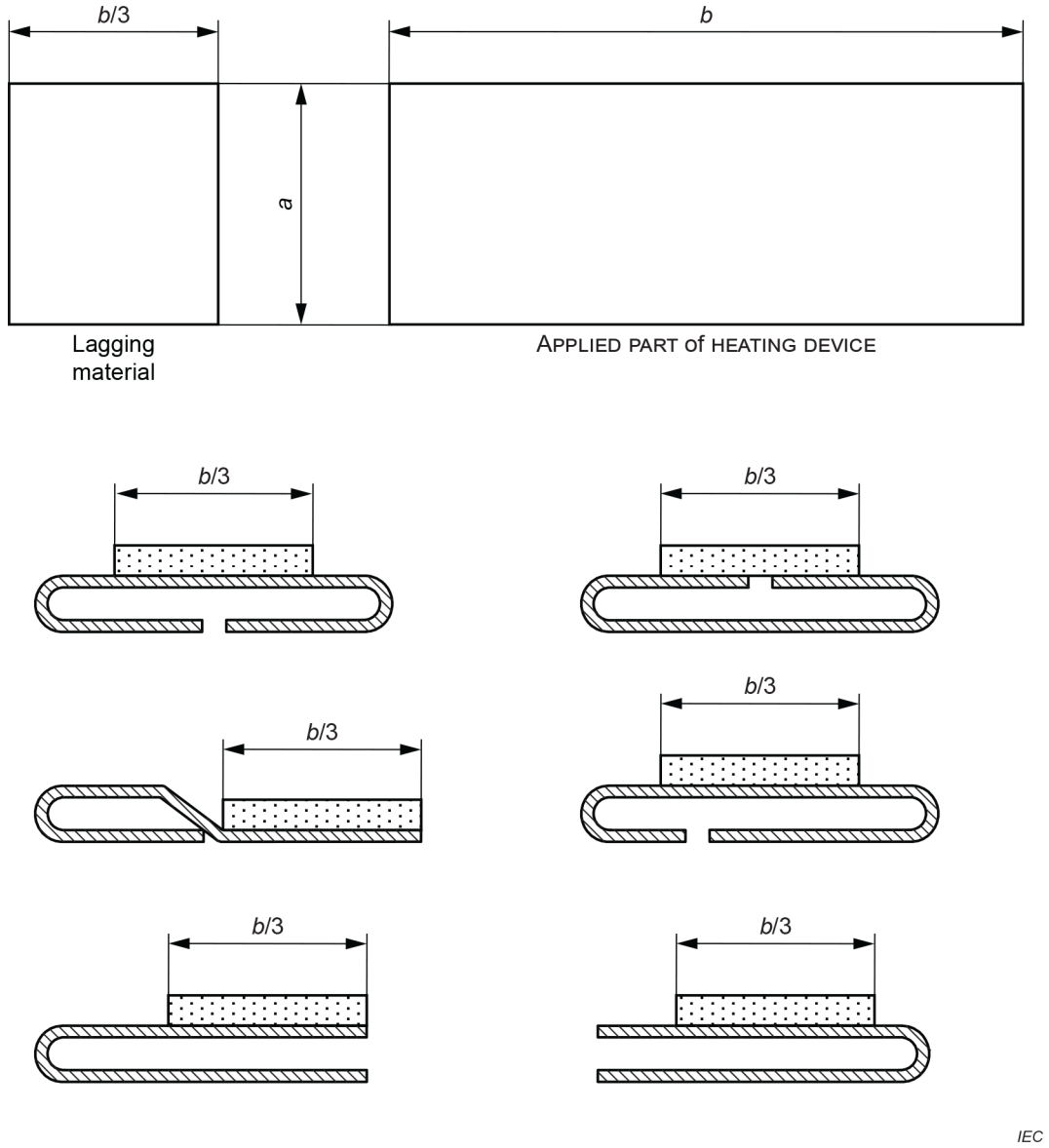
Test 4

RUCK-RESISTANT BLANKETS and PADS are operated under the CONDITIONS OF ADEQUATE HEAT DISCHARGE as specified in Annex EE and the flexible part folded in such a manner that produces the most unfavourable double-thickness fold. The folds are parallel to one of the edges of the flexible part, the position of the folds and their width chosen so as to produce the most unfavourable result.

The upper surface of the flexible part is uncovered or partially covered by a sheet of LAGGING MATERIAL, whichever is the more unfavourable. The length of this covering is equal to the length of that edge which is parallel to the fold and the width is equal to one-third of the length of the adjacent edge.

The LAGGING MATERIAL has a thickness of approximately 0,5 d as specified in Annex BB.3. It is placed in the most unfavourable position that completely covers the flexible part in the direction parallel to the folds and partially covers it in the direction across the folds.

Examples of the way in which the flexible part is folded and covered are shown in Figure 201.107.



Key

a is the width of the APPLIED PART of the HEATING DEVICE

b is the length of the APPLIED PART of the HEATING DEVICE

Figure 201.107 – Examples of folds

201.13.1.2.101.3 Loss of fluid from a fluid-filled MATTRESS

If a HEATING DEVICE utilizes a fluid-filled MATTRESS and a heating part intended for use under the MATTRESS, means shall be provided to ensure that, in the event of leakage of the fluid, the CONTACT SURFACE TEMPERATURE of the MATTRESS shall not exceed the temperature permitted in SINGLE FAULT CONDITION as specified in 201.11.1.2.1.101.3 and the maximum CONTACT SURFACE TEMPERATURE shall be reported in the ACCOMPANYING DOCUMENTS.

Compliance is checked by allowing the fluid to drain from the MATTRESS and measuring the CONTACT SURFACE TEMPERATURE.

201.13.1.2.101.4 Loss of liquid from a liquid-filled BLANKET

Means shall be provided to ensure that, in the event of leakage of the liquid from a liquid-filled BLANKET, the CONTACT SURFACE TEMPERATURE of the BLANKET shall not exceed the temperature permitted in SINGLE FAULT CONDITION.

Compliance is checked by allowing the liquid to drain from the BLANKET and measuring the CONTACT SURFACE TEMPERATURE.

201.13.1.2.101.5 * Blockage of a fluid circulation system

The temperature at any point on the contact surface shall not exceed 43 °C in the event of a blockage in the fluid circulation system.

Compliance is checked under CONDITIONS OF ADEQUATE HEAT DISCHARGE, by setting the temperature control to maximum until steady-state conditions are reached, blocking the circulation system between the fluid heater and the HEATING DEVICE for 10 s, then removing the blockage and measuring the CONTACT SURFACE TEMPERATURE immediately above the fluid inlet.

This test is then repeated for a blockage period of 2 min.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause 14 of the general standard applies except as follows:

201.14.13 * PEMS intended to be incorporated into an IT-NETWORK

Addition:

NOTE See rationale.

201.15 Construction of ME EQUIPMENT

Clause 15 of the general standard applies, except as follows:

201.15.4 ME EQUIPMENT components and general assembly

201.15.4.1 Construction of connectors

Addition:

201.15.4.1.101 Connections between different parts of a HEATING DEVICE

See also 8.6 of the general standard.

Plugs and socket-outlets, and other connecting devices on flexible cords used for an intermediate connection between different parts of a HEATING DEVICE shall not be interchangeable with plugs and socket-outlets complying with IEC 60083, or with connectors and APPLIANCE INLETS complying with IEC 60320-1, if connection of these parts to the SUPPLY MAINS could cause an unacceptable RISK.

Compliance is checked by inspection and manual testing.

For a connector intended to accept a HOSE for fluids, means shall be provided to prevent the HOSE from disengaging unintentionally from a connector on a control unit, a fluid-filled MATTRESS, or other HEATING DEVICE supplied by warmed fluid.

Compliance is checked by inspection and by applying a force of 50 N in the least favourable direction. For a HOSE connected to a FORCED AIR DEVICE BLANKET, the force shall be at least 20 N.

201.15.4.2 Temperature and overload control devices

201.15.4.2.1 Application

Addition:

201.15.4.2.1.101 * Temperature and overload control devices – Additional requirements for application

Any temperature sensor attached directly to the PATIENT may be used to control the heating, but such sensors shall not be used to control the maximum temperature that the HEATING DEVICE can attain. That maximum temperature shall be controlled only as a result of measurements made by a sensor or sensors appropriately positioned in the HEATING DEVICE. See also IEC 60601-1-10:2007 and IEC 60601-1-10:2007/AMD1:2013.

A HEATING DEVICE shall be equipped with an independent THERMAL CUT-OUT to eliminate the RISK of excessive CONTACT SURFACE TEMPERATURE.

For liquid-filled devices, the CONTACT SURFACE TEMPERATURE shall not exceed the limits in Table 201.102, which does not apply to INFANTS:

Table 201.102 – Temperature limits in dependency to time

Contact surface temperature °C	Maximum s
43,5	10 000
44,0	6 000
44,5	3 300
45,0	1 990
45,5	1 000
46,0	650
46,5	350
47,0	225
47,5	110
48,0	80
48,5	60
49,0	38
49,5	28
50,0	22
50,5	17

For INFANTS, the temperature shall not exceed 43 °C.

