

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
essentielles des tables d'opération

<https://standards.iteh.ai/catalog/standards/iec/3a8f0e9f-31df-4e63-b204-a0f30c038050/iec-60601-2-46-2023>



THIS PUBLICATION IS COPYRIGHT PROTECTED

Copyright © 2023 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 Secretariat
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 It also gives information on projects, replaced and withdrawn publications.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 Products & Services Portal - products.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 22 300 terminological entries in English and French, with equivalent terms in 19 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 Products & Services Portal - products.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 22 300 articles terminologiques en anglais et en français, ainsi que les termes équivalents dans 19 langues additionnelles. Egalement appelé Vocabulaire Electrotechnique International (IEV) en ligne.



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

<https://standards.iteh.ai/catalog/standards/iec/3a8f0e9f-31df-4e63-b204-a0f30c038050/iec-60601-2-46-2023>

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

ICS 11.140

ISBN 978-2-8322-7028-8

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.....	3
INTRODUCTION.....	6
201.1 Scope, object and related standards	7
201.2 Normative references.....	9
201.3 Terms and definitions.....	9
201.4 General requirements	10
201.5 General requirements for testing ME EQUIPMENT.....	10
201.6 Classification of ME EQUIPMENT and ME SYSTEMS	10
201.7 ME EQUIPMENT identification, marking and documents	11
201.8 Protection against electrical HAZARDS from ME EQUIPMENT.....	11
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS.....	11
201.10 Protection against unwanted and excessive radiation HAZARDS	14
201.11 Protection against excessive temperatures and other HAZARDS	14
201.12 Accuracy of controls and instruments and protection against hazardous outputs	15
201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT	15
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS).....	15
201.15 Construction of ME EQUIPMENT	15
201.16 ME SYSTEMS.....	15
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	15
202 Electromagnetic disturbances – Requirements and tests	16
203 *Radiation protection in diagnostic X-ray equipment	19
Annexes	20
Annex G (normative) Protection against HAZARDS of ignition of flammable anaesthetic mixtures.....	21
Annex AA (informative) Particular guidance and rationale.....	22
Bibliography.....	26
Index of defined terms used in this particular standard.....	27
Figure 202.101 – ENCLOSURE ad hoc test.....	17
Figure 202.102 – POWER SUPPLY CORD ad hoc test.....	18
Figure 202.103 – ACCESSORY cable ad hoc test	18
Figure AA.1 – Recommended distribution of mass in excess of 135 kg and examples of application	22
Figure AA.2 – Typical stress-strain curve.....	24
Figure AA.3 – Typical bending line along the length L_0 of a beam	24
Table 201.101 – Determination of TENSILE SAFETY FACTOR.....	13
Table AA.1 – Recommended distribution of mass in excess of 135 kg and examples of application	23

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.

IEC 60601-2-46 has been prepared by subcommittee 62D: Particular medical equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems. It is an International Standard.

This fourth edition cancels and replaces the third edition published in 2016. This edition constitutes a technical revision.

This edition includes the following significant technical change with respect to the previous edition: structural alignment with IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

The text of this International Standard is based on the following documents:

Draft	Report on voting
62D/1939/CDV	62D/1989/RVC

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications.

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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 AND IEC 60601-1:2005/AMD2:2020, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this document, the term

- "clause" means one of the 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 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 document will remain unchanged until the stability date indicated on the IEC website under 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.

iTeh Standards
(<https://standards.iteh.ai>)
Document Preview

[IEC 60601-2-46:2023](#)

<https://standards.iteh.ai/catalog/standards/iec/3a8f0e9f-31df-4e63-b204-a0f30c038050/iec-60601-2-46-2023>

INTRODUCTION

This particular standard concerns the BASIC SAFETY and ESSENTIAL PERFORMANCE of OPERATING TABLES.

It amends and supplements IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

The aim of this document is to update it with reference to IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 through reformatting and technical changes.

The requirements of this particular standard take priority over those of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

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 document.

iTeh Standards
(<https://standards.iteh.ai>)
Document Preview

[IEC 60601-2-46:2023](#)

<https://standards.iteh.ai/catalog/standards/iec/3a8f0e9f-31df-4e63-b204-a0f30c038050/iec-60601-2-46-2023>

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

IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, Clause 1, applies, except as follows:

201.1.1 Scope

Replacement:

This part of IEC 60601 specifies safety requirements for OPERATING TABLES, whether or not having electrical parts, including TRANSPORTERS, used for the transportation of the OPERATING TABLE top to or from the base or pedestal of an OPERATING TABLE with detachable OPERATING TABLE top.

