

INTERNATIONAL STANDARD

NORME INTERNATIONALE



Medical electrical equipment –

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

Appareils électromédicaux –

Partie 2-35: Exigences particulières pour la sécurité de base et les performances essentielles des dispositifs de réchauffage utilisant des couvertures, des coussins ou des matelas chauffants et destinés au réchauffage des patients en usage médical



THIS PUBLICATION IS COPYRIGHT PROTECTED

Copyright © 2009 IEC, Geneva, Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either IEC or IEC's member National Committee in the country of the requester.

If you have any questions about IEC copyright or have an enquiry about obtaining additional rights to this publication, please contact the address below or your local IEC member National Committee for further information.

Droits de reproduction réservés. Sauf indication contraire, aucune partie de cette publication ne peut être reproduite ni utilisée sous quelque forme que ce soit et par aucun procédé, électronique ou mécanique, y compris la photocopie et les microfilms, sans l'accord écrit de la CEI ou du Comité national de la CEI du pays du demandeur.

Si vous avez des questions sur le copyright de la CEI ou si vous désirez obtenir des droits supplémentaires sur cette publication, utilisez les coordonnées ci-après ou contactez le Comité national de la CEI de votre pays de résidence.

IEC Central Office
3, rue de Varembe
CH-1211 Geneva 20
Switzerland
Email: inmail@iec.ch
Web: www.iec.ch

About the IEC

The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

About IEC publications

The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigenda or an amendment might have been published.

- Catalogue of IEC publications: www.iec.ch/searchpub

The IEC on-line Catalogue enables you to search by a variety of criteria (reference number, text, technical committee,...). It also gives information on projects, withdrawn and replaced publications.

- IEC Just Published: www.iec.ch/online_news/justpub

Stay up to date on all new IEC publications. Just Published details twice a month all new publications released. Available on-line and also by email.

- Electropedia: www.electropedia.org

The world's leading online dictionary of electronic and electrical terms containing more than 20 000 terms and definitions in English and French, with equivalent terms in additional languages. Also known as the International Electrotechnical Vocabulary online.

- Customer Service Centre: www.iec.ch/webstore/custserv

If you wish to give us your feedback on this publication or need further assistance, please visit the Customer Service Centre FAQ or contact us:

Email: csc@iec.ch

Tel.: +41 22 919 02 11

Fax: +41 22 919 03 00

A propos de la CEI

La Commission Electrotechnique Internationale (CEI) est la première organisation mondiale qui élabore et publie des normes internationales pour tout ce qui a trait à l'électricité, à l'électronique et aux technologies apparentées.

A propos des publications CEI

Le contenu technique des publications de la CEI est constamment revu. Veuillez vous assurer que vous possédez l'édition la plus récente, un corrigendum ou amendement peut avoir été publié.

- Catalogue des publications de la CEI: www.iec.ch/searchpub/cur_fut-f.htm

Le Catalogue en-ligne de la CEI vous permet d'effectuer des recherches en utilisant différents critères (numéro de référence, texte, comité d'études,...). Il donne aussi des informations sur les projets et les publications retirées ou remplacées.

- Just Published CEI: www.iec.ch/online_news/justpub

Restez informé sur les nouvelles publications de la CEI. Just Published détaille deux fois par mois les nouvelles publications parues. Disponible en-ligne et aussi par email.

- Electropedia: www.electropedia.org

Le premier dictionnaire en ligne au monde de termes électroniques et électriques. Il contient plus de 20 000 termes et définitions en anglais et en français, ainsi que les termes équivalents dans les langues additionnelles. Egalement appelé Vocabulaire Electrotechnique International en ligne.

- Service Clients: www.iec.ch/webstore/custserv/custserv_entry-f.htm

Si vous désirez nous donner des commentaires sur cette publication ou si vous avez des questions, visitez le FAQ du Service clients ou contactez-nous:

Email: csc@iec.ch

Tél.: +41 22 919 02 11

Fax: +41 22 919 03 00

INTERNATIONAL STANDARD

NORME INTERNATIONALE



Medical electrical equipment –

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

Appareils électromédicaux –

Partie 2-35: Exigences particulières pour la sécurité de base et les performances essentielles des dispositifs de réchauffage utilisant des couvertures, des coussins ou des matelas chauffants et destinés au réchauffage des patients en usage médical