Except for FORCED AIR DEVICES and circulating liquid devices, the THERMAL CUT-OUT shall prevent the CONTACT SURFACE TEMPERATURE from exceeding 41 °C (see also 201.11.1.2.1.101.3).

For FORCED AIR DEVICES, the THERMAL CUT-OUT shall activate within 10 min after the occurrence of the SINGLE FAULT CONDITION described in Annex GG or when the CONTACT SURFACE TEMPERATURE exceeds 56 °C. To prevent injury, the hazardous condition shall be eliminated by the CONTROLLER (see 201.11.1.2.1.102.3).

NOTE The independent THERMAL CUT-OUT can be either a non-SELF-RESETTING THERMAL CUT-OUT, or a SELF-RESETTING THERMAL CUT-OUT.

The effectiveness of the independent THERMAL CUT-OUT shall not be affected by any change or fault in the control THERMOSTAT and its associated system.

For HEATING DEVICES other than FORCED AIR DEVICES, compliance is checked by inspection under the conditions of 201.12.4.101 and by the following tests:

THERMAL CUT-OUTS and OVER-CURRENT RELEASES are tested by operating the HEATING DEVICE under the conditions described in Clause 13 of the general standard.

Non-SELF-RESETTING THERMAL CUT-OUTS are caused to operate 10 times.

SELF-RESETTING THERMAL CUT-OUTS and self-resetting OVER-CURRENT RELEASES are caused to operate 200 times.

Additional subclauses:

201.15.4.101 Fixation of heating elements and internal wiring

201.15.4.101.1 Securing the fixation of heating elements and internal wiring

Heating elements and internal wiring shall be secured in their intended positions.

NOTE The fixation of the heating elements can be achieved by the use of sewn construction, separate fixing devices or bonded construction (for example R/F welded or glued).

If the heating element or the internal wiring, or both, are supported by a separate layer of material, this material shall be firmly secured to the ENCLOSURE so as to prevent internal RUCKING.

If the fixation of the heating elements is achieved by bonded construction, the HEATING DEVICE shall fulfil the requirements of 201.9.1.102.

Crossing of internal wires with each other or with the heating elements shall be avoided as far as possible. Where such crossing is unavoidable, the internal wiring shall be additionally secured to prevent any relative movement. Precautions shall be taken to ensure that the insulation between the conductors cannot be damaged in NORMAL USE.

Compliance is checked by inspection and by the relevant tests of 201.15.4.101.2.

201.15.4.101.2 Means for fixation of the heating elements

If the fixation of the heating elements is achieved by means of sewed seams, it shall consist of at least two separate seams between every two adjacent parts of the heating elements, so that if one seam comes apart, contact between adjacent parts of the heating elements is prevented.

If the fixation of heating elements is made by a number of separate fixation devices, every fixation device shall secure a length of the heating element not less than 20 mm in length. The distance between two consecutive fixation devices along a heating element shall not exceed 100 mm. The fixation devices themselves shall be firmly secured.

Compliance is checked by inspection and by the following tests:

Heating elements which are secured by means of appropriate fixation devices are subjected to a force of 2 N between two consecutive fixation devices on the least favourable point and in the least favourable direction towards an adjacent part of any heating element. When subjected to the force, the distance at any point between two adjacent parts of the heating elements shall be not less than 50 % of the corresponding distance when not subjected to the force. The force is applied by means of a standard test finger as shown in Figure 7 of the general standard.

A separate fixation device is subjected for 1 min to a pull of 30 N perpendicular to the surface to which it is fastened. During the test, the fixation device shall not become loose.

201.15.4.102 Ruck-resistant BLANKETS

RUCK-RESISTANT BLANKETS shall be so constructed that RUCKING of the flexible part is unlikely. The RUCK-RESISTANCE g, as calculated from the formula $g = F/X$ (see Figure 201.108), shall not be less than 2,5.

Compliance is checked by the following test:

a) Where only a part of a BLANKET has stiffening means, which is not representative of the rest of the BLANKET, remove such stiffening.

b) The BLANKET is operated at RATED input and in accordance with CONDITIONS OF ADEQUATE HEAT DISCHARGE for 3 h, after which it is removed from the sheets of LAGGING MATERIAL and while still connected to the supply, laid flat on a horizontal surface. It is positioned so that a diagonal of the flexible part is perpendicular to the edge of the surface.

c) A wooden board measuring 1 m × 1 m × 20 mm thick is placed over the BLANKET and positioned so that the edge of the board aligns with the edge of the surface.

d) The flexible part and board are then slid together until the edge of the board overhangs the edge of the surface by 300 mm.

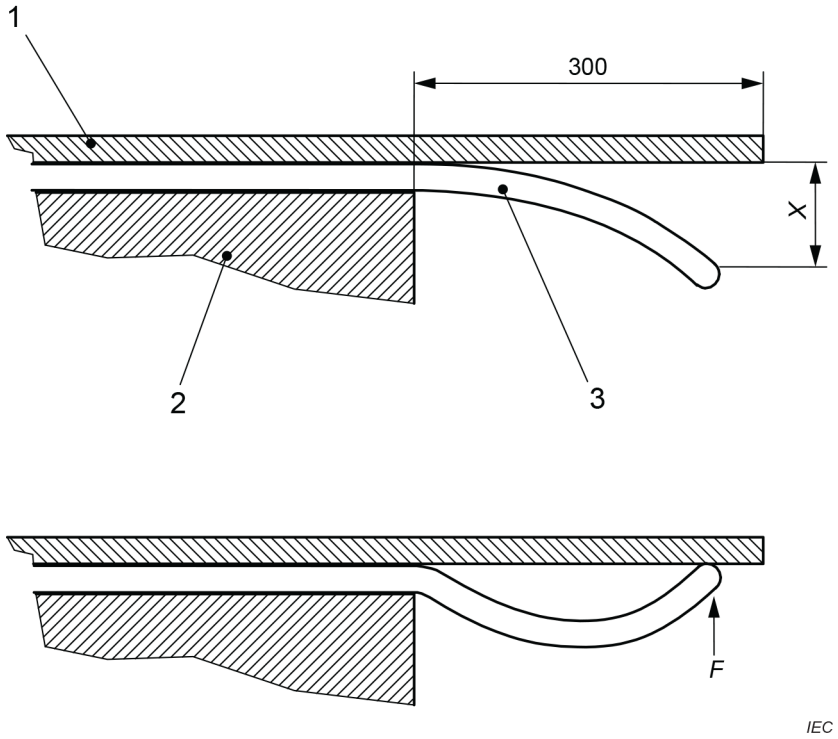
e) The deflection X, in metres, of the overhanging corner of the flexible part is measured as shown in Figure 201.108.

f) The force F, in newtons, required to lift the overhanging corner to the lower surface of the board is then measured.

g) The measurement is repeated on the other corners, with the exception of any corner containing the APPLIANCE INLET or cord entry.

h) The RUCK resistance, g, is calculated for each of the corners measured.

Dimensions in millimetres



Key

X deflection, in metres, of the overhanging corner of the flexible part

F force in newtons (N) required to lift the overhanging corner to the lower surface of the board

1 wooden board

2 horizontal surface

3 BLANKET

Figure 201.108 – Positions of a BLANKET for the RUCK-RESISTANCE test

201.15.4.103 UNDER-BLANKETS

UNDER-BLANKETS, other than RUCK-RESISTANT BLANKETS, FORCED AIR DEVICE BLANKETS, and circulating liquid BLANKETS, shall be provided with means to prevent RUCKING. The means used for this purpose shall be permanently attached, ensure that the BLANKET cannot ruck in any direction, and not cause damage to the BLANKET in NORMAL USE. If tapes or similar means are provided for this purpose, they shall be so positioned and of such a length that the BLANKET can be readily and effectively secured to the maximum size of MATTRESS for which it is intended. Pins shall not be used.

Compliance is checked by inspection.

201.16 ME SYSTEMS

Clause 16 of the general standard applies.

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

Clause 17 of the general standard applies.

202 ELECTROMAGNETIC DISTURBANCES – Requirements and tests

IEC 60601-1-2:2014 applies except as follows:

202.8.9 IMMUNITY TEST LEVELS

Addition:

For radiated radio-frequency electromagnetic fields, the HEATING DEVICE and/or system shall

– continue to perform its intended function as specified by the MANUFACTURER at the level up to 3 V/m for the frequency range of the collateral standard of EMC.

NOTE A HEATING DEVICE is not considered to be used in a HOME HEALTHCARE ENVIRONMENT.

208 General requirements, tests and guidance for ALARM SYSTEMS IN MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS

IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012 apply, except as follows:

208.6.8.4 Termination of inactivation of ALARM SIGNALS

Addition:

208.6.8.4.101 Additional requirements for termination of inactivation of ALARM SIGNALS

The duration of AUDIO PAUSED for the ALARM CONDITIONS required by this document shall not exceed 10 min without OPERATOR intervention.

NOTE This permits an OPERATOR to deliberately extend the AUDIO PAUSED by direct action.

Compliance is checked by functional testing.