NOTE See also IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 4.2.

This particular standard does not apply to

- dental PATIENT chairs (see ISO 7494-1),
- examination chairs and couches,
- PATIENT-supporting systems of diagnostic, interventional and therapeutic equipment (see IEC 60601-2-54 or IEC 60601-2-43),
- OPERATING TABLE heating blankets (see IEC 60601-2-35),
- PATIENT transfer equipment,
- delivery tables and delivery beds,
- medical beds (see IEC 60601-2-52 and EN 50637), and
- field tables.

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 201.3.203.

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, Clause 2, and Clause 201.2 of this particular standard.

IEC 60601-1-2 and IEC 60601-1-3 apply as modified in Clauses 202 and 203 respectively. IEC 60601-1-8, IEC 60601-1-9, IEC 60601-1-10, IEC 60601-1-11 and IEC 60601-1-12 do 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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

The numbering of clauses and subclauses of this particular standard corresponds to that of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 with the prefix "201" (e.g. 201.1 in this document addresses the content of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, Clause 1) 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 IEC 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and applicable collateral standards are specified by the use of the following words:

"Replacement" means that the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard.

"Amendment" means that the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered starting from 201.101. However, due to the fact that definitions in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered 3.1 through 3.154, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

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

The term "this document" is used to make reference to IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 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

IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, Clause 2, applies, except as follows:

Replacement:

IEC 60601-1-3:2008, *Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral standard: Radiation protection in diagnostic X-ray equipment*
Amendment 1:2013
Amendment 2:2021

ISO 2878:2017, *Rubber, vulcanized or thermoplastic – Antistatic and conductive products – Determination of electrical resistance*

Addition:

IEC 60601-2-2:2017, *Medical electrical equipment – Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories*

IEC 60601-2-43:2022, *Medical electrical equipment – Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures*

IEC 60601-2-54:2022, *Medical electrical equipment – Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- IEC Electropedia: available at <https://www.electropedia.org/>
- ISO Online browsing platform: available at <https://www.iso.org/obp>

NOTE An index of defined terms is found on page 28.

Addition:

201.3.201

MOBILE OPERATING TABLE

OPERATING TABLE intended to be relocated from one location to another while supported by its own wheels or equivalent means

201.3.202

NORMAL POSITION

position of the OPERATING TABLE top with all sections set in the horizontal position

201.3.203**OPERATING TABLE**

device with the INTENDED USE of supporting and positioning a PATIENT during surgical procedures for not more than 24 h

Note 1 to entry: This includes pre- and post-operative phases in general, surgical/medical procedures under medical supervision.

Note 2 to entry: The device may serve as a PATIENT-supporting systems during diagnostic, interventional and therapeutic procedures but still considered to be a separate ME EQUIPMENT.

201.3.204**TRANSPORTER**

device intended for the transportation of an OPERATING TABLE top to or from the base or pedestal of an OPERATING TABLE, or the transportation of the OPERATING TABLE top complete with the base

Note 1 to entry: This definition does not include devices intended to simplify the transport of the PATIENT from one location to another without the transfer of parts associated with an OPERATING TABLE.

Note 2 to entry: The transportation can be done with or without a PATIENT in place.

201.3.205**TRENDELENBURG POSITION**

supine PATIENT position where the body is in a single plane, with that plane inclined so that the head is lower than the pelvis

201.4 General requirements

IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, Clause 4, applies, except as follows.

201.4.3 Essential performance

Addition:

[IEC 60601-2-46:2023](https://standards.iteh.ai/catalog/standards/iec/3a8f0e9f-31df-4e63-b204-a0f30c038050/iec-60601-2-46-2023)

<https://standards.iteh.ai/catalog/standards/iec/3a8f0e9f-31df-4e63-b204-a0f30c038050/iec-60601-2-46-2023>

Besides the definition of the MANUFACTURER, the following shall be considered ESSENTIAL PERFORMANCE for OPERATING TABLES: supporting a PATIENT without unintended movement (motorized or not) leading to an unacceptable RISK in a SINGLE FAULT CONDITION.

201.4.7 SINGLE FAULT CONDITION for ME EQUIPMENT

Addition:

The MANUFACTURER should provide means, where practical, to ensure that, in a SINGLE FAULT CONDITION, the PATIENT support platform of the OPERATING TABLE can return to a position for emergency treatment.