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

PRICE CODE
CODE PRIX

XB

ICS 11.140

ISBN 2-8318-1065-7

CONTENTS

FOREWORD.....	4
INTRODUCTION.....	7
201.1 Scope, object and related standards	8
201.2 Normative references.....	10
201.3 Terms and definitions.....	10
201.4 General requirements	13
201.5 General requirements for testing ME EQUIPMENT	14
201.6 Classification of ME EQUIPMENT and ME SYSTEMS.....	14
201.7 ME EQUIPMENT identification, marking and documents	14
201.8 Protection against electrical HAZARDS from ME EQUIPMENT	17
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS	22
201.10 Protection against unwanted and excessive radiation HAZARDS	24
201.11 Protection against excessive temperatures and other HAZARDS	24
201.12 Accuracy of controls and instruments and protection against hazardous outputs	27
201.13 HAZARDOUS SITUATIONS and fault conditions	32
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	37
201.15 Construction of ME EQUIPMENT.....	37
201.16 ME SYSTEMS	41
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	41
202 Electromagnetic compatibility – Requirements and tests	42
208 General requirements, tests and guidance for ALARM SYSTEMS in MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS.....	42
210 * Requirements for the development of physiologic closed-loop controllers	42
Annex D (informative) Symbols on marking.....	43
Annex AA (informative) Particular guidance and rationale.....	44
Annex BB (normative) Determination of the LAGGING MATERIAL	55
Annex CC (normative) *Determination of heat transfer towards the PATIENT	56
Annex DD (normative) *Determination of heat transfer away from the PATIENT	58
Annex EE (normative) Conditions of adequate heat discharge	59
Annex FF (normative) Test procedure for maximum CONTACT SURFACE TEMPERATURE for FORCED AIR DEVICES.....	60
Annex GG (normative) Test procedure for maximum CONTACT SURFACE TEMPERATURE for FORCED AIR DEVICES under SINGLE FAULT CONDITION.....	62
Annex HH (normative) Safety test procedure for average CONTACT SURFACE TEMPERATURE for FORCED AIR DEVICES.....	63
Bibliography.....	65
Index of defined terms used in this particular standard.....	66

Figure 201.101 – Positioning of temperature sensors on the contact surface of the heated area of a HEATING DEVICE (see 201.12.4.101 and 201.12.4.105)..... 11

Figure 201.102 – Example of the positioning of temperature sensors on the contact surface of the heated areas of a HEATING DEVICE having more than one separately heated area

Figure 201.103 a) – Apparatus for the spark ignition test – Detail A: The apparatus (see 201.8.8.4.101).....	19
Figure 201.103 b) – Apparatus for the spark ignition test – Detail B: Lower member of mask.....	20
Figure 201.103 c) – Apparatus for the spark ignition test – Detail C: Upper member of mask.....	20
Figure 201.103 – Apparatus for the spark ignition test	20
Figure 201.104 – Ramp for the impact test on PADS	23
Figure 201.105 – Partial covering conditions.....	25
Figure 201.106 – Method of folding BLANKETS	34
Figure 201.107 – Examples of folds	36
Figure 201.108 – Positions of a BLANKET for the RUCK-RESISTANCE test.....	41
Figure HH.1 – Sensor locations – Average CONTACT SURFACE TEMPERATURE.....	64
Table 201.101 – *Additional ESSENTIAL PERFORMANCE requirements	13
Table 201.102 – Temperature limits in dependency to time	38

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

FOREWORD

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as “IEC Publication(s)”). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
- 2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
- 3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
- 4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
- 5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
- 6) All users should ensure that they have the latest edition of this publication.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
- 8) Attention is drawn to the normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 80601-2-35 has been prepared by IEC technical committee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice, and subcommittee 1: Breathing attachments and anaesthetic machines, of ISO technical committee 121: Anaesthetic and respiratory equipment.

This second edition cancels and replaces the first edition published in 1996. This edition constitutes a technical revision.

This new edition provides consistency with the third edition of IEC 60601-1, as well as with the four other particular standards related to paediatric equipment for which the committee is responsible.

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

FDIS	Report on voting
62D/784A/FDIS	62D/804/RVD

Full information on the voting for the approval of this particular standard can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by 15 P-members out of 15 having cast a vote.

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

In this standard, the following print types are used:

- Requirements and definitions: roman type.
- *Test specifications: italic type.*
- Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

- “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
- “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 60601 series, published under the general title: *Medical electrical equipment* can be found on the IEC website.

The committee has decided that the contents of this particular standard will remain unchanged until the maintenance result date indicated on the IEC web site under "<http://webstore.iec.ch>" in the data related to the specific publication. At this date, the publication will be

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

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

INTRODUCTION

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

This particular standard amends and supplements IEC 60601-1 (third edition, 2005) *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*, hereinafter referred to as the general standard. The text of this particular standard relating to forced air warmers is based on ASTM F2196-02, *Standard specification for circulating liquid and forced air patient temperature management devices*.

The requirements are followed by specifications for the relevant tests.

A "general guidance and rationale" section giving some explanatory notes, where appropriate, about the more important requirements is included in Annex AA.

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

MEDICAL ELECTRICAL EQUIPMENT –

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

201.1 Scope, object and related standards

Clause 1 of the general standard¹⁾ applies, except as follows:

201.1.1 * Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of HEATING DEVICES using BLANKETS, PADS or MATTRESSES in medical use, also referred to as ME EQUIPMENT. HEATING DEVICES intended to prewarm a bed are included in the scope of this International Standard.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

If a clause or subclause is specifically intended to apply to a specifically defined type of ME EQUIPMENT, as is the case with FORCED AIR DEVICES, then the clause or subclause is entitled as such. Clauses or subclauses that apply to all types of ME EQUIPMENT within the scope of this standard are not specifically entitled.

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

NOTE See also 4.2 of the general standard.

This particular standard does not apply to:

- HEATING DEVICES intended for physiotherapy;
- radiant warmers; for information, see IEC 60601-2-21 [12]²⁾;
- incubators; for information, see IEC 60601-2-19 [10];
- transport incubators, for information, see IEC 60601-2-20 [11];
- cooling devices.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements, which minimize HAZARDS to PATIENTS, and OPERATORS for heating

¹⁾ The general standard is IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.