210 * Requirements for the development of PHYSIOLOGIC CLOSED-LOOP CONTROLLERS

IEC 60601-1-10:2007 and IEC 60601-1-10:2007/AMD1:2013 apply, except as follows:

Amendment:

IEC 60601-1-10:2007 and IEC 60601-1-10:2007/AMD1:2013 apply for HEATING DEVICES that operate as PHYSIOLOGIC CLOSED-LOOP CONTROLLERS by controlling the PHYSIOLOGIC VARIABLE of PATIENT temperature using feedback that is measured from a PATIENT.

NOTE The COMMAND VARIABLE is the PATIENT temperature (e.g. core, skin, rectal oesophageal, etc. setting).

Annexes

The annexes of the general standard apply, except as follows:

Annex D
(informative)

Symbols on marking

Annex D of the general standard applies except as follows:

Table D.2 – Safety signs

Addition:

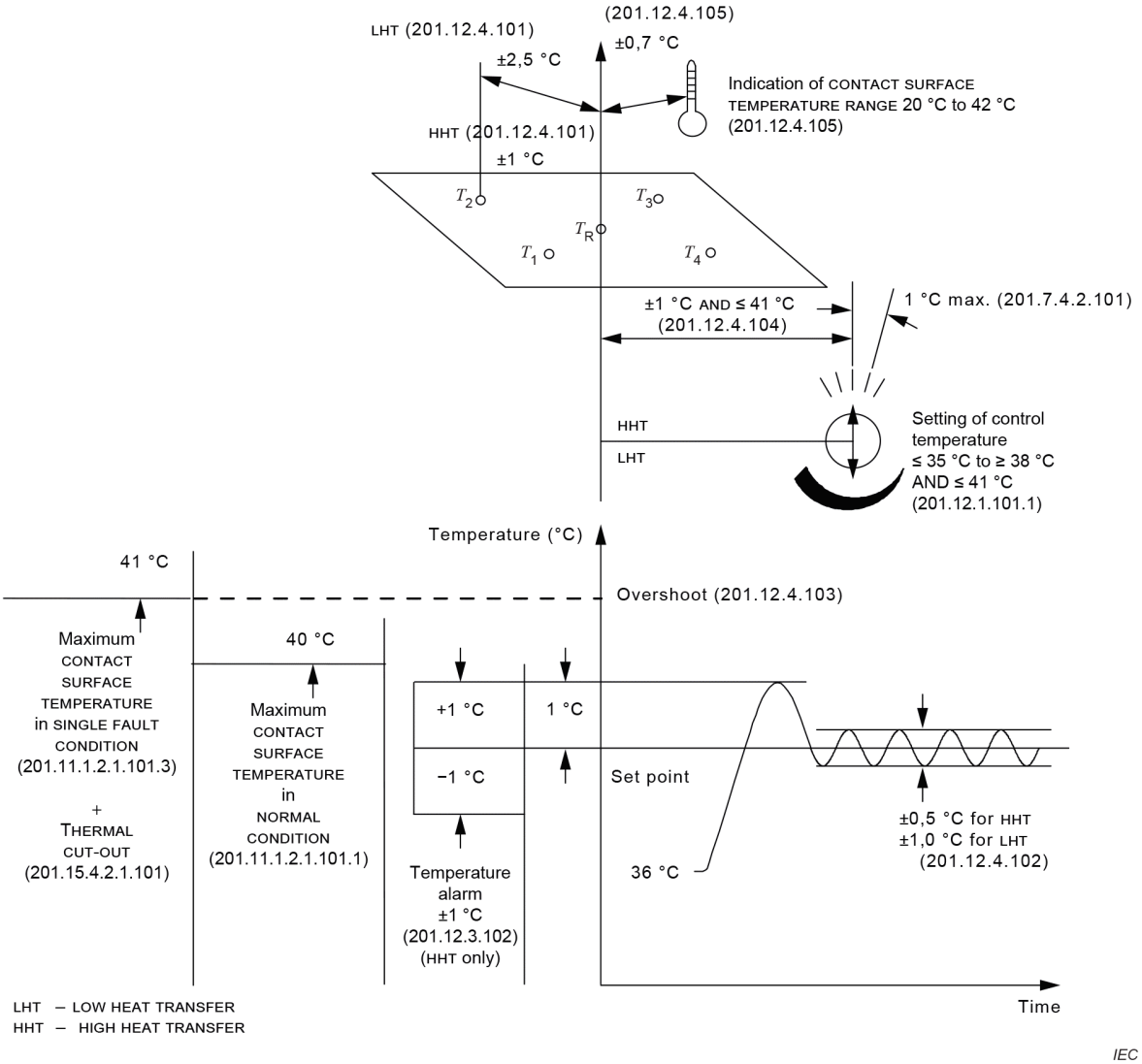
11			No FREE HOSING

Annex AA
(informative)

Particular guidance and rationale

AA.1 General guidance

Compliance with the minimum safety requirements specified in this particular standard is predominantly checked by measurement of physical quantities such as the temperature. In most cases, the spatial location of the measuring site or the temporal development of the quantity is of interest. Therefore, the expert group of this document considered it helpful to provide a synopsis of the requirements of this document. Hence, Figure AA.1 illustrates the requirements and their schematic measuring sites or expected temporal development. The requirements as given by their clauses are set in brackets.



NOTE Numbers in brackets indicate the relevant subclauses.

Figure AA.1 – Illustration of the main requirements of this document

AA.2 Rationale for particular clauses and subclauses

The following are rationales for specific clauses and subclauses in this particular standard, with clause and subclause numbers corresponding to those in the body of the document. The numbering is, therefore, not consecutive.

It is considered that knowledge of the reasons for these requirements will not only facilitate the proper application of the document but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However, Annex AA does not form part of the requirements of this standard.

Subclause 201.1.1 – Scope

Hospital wards include those for both adults and INFANTS. Use in nursing homes might include helpless PATIENTS who might suffer from the uncontrolled application of heat.

Qualification of specifications for certain types of ME EQUIPMENT in this particular standard is necessary because attention needs to be given to features of HEATING DEVICES which are used to warm PATIENTS in operating rooms, intensive care units and other areas of healthcare facilities, often when the PATIENT is unable to react if excessive temperatures are produced.

Utilization of these devices is increasing as a result of the multiple articles in the recent medical literature documenting the complications and morbidity associated with decreased body temperature in surgical PATIENTS [4]. These devices are used in other areas of medical practice such as post-anaesthetic care units, PATIENT transport systems (e.g. ambulances and helicopters), nursing homes, and healthcare facilities where PATIENTS might suffer from the uncontrolled application of heat.

It has been estimated that FORCED AIR DEVICES are used at least 7 million times a year in the USA alone. Although these devices have an extraordinarily safe history, their increasing use (as well as their relative ease of application) in preventing or treating hypothermia indicates the need for a standard dealing with their essential requirements.

Pre-warming BLANKETS are not excluded from this particular standard because it is known that, either intentionally or accidentally, hospital personnel do on occasion continue to use a pre-warming BLANKET on a bed after a PATIENT has been moved onto the bed. Because there is no way that it can be certain that a pre-warming BLANKET is always removed before this happens, such pre-warming BLANKETS are required to satisfy the requirements of this particular standard in order to avoid the possibility of an unacceptable RISK.

The joint working committee recognized that the specified devices may also be used to provide cooling to prevent or treat hyperthermia. However, the joint working group did not identify any significant HAZARDOUS SITUATIONS associated with cooling therapy. Therefore, the scope of this particular specification is limited to the use of the specified devices for warming only.

Table 201.101 – Additional ESSENTIAL PERFORMANCE requirements

The experts of the working group determined that these requirements were the essential requirements that a HEATING DEVICE should be required to meet.

The intended use of a HEATING DEVICE is to apply heat to a PATIENT and to keep the temperature stable within a safe range. The accuracy of the set temperature is required to be maintained within the range required by this document and is listed as a requirement in the ESSENTIAL PERFORMANCE table. If the temperature varies beyond the range listed in the requirement, then an ALARM CONDITION should be generated.

It should be noted that the time relationship between PATIENT and warming therapy treatment was evaluated in the discussion to resolve essential requirements. These devices, as opposed to ventilators or implantable devices, have real measurable response times built into most failure mode activities. Therefore, it was considered appropriate that, combined with the requirement to define thermal performance, a failure to maintain this state if accompanied by an appropriate ALARM CONDITION, which would allow a clinician to perform the appropriate mitigating actions, would be the essential requirements for these devices.

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

Markings that instruct OPERATORS that the HOSE NOZZLE is required to be connected to a BLANKET were added because failure to do so has been associated with burn injuries [5], [6], [7]. The practice, commonly known as FREE HOSING, is a HAZARDOUS SITUATION which can lead to thermal injury. FREE HOSING is the primary HAZARDOUS SITUATION identified in the Food and Drug Administration (FDA) Medical Device Reports (MDR) for these devices and is specifically identified in the Emergency Care Research Institute (ECRI) Problem Reporting System as a HAZARDOUS SITUATION.

Warning labels have proven to provide equivalent safety as demonstrated by the order-of-magnitude decrease in adverse events reported from 2002 to 2006 in the FDA Manufacturer and User Device Experience (MAUDE) reports for FORCED AIR DEVICES. See also the rationale for Subclause 201.7.9.2.2.101 k).

