

# INTERNATIONAL STANDARD

## NORME INTERNATIONALE

**Medical electrical equipment –  
Part 2-46: Particular requirements for the basic safety and essential performance  
of operating tables**

**Appareils électromédicaux –  
Partie 2-46: Exigences particulières pour la sécurité de base et les performances  
essentielle des tables d'opération**



**THIS PUBLICATION IS COPYRIGHT PROTECTED**  
**Copyright © 2010 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](mailto:inmail@iec.ch)  
Web: [www.iec.ch](http://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](http://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 It also gives information on projects, withdrawn and replaced publications.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](http://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](http://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](http://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](mailto: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](http://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](http://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](http://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](http://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](mailto:csc@iec.ch)

Tél.: +41 22 919 02 11

Fax: +41 22 919 03 00

# INTERNATIONAL STANDARD

## NORME INTERNATIONALE

**Medical electrical equipment –  
Part 2-46: Particular requirements for the basic safety and essential performance  
of operating tables**

**Appareils électromédicaux –  
Partie 2-46: Exigences particulières pour la sécurité de base et les performances  
essentielle des tables d'opération**

INTERNATIONAL  
ELECTROTECHNICAL  
COMMISSION

COMMISSION  
ELECTROTECHNIQUE  
INTERNATIONALE

PRICE CODE  
CODE PRIX

R

ICS 11.140

ISBN 978-2-88912-290-5

## CONTENTS

FOREWORD.....	3
INTRODUCTION .....	5
201.1 Scope, object and related standards.....	6
201.2 Normative references.....	8
201.3 Terms and definitions.....	8
201.4 General requirements.....	9
201.5 General requirements for testing ME EQUIPMENT .....	9
201.6 Classification of ME EQUIPMENT and ME SYSTEMS.....	9
201.7 ME EQUIPMENT identification, marking and documents.....	9
201.8 Protection against electrical HAZARDS from ME EQUIPMENT.....	10
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS.....	10
201.10 Protection against unwanted and excessive radiation HAZARDS.....	13
201.11 Protection against excessive temperatures and other HAZARDS.....	13
201.12 Accuracy of controls and instruments and protection against hazardous outputs.....	13
201.13 Hazardous situations and fault conditions.....	13
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) .....	13
201.15 Construction of ME EQUIPMENT.....	14
201.16 ME SYSTEMS .....	14
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS.....	14
202 Electromagnetic compatibility – Requirements and tests.....	14
Annexes.....	16
Annex G (normative) Protection against HAZARDS of ignition of flammable anaesthetic mixtures.....	16
Annex AA (informative) Particular guidance and rationale.....	17
Index of defined terms used in this particular standard.....	19
Figure AA.1 – Recommended distribution of mass in excess of 135 kg and examples of application.....	17
Table 201.101 – Determination of TENSILE SAFETY FACTOR.....	12
Table AA.1 – Recommended distribution of mass in excess of 135 kg and examples of application:.....	18

## INTERNATIONAL ELECTROTECHNICAL COMMISSION

## MEDICAL ELECTRICAL EQUIPMENT –

**Part 2-46: Particular requirements for the basic safety  
and essential performance of operating tables**

## 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 60601-2-46 has been prepared by IEC subcommittee 62D Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces the first edition published in 1998 and constitutes a technical revision. This edition of IEC 60601-2-46 was revised to align structurally with the 2005 edition of IEC 60601-1.

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

FDIS	Report on voting
62D/870/FDIS	62D/888/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.

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 publication will remain unchanged until the stability 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.

## INTRODUCTION

This particular standard concerns the BASIC SAFETY and ESSENTIAL PERFORMANCE of OPERATING TABLES. It 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 aim of this third edition is to bring this particular standard up to date with reference to the third edition of the general standard through reformatting and technical changes.

The requirements of this particular standard take priority over those of the general standard.

A “General guidance and rationale” for the more important requirements of this particular standard is included in Annex AA. It is considered that knowledge of the reasons for these requirements will not only facilitate the proper application of the standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However, Annex AA does not form part of the requirements of this Standard.

Withdrawn

## MEDICAL ELECTRICAL EQUIPMENT –

### Part 2-46: Particular requirements for the basic safety and essential performance of operating tables

#### 201.1 Scope, object and related standards

Clause 1 of the general standard<sup>1)</sup> applies, except as follows:

##### 201.1.1 Scope

*Replacement:*

This particular standard specifies safety requirements for OPERATING TABLES, whether or not having electrical parts, including TRANSPORTERS, used for the transportation of the table top to or from the base or pedestal of an OPERATING TABLE with detachable table top.

NOTE See also 4.2 of the General Standard.

This particular standard does not apply to

- dental patient chairs;
- examination chairs and couches;
- patient-supporting systems of diagnostic and therapeutic devices;
- OPERATING TABLE heating blankets;
- patient transfer equipment;
- delivery tables and beds;
- medical beds;
- field tables.

NOTE If OPERATING TABLES will be used in combination with diagnostic and/or therapeutic devices the relevant requirements of each particular standard have to be considered.

##### 201.1.2 Object

*Replacement:*

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for OPERATING TABLES as defined in 201.3.201 and hereinafter also referred to as ME EQUIPMENT.

##### 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.

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