²⁾ Figures in square brackets refer to the Bibliography.

devices using BLANKETS, PADS or MATTRESSES and intended for heating in medical use and to specify tests for demonstrating compliance with these requirements.

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

IEC 60601-1-2, IEC 60601-1-8 and IEC 60601-1-10 apply as modified in Articles 202, 208 and 210 respectively. IEC 60601-1-3 does not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix "201" (e.g. 201.1 in this standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix "20x" where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

"Addition" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses or figures which are additional to those of the general standard are numbered starting from 201.101. However due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses or figures which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this standard" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

NOTE Informative references are listed in the Bibliography.

Clause 2 of the general standard applies, except as follows:

Amendment:

IEC 60601-1-2:2007, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*

IEC 60601-1-8:2006, *Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

ISO 14971:2007, *Medical devices – Application of risk management to medical devices*

Addition:

IEC 60601-1-10:2007, *Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers*

ISO 2439:2008, *Flexible cellular polymeric materials – Determination of hardness (indentation technique)*

ISO 3743-1:1994, *Acoustics – Determination of sound power levels of noise sources – Engineering methods for small, movable sources in reverberant fields – Part 1: Comparison method for hard-walled test rooms*

201.3 Terms and definitions

NOTE An index of defined terms used in this document is found beginning on page 66.

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, apply, except as follows:

Addition:

201.3.201

BLANKET

for FORCED AIR DEVICES, APPLIED PART of HEATING DEVICE intended to be used with a CONTROLLER to transfer thermal energy to all or part of the body of a PATIENT; for other than FORCED AIR DEVICES, APPLIED PART of HEATING DEVICE, which can be folded, for use under or over a PATIENT

201.3.202

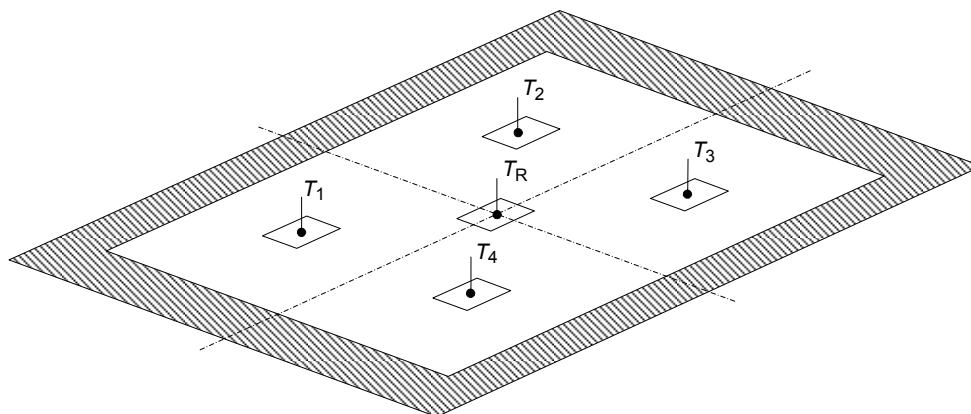
CONDITIONS OF ADEQUATE HEAT DISCHARGE

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

201.3.203**CONTACT SURFACE TEMPERATURE**

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

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



IEC 1992/09

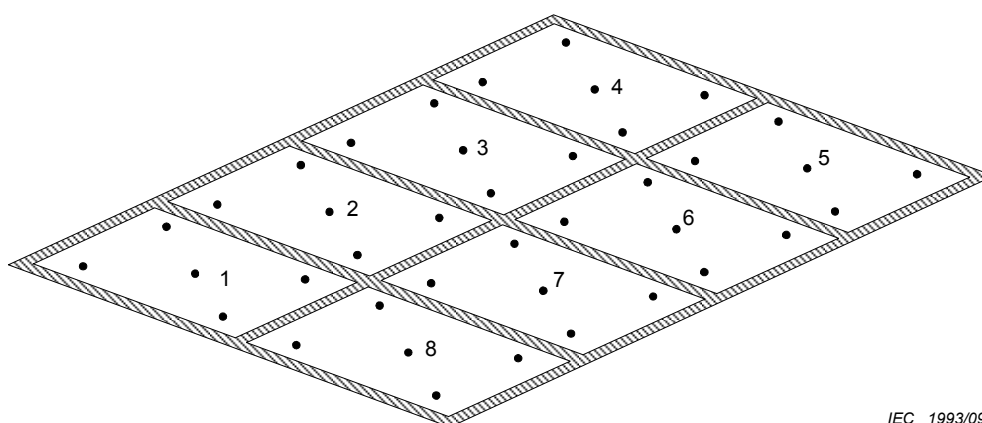
Key

T_R CONTACT SURFACE TEMPERATURE reference point on the contact surface

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



Figure 201.101 – Positioning of temperature sensors on the contact surface of the heated area of a HEATING DEVICE
(see 201.12.4.101 and 201.12.4.105)



IEC 1993/09

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

Figure 201.102 – Example of the positioning of temperature sensors on the contact surface of the heated areas of a HEATING DEVICE having more than one separately heated area

201.3.204

CONTROLLER

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

NOTE This includes the HOSE, if present.