The joint working group deleted previous recommendations for testing of the CONTROLLER SAFETY DEVICE because the procedure can expose the PATIENT to temperatures above 48 °C during the test cycle [8], [9].

Subclause 201.7.2.1.101.3 – Temperature sensors

Temperature sensors are required to be individually marked for their intended use because some sensors are used to control the power to the heater while others are used only to indicate the temperature. Temperature sensors which are detachable from the CONTROLLER can be used to adjust the heating system, while others can provide a visual indication of temperature only. A HAZARDOUS SITUATION can exist if such sensors are interchanged, for example if a PATIENT's temperature rises and the heating needs to be reduced.

Subclause 201.7.9.2.2.101 k) – Additional requirements for warning and safety notices

The following is the rationale for the implementation of a warning label to address concerns about the practice of FREE HOSING when using FORCED AIR DEVICES.

FREE HOSING is the use of a forced-air warming unit with its HOSE but without a BLANKET. The HOSE of the warming unit is placed under the surgical drapes or cotton BLANKETS with the air from the HOSE being applied directly to the PATIENT's skin without being dispersed by a BLANKET.

This practice is an intentional misuse of the device. If done for an extended period of time and if the HOSE is placed very close to the PATIENT skin, there is a potential to cause a severe burn. Like many misuse practices, the potential severity of the RISK can be high. But it important to note that very few FREE HOSING events result in serious injury.

A number of factors shall occur simultaneously to cause a serious injury:

– a user shall choose to misuse the product by FREE HOSING;
– the warming unit temperature shall be set to the "High" setting;
– the end of the HOSE shall be placed adjacent and perpendicular to PATIENT's tissue;

– exposure to the FREE HOSING shall be for an extended period of time.

Over the last 10 years of product use, based on the FDA's adverse event database from all MANUFACTURERS' products, the total number of reported occurrences resulting in injury to a PATIENT is 9. During that same period, the number of uses is known to be over 80 million, resulting is a rate of incidence of approximately 1 injury for each 10 million uses. In spite of this extremely low rate, the committee felt that the issue of FREE HOSING ought to be addressed in some manner.

The recommended methodology for RISK reduction should be used to determine the appropriate action to take. The following are possible approaches.

1) Inherent safety by design

   The only way to completely eliminate this RISK by design would be to lower the temperature of the air used to warm the PATIENTS. Because of the thermal transfer properties of convective warming, this is not a practical option because lowering the air temperature to a point that would be safe under all occurrences of this misuse would render the device useless for warming PATIENTS under therapeutic conditions.

2) Protective measures in the medical device itself

   – While an "interlock" type technique was considered by the committee, this is an inadvisable approach for a number of reasons.

   – The practice of FREE HOSING is an intentional misuse. It was felt that if a clinician is intent on misusing a device, he/she would be able to defeat an interlock system.

   – Based on MANUFACTURER-gathered information, most incidents of FREE HOSING seemed to be done out of ignorance of the potential RISK, not an intent to take the RISK of putting PATIENTS in HARM's way to reduce healthcare costs.

   – Adding an interlock type system is not warranted based on the rate of incidence. With the added concern over the lack of continued development in this industry and the need to educate users, a RISKS/benefits analysis demonstrates that requiring such a change would not be the best approach.

3) Information for safety

   Based on the analysis described above, it was agreed that the best method for avoiding this practice would be to provide additional information to the users about the dangers of FREE HOSING by means of warning labels, with a label required both at the end of the HOSE near the PATIENT, and on the warming device itself. In addition to educating the users, this approach would allow all current devices to be updated with the new labels and information.

Implementation of RISK CONTROL measures

While the requirements in ASTM F 2196-02 were applicable only to newly developed units, all MANUFACTURERS took it upon themselves to add warning labels and information to their currently marketed products. In addition to the labelling, one of the MANUFACTURERS developed a highly successful educational campaign about FREE HOSING that was provided to healthcare institutions. In the United States, the Food and Drug Administration (FDA) joined in this educational effort, featuring the MANUFACTURER's program in one of their Safety Update videos. In addition, ECRI published a report about FREE HOSING, identifying the need for education and proper use as key to avoiding problems.

The rate of incidents related to FREE HOSING has always been extremely low. Importantly, these campaigns and the labelling required in ASTM F 2196-02 has resulted in a reduced number of reported incidents of the problems associated with FREE HOSING in the last five years (based on FDA's MAUDE system reports and reports from the MANUFACTURERS of FORCED AIR DEVICES) for those devices that displayed the ASTM F 2196 "no FREE HOSING" symbol. The rate of incidents during the 5 years prior to the implementation of the information requirements was approximately 1 incident for every 4 million uses.

The rate of incidents during the 5 years since the implementation of the information requirements is approximately 1 incident for every 26 million uses. In addition, it has been confirmed that incidents that occurred during the most recent 5-year period involved warming units manufactured prior to the implementation of the warning label. In summary, no FREE HOSING injuries have occurred involving warming units produced since the implementation of the ASTM warning label.

Subclause 201.7.9.2.9.103 d) – Additional requirements for operating instructions for BLANKETS

CONTROLLER/BLANKET commingling: The use of specified CONTROLLERS and BLANKETS is a safe and accepted practice. The joint working group agreed, however, to limit the practice of commingling different CONTROLLERS and BLANKETS to those specific models shown to function together safely. Evidence has shown that unsafe variations even within same model numbers can occur. Details need to be specific to inform OPERATORS which combinations have been tested and determined to be safe.

Subclause 201.7.9.2.9.103 e) & f) – Additional requirements for operating instructions for BLANKETS

Warnings against using the device distal to arterial cross clamping or with a PATIENT with an ischemic limb were added by the joint working group because failure to do so has been associated with burn injuries [10], [11]. These warnings/instructions are necessary to inform the OPERATOR of the conditions in which the device cannot be safely used. This information is important enough that it should be included in the instructions for use.

Subclause 201.8.1 – Fundamental rule of protection against electric shock

This requirement rules out dependence for safety on the use of what might be considered to be a suitably non-conducting liquid or insulating oil as a circulation fluid. This was thought necessary because there is no way that a MANUFACTURER could ensure that no oil or non-conducting liquid used would be contaminated with, or even replaced entirely by, water or other conducting liquid.

Subclause 201.8.5.1.2.101 – Additional requirements for MEANS OF PATIENT PROTECTION (MOPP)

The requirement that HEATING DEVICES are to be supplied via a mains isolating transformer for safety reasons should not be taken as an indication that the secondary supply has to be at low voltage. Reasons for requiring such a transformer include:

– according to the general standard, it would be possible for a PAD or BLANKET to incorporate DOUBLE INSULATION or REINFORCED INSULATION. However, insulation inside a PAD or BLANKET is susceptible to damage and therefore cannot be relied on to provide two MEANS OF PATIENT PROTECTION.
– lower RISK should a HEATING DEVICE become trapped and damaged by a bed-frame;
– lower RISK if a HEATING DEVICE is perforated by a sharp object.

For the purpose of this particular standard, the electrical impedance of circulation fluid is considered to provide no electrical isolation.

Subclause 201.8.11.1.101 Isolation from the SUPPLY MAINS

A SUPPLY MAINS isolation switch is needed because ME EQUIPMENT using only a suitable plug device as a means for isolation from the SUPPLY MAINS could result in a FALSE POSITIVE ALARM CONDITION indicating SUPPLY MAINS failure or low temperature when the HEATING DEVICE is connected to the SUPPLY MAINS but not actually in use (see also 8.11.1 of the general standard).

Subclause 201.9.1.102 – Bonded construction

Circulating liquid BLANKETS operate by circulating a liquid under modest pressure. These BLANKETS are designed to optimize flow and heat transfer. The various designs result in substantial variations in seal geometry of the entire PAD. That seal geometry results in a PAD that is fit for use.

Isolation of a small section of the seal geometry by cutting strips denies the PAD its combined element strength. For example, if one analyses a 1 mm × 1 mm seal it can fail, while that same 1 mm × 1 mm seal, when combined with other 1 mm × 1 mm seals and other seal geometry, becomes a stronger entity, possibly to the point of forming a fully functioning, safe and effective circulating liquid BLANKET. Therefore, any test of this type of device should evaluate the combined strength of all seal elements, not just isolated sections.

Circulating liquid BLANKETS using bonded construction need to have sufficient strength and/or seal integrity to withstand such handling as can be experienced in NORMAL USE, without separation of the layers which are bonded.

Subclause 201.9.8.3.1 – General

A baby can crawl out of an open port and fall to the floor. Side panels can collapse, allowing the baby to roll out of a bassinet. Poorly designed barriers can fail to retain the baby.

Subclause 201.11.1.2.1.102.1 – Maximum CONTACT SURFACE TEMPERATURE in NORMAL CONDITION

Studies noting the relationship between skin temperature and thermal injury have been published. Among the most significant are those by Moritz and Henriques [12] [13] and Stoll and Greene [14]. However, these studies relate only to devices that use radiant energy transfer or a heat transfer medium such as water. Forced air has significantly less heat transfer capacity than water. Published studies that correlate thermal injuries with FORCED AIR DEVICES used for warming have not been found.

