

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
essentiels des dispositifs de réchauffage utilisant des couvertures, des
coussins ou des matelas et destinés au réchauffage des patients en usage
médical**



THIS PUBLICATION IS COPYRIGHT PROTECTED

Copyright © 2020 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 l'IEC ou du Comité national de l'IEC du pays du demandeur. Si vous avez des questions sur le copyright de l'IEC ou si vous désirez obtenir des droits supplémentaires sur cette publication, utilisez les coordonnées ci-après ou contactez le Comité national de l'IEC de votre pays de résidence.

IEC Central Office
3, rue de Varembe
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
info@iec.ch
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 corrigendum or an amendment might have been published.

IEC publications search - webstore.iec.ch/advsearchform

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 It also gives information on projects, replaced and withdrawn publications.

IEC Just Published - webstore.iec.ch/justpublished

Stay up to date on all new IEC publications. Just Published details all new publications released. Available online and once a month by email.

IEC Customer Service Centre - webstore.iec.ch/csc

If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: sales@iec.ch.

IEC online collection - oc.iec.ch

Discover our powerful search engine and read freely all the publications previews. With a subscription you will always have access to up to date content tailored to your needs.

Electropedia - www.electropedia.org

The world's leading online dictionary on electrotechnology, containing more than 22 000 terminological entries in English and French, with equivalent terms in 18 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

A propos de l'IEC

La Commission Electrotechnique Internationale (IEC) 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 IEC

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

Recherche de publications IEC - webstore.iec.ch/advsearchform

La recherche avancée permet de trouver des publications IEC en utilisant différents critères (numéro de référence, texte, comité d'études, ...). Elle donne aussi des informations sur les projets et les publications remplacées ou retirées.

IEC Just Published - webstore.iec.ch/justpublished

Restez informé sur les nouvelles publications IEC. Just Published détaille les nouvelles publications parues. Disponible en ligne et une fois par mois par email.

Service Clients - webstore.iec.ch/csc

Si vous désirez nous donner des commentaires sur cette publication ou si vous avez des questions contactez-nous: sales@iec.ch.

IEC online collection - oc.iec.ch

Découvrez notre puissant moteur de recherche et consultez gratuitement tous les aperçus des publications. Avec un abonnement, vous aurez toujours accès à un contenu à jour adapté à vos besoins.

Electropedia - www.electropedia.org

Le premier dictionnaire d'électrotechnologie en ligne au monde, avec plus de 22 000 articles terminologiques en anglais et en français, ainsi que les termes équivalents dans 16 langues additionnelles. Egalement appelé Vocabulaire Electrotechnique International (IEV) en ligne.

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 et destinés au réchauffage des patients en usage
médical**

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

ICS 11.040.01; 11.140

ISBN 978-2-8322-1015-8

**Warning! Make sure that you obtained this publication from an authorized distributor.
Attention! Veuillez vous assurer que vous avez obtenu cette publication via un distributeur agréé.**

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	18
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS	24
201.10 Protection against unwanted and excessive radiation HAZARDS	26
201.11 Protection against excessive temperatures and other HAZARDS	26
201.12 Accuracy of controls and instruments and protection against hazardous outputs	28
201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT	33
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS).....	38
201.15 Construction of ME EQUIPMENT.....	38
201.16 ME SYSTEMS	42
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	42
202 ELECTROMAGNETIC DISTURBANCES – Requirements and tests.....	43
208 General requirements, tests and guidance for ALARM SYSTEMS IN MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS	43
210 * Requirements for the development of PHYSIOLOGIC CLOSED-LOOP CONTROLLERS	43
Annexes	44
Annex D (informative) Symbols on marking.....	44
Annex AA (informative) Particular guidance and rationale.....	45
Annex BB (normative) Determination of the LAGGING MATERIAL	57
Annex CC (normative) * Determination of heat transfer towards the PATIENT	58
Annex DD (normative) * Determination of heat transfer away from the PATIENT	60
Annex EE (normative) CONDITIONS OF ADEQUATE HEAT DISCHARGE	61
Annex FF (normative) Test procedure for maximum CONTACT SURFACE TEMPERATURE for FORCED AIR DEVICES.....	62
Annex GG (normative) Test procedure for maximum CONTACT SURFACE TEMPERATURE for FORCED AIR DEVICES under SINGLE FAULT CONDITION.....	64
Annex HH (normative) Safety test procedure for average CONTACT SURFACE TEMPERATURE for FORCED AIR DEVICES.....	65
Bibliography.....	67
Index of defined terms used in this document	69
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	12
Figure 201.103 – Apparatus for the spark ignition test	22
Figure 201.104 – Ramp for the impact test on PADS	24
Figure 201.105 – Partial covering conditions.....	26
Figure 201.106 – Method of folding BLANKETS	35
Figure 201.107 – Examples of folds	37
Figure 201.108 – Positions of a BLANKET for the RUCK-RESISTANCE test.....	42
Figure AA.1 – Illustration of the main requirements of this document	45
Figure HH.1 – Sensor locations – Average CONTACT SURFACE TEMPERATURE.....	66
Table 201.101 – * Additional ESSENTIAL PERFORMANCE requirements	14
Table 201.102 – Temperature limits in dependency to time.....	39

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 60601-2-35 has been prepared by IEC technical committee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

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

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

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

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

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

In this document, the following print types are used:

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

In referring to the structure of this document, the term

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

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

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

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

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

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

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

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

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

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

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

INTRODUCTION

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

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

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 part of 60601 International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of HEATING DEVICES using BLANKETS, PADS or MATTRESSES in medical use, also referred to as ME EQUIPMENT. HEATING DEVICES intended to prewarm a bed are included in the scope of this document.

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

If a clause or subclause is specifically intended to be applicable to a specifically defined type of ME EQUIPMENT, as is the case with FORCED AIR DEVICES, then the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

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

NOTE See also 4.2 of the general standard.

This document does not apply to:

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

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

² Figures in square brackets refer to the Bibliography.