201.3.205

FORCED AIR DEVICE

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

201.3.206

FREE HOSING

hazardous practice or condition of using the CONTROLLER without a BLANKET

201.3.207

HEATING DEVICE

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

201.3.208

HIGH HEAT TRANSFER

thermal characteristic of a HEATING DEVICE as determined according to Annex CC or Annex DD

201.3.209

HOSE

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

201.3.210

INFANT

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

201.3.211

LAGGING MATERIAL

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

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

201.3.212

LOW HEAT TRANSFER

thermal characteristic of a HEATING DEVICE as determined according to Annex CC or Annex DD

201.3.213

MATTRESS

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

201.3.214

NOZZLE

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

201.3.215

OVER-BLANKET

BLANKET designed to be used over a PATIENT

201.3.216**PAD**

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

201.3.217**RUCK**

an unintended fold in a normally even surface

201.3.218**RUCK-RESISTANT BLANKET**

BLANKET having a construction such that RUCKING of the flexible part is unlikely

201.3.219**UNDER-BLANKET**

BLANKET designed to be used under a PATIENT

201.4 General requirements

Clause 4 of the general standard applies except as follows:

201.4.3 ESSENTIAL PERFORMANCE

Addition:

201.4.3.101 Additional requirements for ESSENTIAL PERFORMANCE

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

Table 201.101 – *Additional ESSENTIAL PERFORMANCE requirements

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

201.4.5 Equivalent safety for ME EQUIPMENT or ME SYSTEMS

Addition:

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

Additional subclause:

201.4.101 Combination of equipment

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

201.5 General requirements for testing ME EQUIPMENT

Clause 5 of the general standard applies.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

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

201.6.2 Protection against electric shock

Amendment:

Replace the last paragraph with the following:

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

201.7 ME EQUIPMENT identification, marking and documents

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

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

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

Addition:

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

201.7.2.1.101.1 HEATING DEVICES (other than for FORCED AIR DEVICES)

A HEATING DEVICE shall be marked as follows:

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

201.7.2.1.101.2 CONTROLLERS

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

- a) The HOSE shall be marked within 15 cm of NOZZLE to caution that the NOZZLE needs to be connected to a BLANKET. The following statement shall accompany the “NO FREE HOSING” safety sign (11), shown in Annex D of this particular standard:
“CAUTION! Hose nozzle MUST 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

(See also 201.12).

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

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

201.7.9.2.2 Warning and safety notices

Addition:

201.7.9.2.2.101 Additional requirements for warning and safety notices

The instructions for use shall additionally contain the following:

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

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

201.7.9.2.9 Operating instructions

Addition:

201.7.9.2.9.101 Additional requirements for start-up PROCEDURE

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

201.7.9.2.9.102 Additional requirements for operating instructions

The following shall appear in the instructions for use:

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

201.7.9.2.9.103 Additional requirements for operating instructions for BLANKETS

The instructions for use for BLANKETS shall contain the following:

- a) a description of system operating modes and PATIENT conditions where the system can be safely used;
- b) a statement that the OPERATOR should monitor the temperature of the PATIENT at regular intervals;
- c) an indication of how the BLANKET is to be positioned during NORMAL USE e.g.:

- i) over the PATIENT,
 - ii) under the PATIENT,
 - iii) directly in contact with the PATIENT,
 - iv) separated from the PATIENT by an intermediate layer, or layers, of material,
 - v) whether it has to be used flat (without creases),
 - vi) whether it can be wrapped around the PATIENT.
- d) *a statement identifying which CONTROLLER(S) can be used safely with the BLANKET. The description shall include, as applicable, the CONTROLLER model number, revision level, product version, options or any other element that could affect the safety of the combination;
- e) *a warning against using the device distal to arterial cross clamping;
- NOTE BLANKETS can be used proximal to the clamped artery without any additional RISK.
- f) a warning describing the possible HAZARD of using the device with ischemic limbs.

201.7.9.2.9.104 Additional requirements for operating instructions for temperature sensors

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

201.7.9.2.13 Maintenance

Addition:

201.7.9.2.13.101 Additional requirements for maintenance

The following shall appear in the documentation:

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

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

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

201.8.1 *Fundamental rule of protection against electric shock

b) SINGLE FAULT CONDITION includes:

Addition:

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

201.8.5.1.2 MEANS OF PATIENT PROTECTION (MOPP)

Addition:

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

A HEATING DEVICE that has an electrical circuit within the APPLIED PART shall incorporate an isolating transformer according to 15.5, excluding 15.5.3 and complying with the following:

A transformer with an output-winding which is electrically separated from earth and the body of the transformer by at least BASIC INSULATION and which is electrically separated from the input-winding by an insulation at least equivalent to DOUBLE INSULATION or REINFORCED INSULATION.