The temperatures of existing devices that have been in widespread use for over ten years and their exceptional safety record provide a reasonable basis for establishing limits. As part of the development of this document, six MANUFACTURERS disclosed BLANKET temperatures under various operational and test conditions. The specified test procedures and safe temperature limits were based on these data.

For FORCED AIR DEVICES, the joint working group considered, but then rejected, use of heat flux test methods to define thermal transmission rate thresholds. Producer members were unable to develop a robust single point test method. Variations in heat flux methods were recorded with minor adjustments in the position of the sensor. Multiple heat flux sensors and a stable heat sink device would be required to produce repeatable test results. Therefore, the joint working group judged that heat flux test methods were impractical for this particular standard, and substituted in its place the modified CONTACT SURFACE TEMPERATURE test methods described in Annex FF.

The joint working group reaffirmed that the forced air warming technology was safe, as demonstrated by over ten years of successful commercial use. No new burn injuries associated with this technology have been reported in the past five years when the system was used correctly. The group agreed that FREE HOSING, the use of the CONTROLLER without a BLANKET, is the only known HAZARDOUS SITUATION that results in thermal injury. Therefore, the joint working group reaffirmed the use of the maximum temperature safety test method, average temperature safety test method, and the SINGLE FAULT safety test method. The group also agreed to incorporate safety limit specifications that are provided by currently manufactured FORCED AIR DEVICES [12], [14].

The CONTACT SURFACE TEMPERATURE of HEATING DEVICES may rise when combined with other heat sources such as heating BLANKETS or PADS. Hence, it is important to specifically consider the impact of such additional heat sources in the RISK MANAGEMENT.

Subclause 201.11.1.2.1.102.3 – Maximum CONTACT SURFACE TEMPERATURE in SINGLE FAULT CONDITION

The 56 °C for 10 min allowance for FORCED AIR DEVICES in a SINGLE FAULT CONDITION is based on RISK assessments of the technology and the history of use.

Thermal injury occurs as a result of human tissue being raised to a temperature level that can cause thermal damage. The threshold is 43 °C, meaning that temperatures below 43 °C will not cause a burn. This threshold is acknowledged in the general standard in Clause 11, where it allows temperatures up to 41 °C with no justification required (less than 43 °C with an additional 1 °C of margin). Once that threshold is reached, clinical studies demonstrate that thermal injury is not only a function of temperature but is also dependent upon exposure time [12], [13], [14], [15].

The increase in temperature of human tissue depends on the ability of the heat source to transfer heat to the tissue. Contacting solid objects (such as those in Tables 23 and 24 of the general standard) transfer heat by means of conduction and can increase tissue temperatures quickly. The tables in the general standard allow different temperatures for various materials because of the varying thermal capacity of those materials. Table 24 allows temperatures of APPLIED PARTS to be as high as 48 °C for 10 min. In the case of forced air warming, it should be emphasized that air has an entropy considerably lower than that of the solid materials in Tables 23 and 24. As a result, warmed air (convective warming) will increase tissue temperatures at a much lower rate than the materials in Tables 23 and 24 (conductive warming).

Further evidence is the fact that many people live and work in areas where the air temperature approaches or exceeds 56 °C (those in desert areas, firemen, cooks, etc.). In fact, IEC 60335-2-53:2007 [11], permits air temperatures above 90 °C.

The 10 min limit was developed based on the ability of the forced air to warm the tissue and historical product use. The temperatures of existing FORCED AIR DEVICES, with their widespread use for over twenty years and exceptional safety record, provide a reasonable basis for establishing these limits. As part of the development of this document, six MANUFACTURERS disclosed BLANKET temperatures under various operational and test conditions. The specified test procedures and safe temperature limits were based on these data. These historical data combined with the low thermal transfer capability of air and textiles provide an acceptable level of RISK for 10 min of exposure to higher air and textile temperatures.

Subclause 11.1.2.1 of the general standard does not define a specific temperature limit for the APPLIED PART. This is likely the result of the need to provide warmer temperatures and to accommodate varying methods of warming. This subclause allows temperatures to exceed the specified limits providing the clinical effects are determined and documented.

The information presented above provides a basis for those clinical effects and demonstrates that an air temperature of 56 °C for a period of 10 min or less is an acceptable RISK.

Subclause 201.11.2 – Fire prevention

During the review of this document, the committee was requested to consider adding a flammability requirement for INFANT MATTRESSES. Because the committee could find no evidence to support an addition of this type, this brief rationale was added.

MATTRESSES or PADS usually consist of two materials, which serve two different functions. The filler functions to support or cradle the INFANT while the surface material acts as a barrier from the inner material. The primary requirements of the filler material are to provide a comfortable surface for long-term stay of the PATIENT. The primary requirement of the surface material which could contact the PATIENT under a SINGLE FAULT CONDITION is to present no HAZARD to the PATIENT. In most clinical applications, the outer surface has been observed to be covered with additional coverings consisting of a natural fibre-based material (cotton or materials supplied by PATIENT's relatives) which is not specifically flame-retardant but functions to further reduce the low abrasion qualities of the PAD's cover with the neonate's skin.

Even if a canopy is provided, the RISK of fire ignition in the area of the MATTRESS is limited since there is no source of ignition inside the canopy and the requirements of 6.5 of the general standard for an OXYGEN RICH ENVIRONMENT have been met. No incident concerning fire ignition inside an incubator has been reported for many years. Also, even with warming MATTRESSES, additional concerns about the toxicity of fumes that can be produced by materials that have been treated with flame-retardant additives were discussed.

Subclause 201.11.6.5.102 – Ingress of liquids

The use of HEATING DEVICES and associated control units for emergency use in outdoor situations is not dealt with in this particular standard (see 201.1.1), but it should be recognized that such HEATING DEVICES should be MATTRESSES with at least a degree of protection of IP X4 and should be marked as such.

Subclause 201.11.8.101 – Interruption of power supply/SUPPLY MAINS ALARM CONDITION

The ALARM CONDITION required in 201.11.8.101 in this particular standard is to indicate to the OPERATOR that the HEATING DEVICE is no longer supplying heat to the PATIENT.

A LOW HEAT TRANSFER HEATING DEVICE or FORCED AIR DEVICE may be equipped with an ALARM SYSTEM that includes a LOW PRIORITY TECHNICAL ALARM CONDITION that indicates a SUPPLY MAINS failure. For LOW HEAT TRANSFER HEATING DEVICES and FORCED AIR DEVICES, loss of SUPPLY MAINS and subsequent loss of therapy represents a low RISK of a harmful situation. Therefore, a LOW PRIORITY TECHNICAL ALARM CONDITION is prudent and justified.

Subclause 201.11.8.102 – Preset values after restoration of power supply/SUPPLY MAINS

The intention of this subclause is to provide a specification for power resumption so as not create a HAZARDOUS SITUATION.

The committee selected ten minutes because it felt that longer than ten minutes would indicate that the device had been unplugged because it was no longer needed and therefore it should not retain the settings. It was also felt that for periods of less than ten minutes power resumption would not create a HAZARDOUS SITUATION and would cover the situation where someone accidentally or deliberately unplugged the device and then replaced the plug.

Subclause 201.12.1.101.2 c) – Control setting and display indications

Reference of the control settings to a relevant output measurement was considered important by the joint working group. High, medium, and low markings are insufficient to characterize the output from a warming unit. However, joint working group members could not agree upon a single test methodology and any methodology is subject to uncontrollable measurement errors. As such, the joint working group agreed that it would be acceptable for the individual MANUFACTURER to provide the RESPONSIBLE ORGANIZATION with a test method. Whatever temperature is measured should be verifiable by a RESPONSIBLE ORGANIZATION using instruction supplied by the MANUFACTURER.

Subclause 201.12.1.101.3 – Weighing scale for INFANTS

Weighing scales used in paediatric ME EQUIPMENT have unique requirements that differ significantly from those of weighing scales used in general commercial or domestic weighing applications. Absolute accuracy is important, however not to the degree of accuracy (1/1 000) required by commercial weighing scales used for monetary transactions. More important from a clinical application is the information provided by weight trends, demonstrating an increasing or decreasing weight of the INFANT. Absolute accuracy is very difficult at best due to electrical leads, tubing, and other PATIENT care devices that cannot be completely eliminated from the measurement.

Because weighing an INFANT is a difficult process requiring both hands of the OPERATOR in the manipulation of the INFANT, it is necessary that the weight reading be held and displayed until the OPERATOR has completed the procedure. The weight reading should be displayed until the OPERATOR has recorded or stored it, if electronic storage is an option.

An INFANT needs to be contained in a heated, controlled environment for an extended period of time. Moving an INFANT for any reason can be harmful to the INFANT's well being. An INFANT often remains in a controlled environment, incubator or radiant warmer for 2 or more weeks. During this time it is necessary for the OPERATOR to check the calibration of the weighing scale. Additionally, it is necessary for the OPERATOR to be able to adjust the calibration with the necessity to remove the scale or move the INFANT.

