

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
essentielle 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 It also gives information on projects, withdrawn and replaced publications.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
essentielle 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 **XB**
CODE PRIX

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	11
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

Witholded

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 first edition cancels and replaces IEC 60601-2-35:1996. 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.

The contents of the corrigenda of March 2012 and February 2015 have been included in this copy.

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.

Withdrawn

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.

Withdrawing