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 $100\text{ cm} \times 30\text{ cm}$ shall be used; or
- b) for an APPLIED PART whose area is less than $100\text{ cm} \times 30\text{ cm}$, the whole APPLIED PART shall be covered by foil.
- c) For a liquid-filled MATTRESS heated by circulation of liquid from a remote unit the liquid is replaced by isotonic saline (0,9 g sodium chloride per liter of water). The PATIENT LEAKAGE CURRENT is measured using an electrode $5\text{ mm} \times 5\text{ mm}$ 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

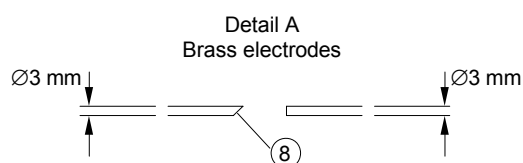
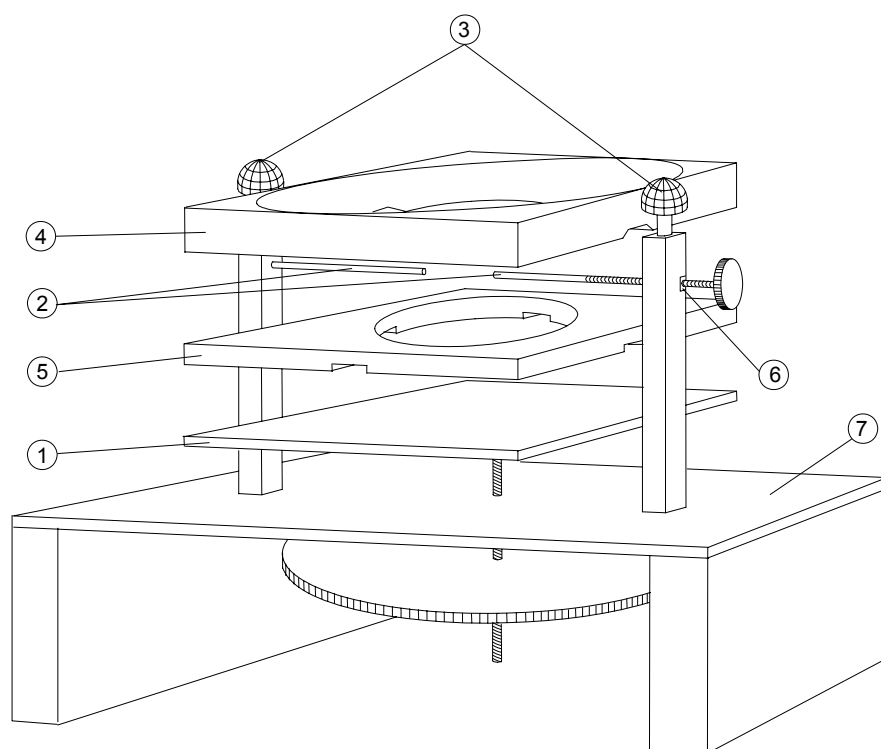
Additional subclauses:

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 $100\text{ mm} \times 200\text{ mm}$ 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 $100\text{ mm} \times 100\text{ mm}$, which is located centrally between the brass pillars. Provision shall be made for the height of the platform to be adjusted.



IEC 1994/09

Key

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

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

Dimensions in mm

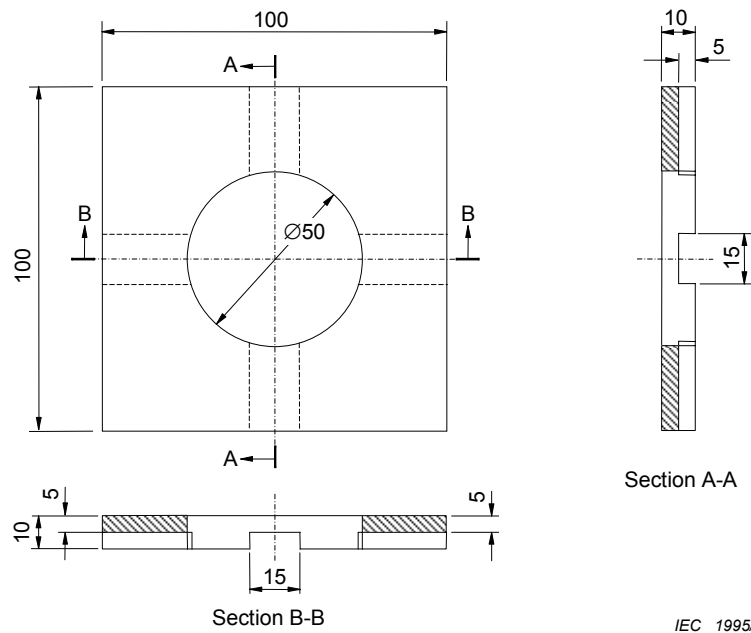
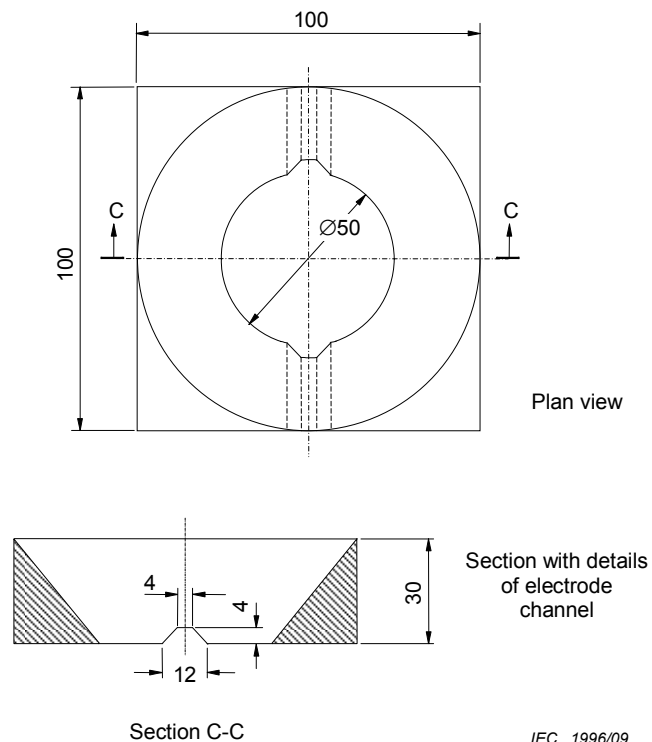


**Figure 201.103 b) – Apparatus for the spark ignition test –
Detail B: lower member of mask**

Dimensions in mm



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.