Subclause 201.12.3.102 – CONTACT SURFACE TEMPERATURE variation ALARM CONDITION

The core temperature of a PATIENT, particularly that of an INFANT, follows directly the CONTACT SURFACE TEMPERATURE of a HIGH HEAT TRANSFER HEATING DEVICE. Thus, a decrease in the CONTACT SURFACE TEMPERATURE of more than 1 °C causes the temperature of the PATIENT to fall by nearly the same amount. The thermal regulation system of the PATIENT reacts against this influence by transferring some blood flow from the peripheral extremities to the core, with consequent lowering of the temperature of arms and legs. The PATIENT is then in a hypothermic condition.

Conversely, an increase in the CONTACT SURFACE TEMPERATURE by more than 1 °C results in a hyperthermic situation, comparable to a fever. The PATIENT reacts to this influence by sweating and an increase of the metabolic rate, pulse rate, etc. It will not be obvious to medical staff whether this change is the result of the clinical condition of the PATIENT or due to the HEATING DEVICE.

Both of these situations cause extreme stress to a PATIENT and therefore such HEATING DEVICES are required to have an ALARM CONDITION that indicates if the CONTACT SURFACE TEMPERATURE varies by more than ±1 °C.

Clinical studies suggest that rectal temperatures between 36 °C and 38 °C represent the acceptable range (normothermia) between hypothermia and hyperthermia [15]. It follows that, if 37 °C is accepted as the normal rectal temperature, an ALARM CONDITION is required if the rectal temperature differs from this by more than ±1 °C. Correspondingly, because the core temperature directly follows the CONTACT SURFACE TEMPERATURE of a HIGH HEAT TRANSFER HEATING DEVICE, such an ALARM CONDITION needs to indicate when the CONTACT SURFACE TEMPERATURE differs by more than ±1 °C from the set temperature.

Subclause 201.12.4.101 – Variation of temperature across the contact surface

For FORCED AIR DEVICES, precision in variation of temperature across the contact surface is a market preference specification and not a minimum performance requirement. It is one of the key market qualities that distinguish the circulating liquid device market from FORCED AIR DEVICE market, thereby allowing both technologies to coexist and satisfy different customer preferences. Variation in temperature across a forced air BLANKET is an accepted performance property for those clinicians who value other characteristics more highly. These include FORCED AIR DEVICES' lighter weight; shorter warm-up times; ease of setup, use and cleanup; disposability; and lower cost. If necessary, the OPERATOR can reduce the variation in a FORCED AIR DEVICE BLANKET temperature by:

1) using an OVER-BLANKET to insulate the upper surface of the FORCED AIR DEVICE BLANKET;
2) using more moderate temperatures. Highest temperatures create greater losses;
3) using smaller drapes. Small paediatric drapes have the least temperature variation;
4) using the proper drape to meet the PATIENT's warming needs.

These OPERATOR mitigations have proven safe and effective in the market for the past 20 years.

Subclause 201.12.4.106 – Avoidance of incorrect connection of parts

There are some recorded incidents of burns from heated PADS which were used without the associated liquid-filled MATTRESS specified by the MANUFACTURER. To avoid the possibility of improper use, the HEATING DEVICE should be designed so that the heater cannot be operated if all parts of the HEATING DEVICE are not properly installed.

For HEATING DEVICES other than FORCED AIR DEVICES, labelling or information contained in the instructions for use is not deemed sufficient. Experience with the use of MEDICAL ELECTRICAL EQUIPMENT in hospitals has shown that it is essential that such HEATING DEVICES be inherently safe by design.

Subclause 201.12.4.107 – Inadvertent changing of control settings

Accepting that the core temperature of a PATIENT directly follows the CONTACT SURFACE TEMPERATURE of a HIGH HEAT TRANSFER HEATING DEVICE, temperature control settings below 35 °C cause a hypothermic situation for the PATIENT, and settings above 38 °C cause a hyperthermic situation. Therefore, unintentional changing of the control setting into either of these temperature ranges has to be prevented by design or guarding.

Subclause 201.13.1.2.101.1 – Electronic component failure in an APPLIED PART

Due to the nature, use and proximity to the PATIENT of electrical components in APPLIED PARTS, additional testing of components was deemed necessary by the joint working group.

Subclause 201.13.1.2.101.2 – Excessive temperature

These requirements are added to include HAZARDOUS SITUATIONS likely to be caused by damage if a HEATING DEVICE is folded.

Subclause 201.13.1.2.101.5 – Blockage of a fluid circulation system

Excessive temperatures can be experienced with fluid circulation systems when the flow is temporarily occluded and then restored.

Two occlusion times were chosen. The 10 s time simulates a short blockage, which can cause the fluid in the heating unit to achieve a higher temperature due to the lack of the cooling effect of fluid returning to the heating unit. The 2 min time is to determine whether or not the temperature control of the heating unit can prevent the temperature of the fluid exceeding the upper temperature limit when no fluid flow is occurring and the heater element has time to raise the temperature of the fluid significantly.

In the circulating liquid systems considered in this document, liquid is heated by a remote CONTROLLER, and then circulated through a BLANKET. The liquid entering the BLANKET is warmer than at any point within the BLANKET. It is reasonable to conclude that the maximum BLANKET CONTACT SURFACE TEMPERATURE will be in close proximity to the inlet. Therefore, the temperature sensors should be located at or near the inlet of the BLANKET.

See also Clause 11 of the general standard, 11.1, 11.1.1, and Table 21 of the general standard.

Subclause 201.14.13 – PEMS intended to be incorporated into an IT-NETWORK

A HEATING DEVICE should have a data interface to support a connection to a clinical information system.

EXAMPLE 1 To acquire the operating mode (fan on, fan off).

EXAMPLE 2 To acquire settings (e.g. on or off, temperature control setting or range).

EXAMPLE 3 To acquire information on ALARM CONDITIONS (ALARM CONDITION, priority).

EXAMPLE 4 To acquire the ALARM SIGNAL inactivation states (e.g. AUDIO PAUSED).

A HEATING DEVICE should have a data interface to support connections for a remote human interface.

EXAMPLE 5 To support command and control.

EXAMPLE 6 To support system status.

EXAMPLE 7 To support distributed ALARMS SYSTEM.

Subclause 201.15.4.2.1.101 – Temperature and overload control devices – Additional requirements for application

Clinical studies suggest that thermal injury is not only a function of surface temperature but is also dependent upon exposure time [13], [14]. The maximum allowable exposure times and temperatures specified in Table 201.102 have been derived from these studies. The lower limit of 43 °C was considered necessary for INFANTS because of the immature and very sensitive skin of this group of PATIENTS.

There are some recorded incidents of burns from HEATING DEVICES used on operating tables [13].

Studies performed by Greenhalgh, et al [16] indicate that pulse oximeter probes were safe up to a temperature of 43 °C for at least 8 h in well-perfused skin.

Significant skin injury has occurred following the use of a HEATING DEVICE with a surface temperature of 42 °C over a period of 1 h or more. An area of ischaemia developed and progressed to full thickness necrosis of the skin at sites of maximum pressure overlying a bony prominence.

Pressure in the skin region under the PATIENT causes constriction of the blood vessels with a reduction of blood flow and heat transfer. Heat applied to such a region of the skin can cause an increase of skin temperature without much heat penetrating into the body.

It is often not clear whether the injuries are burns in the true sense, or areas of pressure necrosis, or partly both. A hard irregular surface predisposes to pressure necrosis and the result can be an injury, which can prolong hospital stay and increase PATIENT discomfort. It is also conceivable that these wounds can be potential sites for systemic bacterial invasions, a particular HARM for a PATIENT. It should be noted that protein is denatured at a temperature of 43 °C.

However, it has not been possible to determine temperature limit values which prevent injury when heat is applied to areas of increased pressure. Caution is therefore needed in the use of HEATING DEVICES with a surface temperature even below the permitted maximum specified values of 40 °C for NORMAL CONDITION and 41 °C for SINGLE FAULT CONDITION.

For FORCED AIR DEVICES, the joint working group initially considered, but then rejected, tests of human volunteers to evaluate the safety of FORCED AIR THERMAL CUT-OUT DEVICES. The joint working group agreed that the tests on human volunteers would be too variable and not valid to evaluate the clinical safety of THERMAL CUT-OUT designs.

Subclause 210 – Requirements for the development of PHYSIOLOGIC CLOSED-LOOP CONTROLLERS

The experts discussed and determined that the terminology of the collateral standard IEC 60601-1-10:2007 and IEC 60601-1-10:2007/AMD1:2013 should be defined for the products included in this document. These are addressed as following:

– the CONTROLLER OUTPUT VARIABLE is the heater power;
– the MANIPULATED VARIABLE is the HEATING DEVICE temperature;
– the PHYSIOLOGIC VARIABLE is the measured temperature of the PATIENT;
– the FEEDBACK VARIABLE is the output of the PATIENT temperature sensor;
– one of the FALLBACK MODES may be to cut off the heater power.

These definitions are for information only and may differ for HEATING DEVICES using different technologies.

Annex CC – Determination of heat transfer towards the PATIENT

An exception was made for HEATING DEVICES used on operating tables because the normal operating room environment has a temperature of 20 °C to 22 °C. Therefore, more heat input is required. If the maximum surface temperature is restricted in NORMAL CONDITION and SINGLE FAULT CONDITION, no significant HAZARD should be presented to the PATIENT.