NOTE 101 Examples of positions for emergency treatment are TRENDELENBURG or positions for cardiopulmonary resuscitation (CPR), emergency back flattening.

201.5 General requirements for testing ME EQUIPMENT

IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, Clause 5, applies.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, Clause 6, applies.

201.7 ME EQUIPMENT identification, marking and documents

IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, Clause 7, applies, except as follows:

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

201.7.2.21 Mass of MOBILE ME EQUIPMENT

IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 7.2.21, does not apply.

201.7.9.2 Instructions for use

201.7.9.2.1 General

Addition:

Instructions for use shall include information regarding potential HAZARDS related to HIGH FREQUENCY SURGICAL EQUIPMENT, cardiac defibrillators and cardiac defibrillator-monitors.

NOTE 101 Potential HAZARDS which need to be considered include but are not limited to: PATIENT burns, explosion HAZARDS or electrical shock of the PATIENT or OPERATOR.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, Clause 8, applies, except as follows:

201.8.6.7 POTENTIAL EQUALIZATION CONDUCTOR

Addition:

Where potential equalization is required, the APPLIED PARTS of OPERATING TABLES with ACCESSIBLE PARTS which are not PROTECTIVELY EARTHED shall be provided with a potential equalization terminal or a potential equalization connector.

For OPERATING TABLES with a POTENTIAL EQUALIZATION terminal, the impedance between the potential equalization terminal or connector and any ACCESSIBLE PART shall not exceed 200 mΩ.

Compliance is checked by using the test method of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 8.6.4.

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, Clause 9, applies, except as follows:

201.9.2.3 Other MECHANICAL HAZARDS associated with moving parts

201.9.2.3.1 *Unintended movement

Addition:

Wireless remote control devices of OPERATING TABLES shall be clearly assigned by internal means to the individual OPERATING TABLES.

Compliance is checked by inspection.

201.9.4 Instability HAZARDS

201.9.4.2.2 *Instability excluding transport position

Item a)

Addition:

OPERATING TABLES shall be subjected to SAFE WORKING LOAD.

NOTE See Figure AA.1 and Table AA.1 for guidance regarding mass distribution.

Additional requirement:

OPERATING TABLES with transferable OPERATING TABLE tops shall be designed and manufactured so as to minimize the RISK of physical injuries and of accidental separation of the OPERATING TABLE tops when being transferred.

Specifications concerning OPERATING TABLE top transfer operations shall indicate in the instructions for use the safety elements inherent in the transfer operation.

Compliance is checked by inspection and the following tests.

Having transferred the OPERATING TABLE top to the TRANSPORTER, the stability in NORMAL USE test of IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 9.4.2.2, shall be carried out. The OPERATING TABLE top shall not disengage from the TRANSPORTER.

The test is then repeated with the OPERATING TABLE top being placed on the base and the stability test is carried out on the base immediately after transfer.

201.9.4.2.4.3 *Movement over a threshold

Addition:

<https://standards.iteh.ai/catalog/standards/iec/3a8f0e9f-31df-4e63-b204-a0b30c038050/iec-60601-2-46-2023>

<https://standards.iteh.ai/catalog/standards/iec/3a8f0e9f-31df-4e63-b204-a0b30c038050/iec-60601-2-46-2023>

If MOBILE OPERATING TABLES and TRANSPORTERS are not able to negotiate such obstacles safely, the MANUFACTURER shall include a warning in the instructions for use or determine which threshold can be negotiated safely and inform the OPERATOR accordingly.

201.9.4.3.1 Instability in transport position

Replacement of items b) and c) of the test procedure:

The MOBILE OPERATING TABLE or TRANSPORTER is placed with the SAFE WORKING LOAD in place, and the locking device (e.g. brakes) activated, on a plane covered with 2 mm to 4 mm thick vinyl flooring material and inclined at 6° from the horizontal plane on a concrete floor. Following initial elastic movement, initial creepage, and initial pivoting of castors, there shall be no movement of the MOBILE OPERATING TABLE or TRANSPORTER greater than 50 mm (in relation to the inclined plane). Any initial movement shall not result in an unacceptable RISK, taking into account the NORMAL USE of the MOBILE OPERATING TABLE or TRANSPORTER.

NOTE See Figure AA.1 and Table AA.1 for guidance regarding mass distribution.

201.9.8 MECHANICAL HAZARDS associated with support systems

201.9.8.1 General

Replacement of first dash:

- The construction of the support, suspension or actuation system shall be designed based upon Table 201.101 and the SAFE WORKING LOAD.