**Figure 201.103 c) – Apparatus for the spark ignition test –
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 201.103b, 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 201.103b 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 fibers 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 MAINS PARTS, components and layout

201.8.11.1.101 * Isolation from the SUPPLY MAINS

Addition:

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

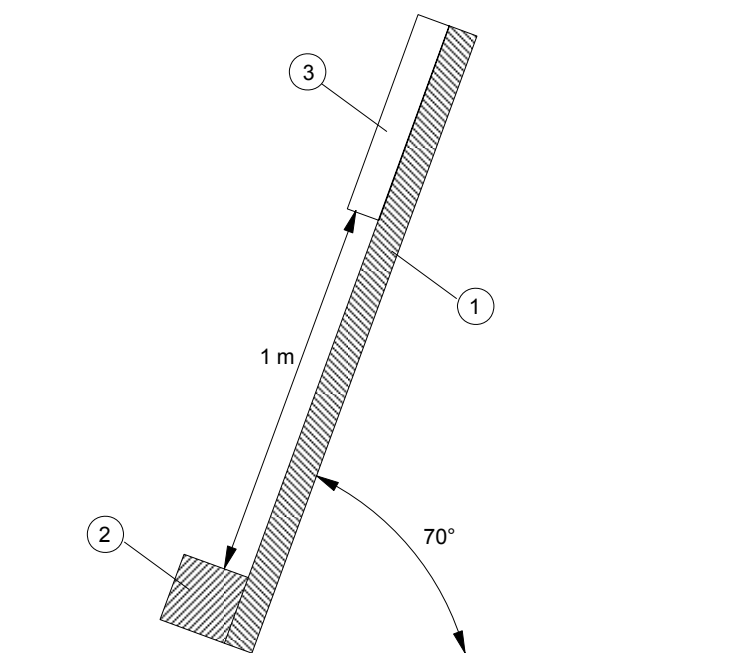
Clause 9 of the general standard applies, except as follows:

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.



IEC 1997/09

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 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 center of the supports and mounting brackets, e.g. 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 Excessive temperatures in ME EQUIPMENT**201.11.1.2.1 APPLIED PARTS intended to supply heat to a PATIENT**

Addition:

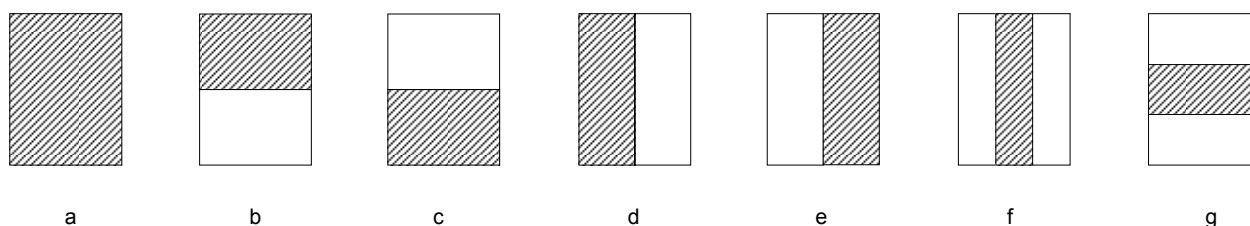
201.11.1.2.1.101 Requirements for HEATING DEVICES other than FORCED AIR DEVICES**201.11.1.2.1.101.1 Maximum CONTACT SURFACE TEMPERATURE in NORMAL CONDITION**

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.



IEC 1998/09

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 EQUIPEMENT 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 (0,9 g sodium chloride per liter 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 standard 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 r.m.s or less shall be at least to IP X2. ME EQUIPMENT using higher voltages shall be to IP X7.

NOTE See also Clause 4 of IEC 60529).

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-enriched 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 $36\text{ °C} \pm 0,2\text{ °C}$.

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 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) $\pm 2,5$ °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 unfavorable 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 $23\text{ °C} \pm 2\text{ °C}$. Four temperature sensors conductively attached to copper plates $65\text{ mm} \times 65\text{ mm} \times 0,5\text{ mm}$, 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) $\pm 0,5\text{ °C}$ in the case of HIGH HEAT TRANSFER HEATING DEVICES; or
- b) $\pm 1\text{ °C}$ 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 $0,1\text{ °C}$).

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 $\pm 0,7$ °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

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 unfavorable 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.