Annex DD – Determination of heat transfer away from the PATIENT

Measurement on current equipment under the conditions of the example in Annex CC provided the following results.

On an insulated LOW HEAT TRANSFER MATTRESS, a temperature rise of less than 1 °C was observed.

On a HIGH HEAT TRANSFER MATTRESS using a gel paediatric MATTRESS, a temperature rise of approximately 2 °C was observed. This represents a heat transfer of 115 Wm^{-2}.

Annex BB
(normative)

Determination of the LAGGING MATERIAL

BB.1 LAGGING MATERIAL

The LAGGING MATERIAL has the following characteristics:

– polyurethane or polystyrene;
– thermal conductivity 0,04 W/(mK) ± 10 %.

For determining the thickness of the sheets of LAGGING MATERIAL to be used, an evenly distributed heat source having dimensions of 1 m × 1 m and an input of 100 W ± 2 W is placed centrally between two layers of LAGGING MATERIAL.

An oxidized copper plate, 65 mm × 65 mm and 0,5 mm thick to which a fine wire thermocouple is attached is placed at the centre and in contact with the upper surface of the heat source and below the LAGGING MATERIAL.

The size of the sheets of LAGGING MATERIAL is at least 1,2 m × 1,2 m.

BB.2 Test procedure

The heat source is connected to the supply and the temperature rise is measured. The thickness of the LAGGING MATERIAL is established when the following steady temperatures are recorded:

– 25 °C ± 1 °C for 0,2*d*;
– 47,5 °C ± 1 °C for 0,5*d*:
– 60 °C ± 2 °C for *d*.

BB.3 Thickness of material

The thickness of the LAGGING MATERIAL below the heat source is required to be at least 2*d*. The heat source may consist of a conductive sheet or two cotton sheets between which a heating conductor is uniformly arranged so that the distance between adjacent runs does not exceed 20 mm.

NOTE 1 The dimension *d* is approximately 36 mm.

NOTE 2 If slight adjustments of the heat discharge are necessary; these can be achieved by adding a few sheets of suitable textile material.

NOTE 3 No additional load is applied to the upper surface of the LAGGING MATERIAL.

Annex CC
(normative)

* Determination of heat transfer towards the PATIENT

The following procedure uses the temperature rise after 1 h in a water-filled plastic bag under stated conditions, as an indicator of the heat transfer from the HEATING DEVICE to the PATIENT.

a) Set the ambient temperature at 23 °C ± 2 °C in a room with an air velocity of less than 0,1 m/s.

b) Operate the HEATING DEVICE, as specified in 201.11.1.2.1.101.1, until a steady CONTACT SURFACE TEMPERATURE of 36 °C is attained.

NOTE 1 For OVER-BLANKETS, see NOTE 3.

c) Remove the LAGGING MATERIAL from the top of the HEATING DEVICE.

d) Place a 2 l plastic bag filled with water at 23 °C, and having a temperature sensor in the centre of the water volume, at the centre of the HEATING DEVICE.

NOTE 2 A suitable plastic bag is the sterile administration bag commonly used for infusion purposes.

Similarly filled plastic bags are placed to cover temperature sensors, including those of THERMAL CUT-OUTS, which could affect the temperature conditions during this procedure. In addition, for HEATING DEVICES whose area is greater than that of an adult person, other similarly filled plastic bags are placed to cover approximately one-third of the area of the HEATING DEVICE.

e) The maximum power which can be applied to the HEATING DEVICE in NORMAL CONDITION or any SINGLE FAULT CONDITION is then applied continuously. This may be achieved either by setting the control THERMOSTAT to its maximum setting, or by disconnecting or disabling the temperature sensor(s) involved in meeting the requirement of 201.11.1.2.1.101.1.

f) After a measuring time *t* of 1 h, or the elapsed time before the THERMAL CUT-OUT operates if this occurs in less than 1 h, measure the temperature of the water in the plastic bag at the centre of the HEATING DEVICE.

g) The RATED heat transfer of the HEATING DEVICE to the PATIENT is designated "HIGH" or "LOW" according to whether the heat transfer to the water in the plastic bag is above or below 115 Wm^{-2}.

Exception:

For HEATING DEVICES intended for use on operating tables, up to 230 Wm^{-2} can be used in the case of BLANKETS and this can be considered as LOW HEAT TRANSFER, if the maximum SURFACE TEMPERATURE under NORMAL CONDITION does not exceed 39 °C (under conditions of 201.11.1.2.1.101.1) and does not exceed 39 °C under SINGLE FAULT CONDITION (see 201.15.4.2).

NOTE 3 For OVER-BLANKETS, the above procedure is carried out in the same way, except that the bag is placed under the OVER-BLANKET (see 201.11.1.2.1.101.1).

NOTE 4 The heat transfer *q* is calculated by:

$$q = \frac{m \cdot c \cdot T}{A \cdot t} \ [Wm^{-2}]$$

where

m is the mass of water in the plastic bag (kg);

c is the specific heat capacity of water (approximately 4180 J/kg/°C from about 16°C to 62 °C);

T is the rise of temperature (°C) of the water;

A is the area of contact between the bag and the HEATING DEVICE (m^2);

t is the time (s).

Example:

A HEATING DEVICE, WHICH increases the temperature of 2 l of water in a plastic bag by 1 °C in 1 h, when an area of 200 cm^2 of the bag is in contact with the surface of the HEATING DEVICE, has a heat transfer of approximately 115 Wm^{-2}.

Annex DD
(normative)

* Determination of heat transfer away from the PATIENT

The following procedure uses the temperature drop in a water-filled plastic bag after 1 h under stated conditions as an indicator of the heat transfer from the PATIENT to the HEATING DEVICE.

a) Set the ambient temperature at 23 °C.

b) Position the HEATING DEVICE where the procedure is to be carried out, and leave it until the CONTACT SURFACE TEMPERATURE has stabilized at 23 °C.

c) Place a 2 l plastic bag filled with water at 36 °C and having a temperature sensor at the centre of the water volume, at the centre of the HEATING DEVICE.

NOTE 1 A suitable plastic bag is the sterile administration bag commonly used for infusion purposes.

Similarly filled plastic bags are placed to cover temperature sensors, including those of THERMAL CUT-OUTS, which could affect the temperature conditions during this procedure. In addition, for HEATING DEVICES whose area is greater than that of an adult person, other similarly filled plastic bags are placed to cover approximately one-third of the area of the HEATING DEVICE.

d) After 1 h, measure the temperature of the water in the plastic bag at the centre of the HEATING DEVICE.

e) The heat transfer from the PATIENT to the HEATING DEVICE is designated "HIGH" or "LOW" according to whether the withdrawal of heat is above or below 230 Wm^{-2}.

NOTE 2 For OVER-BLANKETS, the above procedure is carried out in the same way, except that the plastic bag is placed under the OVER-BLANKET which itself is supported as specified in 201.11.1.2.1.101.1.

NOTE 3 A measurement of the cooling of a plastic bag filled with water initially at 36 °C isolated with a BLANKET and lying on thermal insulation has shown a temperature decrease of 2 °C. This corresponds to a heat transfer of 230 Wm^{-2}.

Annex EE
(normative)

CONDITIONS OF ADEQUATE HEAT DISCHARGE

The flexible part is supported by a piece of plywood, 20 mm thick, situated not less than 300 mm above the floor.

MATTRESSES are placed on the plywood and covered by a sheet of LAGGING MATERIAL.

Other HEATING DEVICES are placed between sheets of LAGGING MATERIAL on a plywood base.

The size of the plywood is such that the LAGGING MATERIAL can be fully supported over its entire area. Unless otherwise specified, the size of the sheets of LAGGING MATERIAL is such that the edges extend at least 100 mm beyond the outline of the heated area.

NOTE The thickness of the sheets of LAGGING MATERIAL is determined as *d*. See Annex BB.

Annex FF
(normative)

Test procedure for maximum CONTACT SURFACE TEMPERATURE for FORCED AIR DEVICES

The purpose of this test is to determine the maximum CONTACT SURFACE TEMPERATURE generated by FORCED AIR DEVICES.

a) LAGGING MATERIAL

The LAGGING MATERIAL has the following characteristics:

Material:	Polyurethane or polystyrene insulation material;
Thermal resistance:	A minimum R-Value rating of 10 when tested in accordance with ASTM C578 [17];
Size:	Not less than the size of the active heating area of the test BLANKET and not less than 25 mm thick.

b) Sensor

The temperature monitoring sensor has the following characteristics:

Material:	Thermocouple or thermistor mounted in intimate thermal contact to a 65 mm × 65 mm × 0,5 mm copper plate;
Accuracy:	± 0,2 °C in the range from 20 °C to 60 °C;
Position:	Positioned at the point of the highest output temperature of the test BLANKET.

c) Test BLANKET

The inflated BLANKET is centred on the LAGGING MATERIAL.

The BLANKET edge containing the heater NOZZLE inlet is positioned 30 cm from the LAGGING MATERIAL edge.