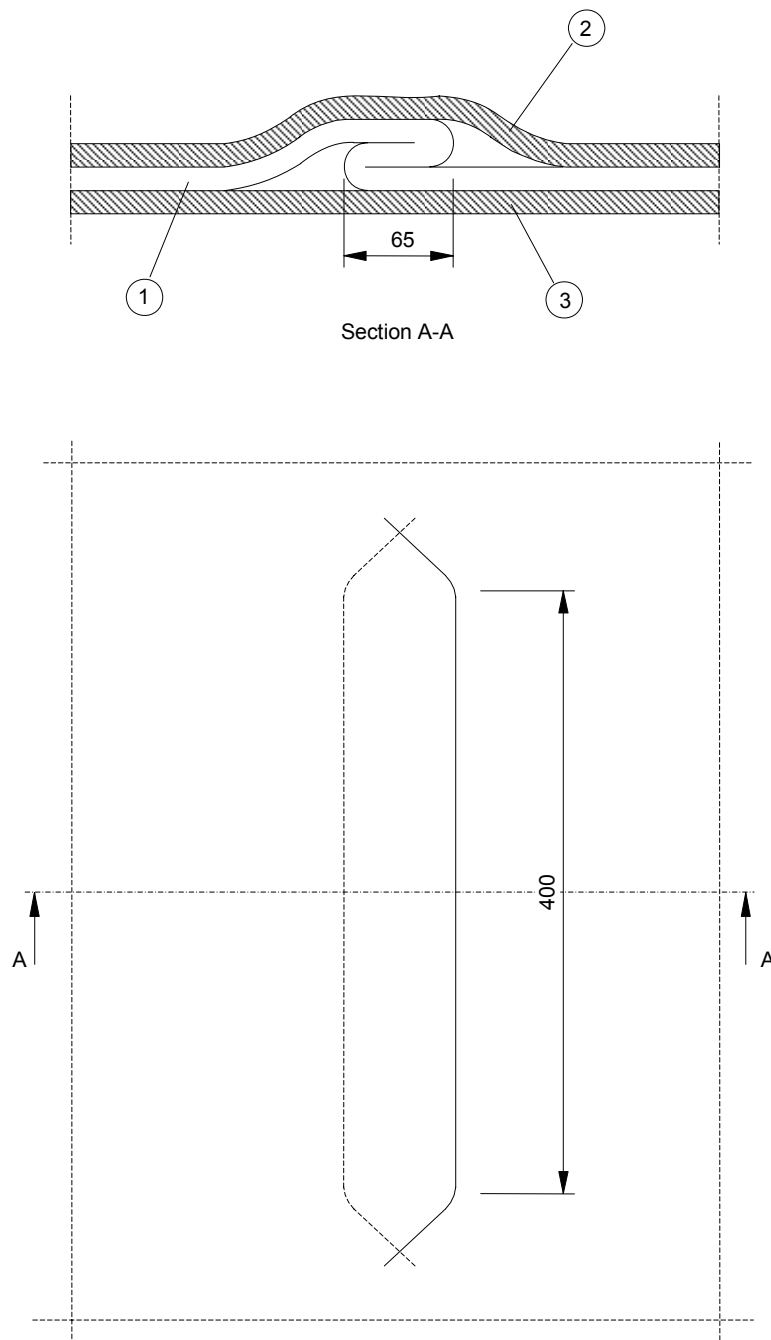
NOTE 1 Rupture of a heating element or of an intentionally weak part in the second sample does not in itself entail a rejection.

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 International Standard. 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 unfavorable 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 unfavorable position.

Dimensions in mm



IEC 1999/09

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 unfavorable 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 unfavorable result.

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

The LAGGING MATERIAL has a thickness of approximately $0,2 d$ as specified in Annex BB. 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 unfavorable position that allows the folds to be completely covered.