The hottest spot of the BLANKET is positioned to contact the sensor.

d) Inlet HOSE and NOZZLE

If the inlet HOSE or NOZZLE has the potential to contact the PATIENT, the maximum contact temperature is tested by placing a sensor between the inlet HOSE or the NOZZLE and the LAGGING MATERIAL.

e) Overlying BLANKET

The overlying BLANKET is a BLANKET (e.g. hospital BLANKET) large enough to cover the active heating area of the test BLANKET and with sufficient weight to maintain contact with the test BLANKET.

The overlying BLANKET is centred over the active heating area of the test BLANKET and the LAGGING MATERIAL.

The edge of the overlying BLANKET nearest the heater NOZZLE inlet is positioned in line with the edge of the LAGGING MATERIAL.

f) Operating conditions

Ambient Temperature of 23 °C ± 2 °C in a draft-free room.

Heater control set to highest settings (temperature and airflow).

Tolerance on the heater control set to the highest temperature variation expected at the ambient temperature test condition.

Supply voltage set to deliver the highest temperature within the MANUFACTURER's specifications.

g) Time

Test the BLANKET until the temperatures stabilize (peak temperature does not increase more than 0,2 °C within 5 min).

h) Report

Report the maximum recorded CONTACT SURFACE TEMPERATURE for the test BLANKET.

Annex GG
(normative)

Test procedure for maximum CONTACT SURFACE TEMPERATURE for FORCED AIR DEVICES under SINGLE FAULT CONDITION

The purpose of this test is to determine the maximum CONTACT SURFACE TEMPERATURE in SINGLE FAULT CONDITION for FORCED AIR DEVICES.

a) LAGGING MATERIAL

Refer to Annex FF.

b) Sensor

Refer to Annex FF.

c) Test BLANKET

Refer to Annex FF.

d) Inlet HOSE and NOZZLE

Refer to Annex FF.

e) Overlying BLANKET

Refer to Annex FF.

f) Operating conditions

Ambient temperature of 23 °C ± 2 °C in a draft-free room.

Heater control set to highest setting (temperature and airflow).

Tolerance on the heater control set to the highest temperature variation expected at the ambient temperature test condition.

Supply voltage set to the lowest voltage allowed by the MANUFACTURER's specifications.

With the CONTROLLER adjusted to deliver the maximum allowable output air temperature, allow the CONTROLLER to operate until the output air temperature is equilibrated for 15 min.

g) SINGLE FAULT CONDITIONS

Establish conditions that cause the CONTROLLER heater to operate in an uncontrolled manner to generate the highest possible CONTACT SURFACE TEMPERATURES for the longest interval of time:

Select or adjust the THERMAL CUT-OUT to the maximum allowed for the CONTROLLER.

Select the lowest tolerances of the heating element.

Apply any SINGLE FAULT CONDITION that causes the heater to turn fully on.

Allow the CONTROLLER to run until THERMAL CUT-OUT activates.

h) Report

Report the maximum recorded contacted temperatures for the test BLANKET.

Record the time required for the THERMAL CUT-OUT to activate.

Annex HH
(normative)

Safety test procedure for average CONTACT SURFACE TEMPERATURE for FORCED AIR DEVICES

The purpose of this test is to determine the average CONTACT SURFACE TEMPERATURE generated by the FORCED AIR DEVICES.

a) LAGGING MATERIAL

Refer to Annex FF.

b) Sensor

Refer to Annex FF.

c) Sensor placement

Sensors are placed in a matrix on 130 mm centred on the LAGGING MATERIAL (see Figure HH.1).

The active heating area of the BLANKET is placed over the matrix, assuring that a sufficient number of sensors are employed to completely underlie the entire "footprint" or "shadow" of the active heating area.

The sensor array may be placed on a 3,175 MM Acrylic (PMMA) board and moved incrementally throughout the test to replicate the matrix under the active heating area.

d) Test BLANKET

Refer to Annex FF.

e) Overlying BLANKET

Refer to Annex FF.

f) Operating conditions

Ambient temperature of 23 °C ± 2 °C in a draft-free room (as defined in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 and ASTM F1690-96 [18]).

Heater control set to highest settings (temperature and airflow).

Tolerance on heater control set to the highest temperature variation expected at the ambient temperature test condition.

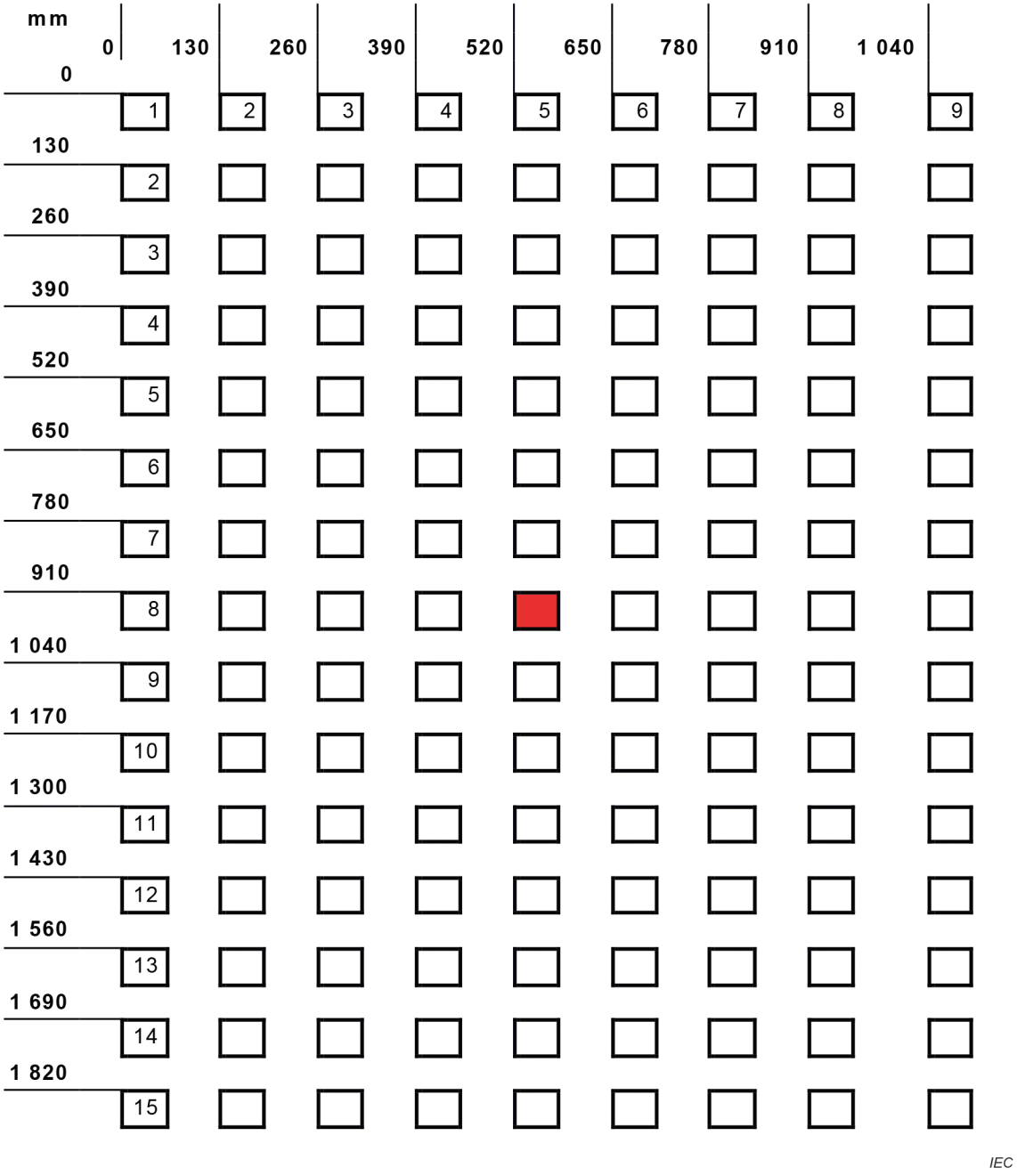
Supply voltage set to deliver the highest temperature within the MANUFACTURER's specifications.

g) Time

Test the BLANKET until the temperature stabilizes (the peak temperature does not increase more than 0,2 °C within 5 min.

h) Report

Report the average recorded CONTACT SURFACE TEMPERATURE for the active heating area of the test BLANKET.



Sensor plate array matrix 65 mm × 65 mm × 0,5 mm copper sensor plates, spaced on 130 mm centres

Figure HH.1 – Sensor locations – Average CONTACT SURFACE TEMPERATURE

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Index of defined terms used in this document

NATIONAL ANNEX JJ

(*National Foreword*)

JJ-1 BIS CERTIFICATION MARKING

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act*, 2016 and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.

(*Continued from second cover*)

The technical committee has reviewed the provisions of the following International Standard referred in this adopted standard and has decided that it is acceptable for use in conjunction with this standard:

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

This standard also makes a reference to the BIS Certification Marking of the product. Details of which are given in National Annex JJ.

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated, expressing the result of a test or analysis shall be rounded off in accordance with IS 2 : 2022 'Rules for rounding off numerical values (*second revision*)'. The number of significant places retained in the rounded off value should be same as that of the specified value in this standard.

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Review of Indian Standards

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This Indian Standard has been developed from Doc No.: MHD 15 (18000).

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