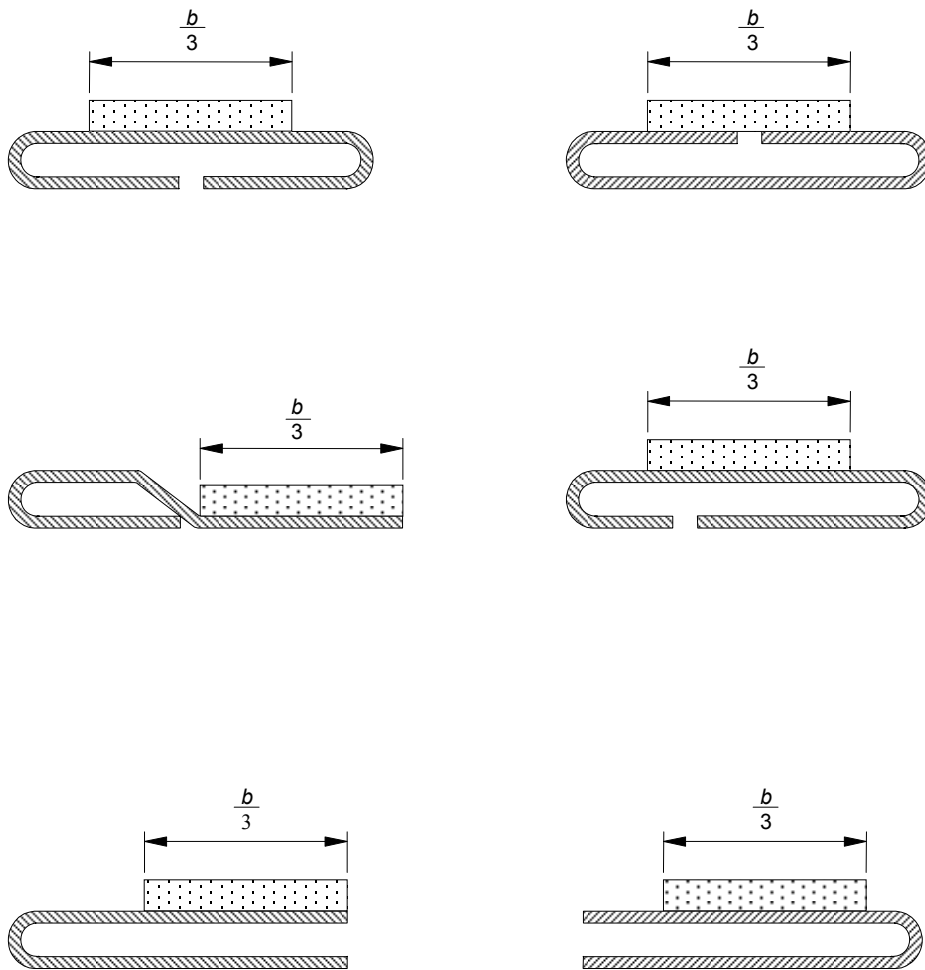
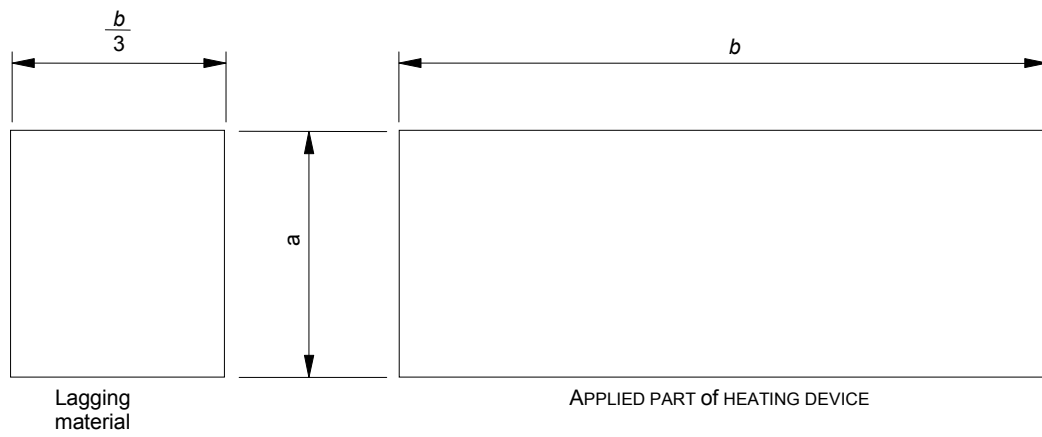
Test 4

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 unfavorable 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 unfavorable result.

The upper surface of the flexible part is uncovered or partially covered by a sheet of LAGGING MATERIAL, whichever is the more unfavorable. 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. It is placed in the most unfavorable 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.



IEC 2000/09

Key

- a is the width of the APPLIED PART of HEATING DEVICE
- b is the length of the APPLIED PART of 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 201.11.1.2.1.103 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 *Connection of PEMS by NETWORK/DATA COUPLING to other equipment

Amendment:

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.

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 the following table, 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



Contact Surface Temperature (°C)	Maximum (s)
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 42 °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 may 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 may 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 fulfill 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 201.15.4.1.102.2.

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.

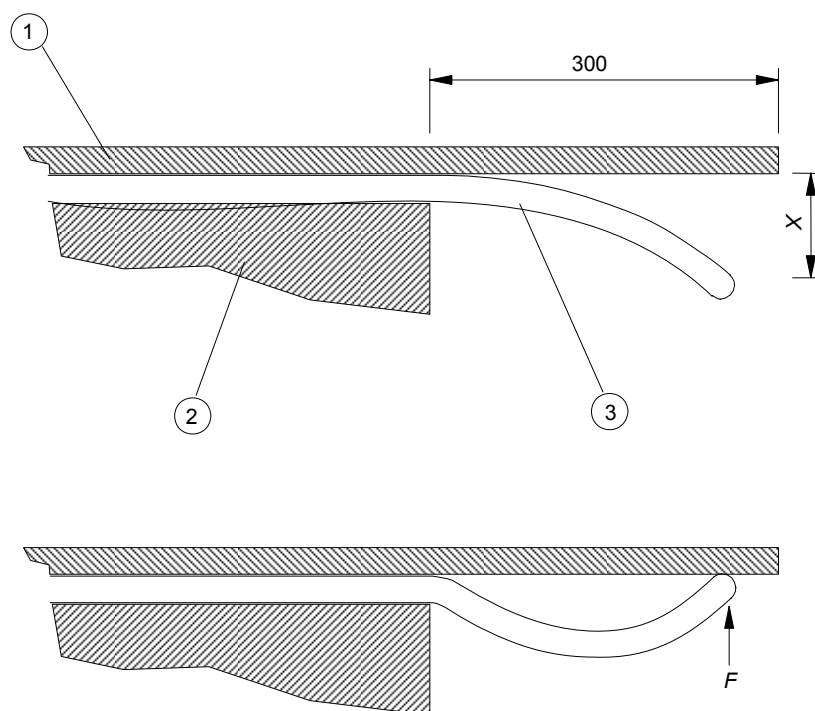
201.15.4.102 Ruck-resistant blankets

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 mm



IEC 2001/09

Key

- X is the deflection in metres, of the overhanging corner of the flexible part.
- F is the 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.