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Responsible committee: CH/62/4 Electromedical equipment

Interested committees:

Title: Draft BS EN IEC 60601-2-46 Medical electrical equipment. Part 2-46: Particular requirements for the basic safety and essential performance of operating tables.

Please notify the secretary if you are aware of any keywords that might assist in classifying or identifying the standard or if the content of this standard

- i) has any issues related to 3rd party IPR, patent or copyright
- ii) affects other national standard(s)
- iii) requires additional national guidance or information

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This draft is issued to allow comments from interested parties; all comments will be given consideration prior to publication. No acknowledgement will normally be sent. **See overleaf for information on the submission of comments.**

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Full document details: 21/30433093 DC

Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

UK Vote

Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

Submission of Comments

- **Annotated drafts are not acceptable and will be rejected.**
- All comments should be submitted online at <https://standardsdevelopment.bsigroup.com/>. You will need to register in order to comment.

Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/Figure/ Table/Note	Type of comment	Commend (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	



62D/1866/CD

COMMITTEE DRAFT (CD)

PROJECT NUMBER:

IEC 60601-2-46 ED4

DATE OF CIRCULATION:

2021-06-04

CLOSING DATE FOR COMMENTS:

2021-08-27

SUPERSEDES DOCUMENTS:

62D/1825/RR

IEC SC 62D : ELECTROMEDICAL EQUIPMENT

SECRETARIAT:

United States of America

SECRETARY:

Ms Ladan Bulookbashi

OF INTEREST TO THE FOLLOWING COMMITTEES:

PROPOSED HORIZONTAL STANDARD:



Other TC/SCs are requested to indicate their interest, if any, in this CD to the secretary.

FUNCTIONS CONCERNED:

☐ EMC

☐ ENVIRONMENT

☐ QUALITY ASSURANCE

☒ SAFETY

This document is still under study and subject to change. It should not be used for reference purposes.

Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

TITLE:

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

NOTE FROM TC/SC OFFICERS:

This revision project is to align with the Amendment projects of the IEC 60601-1 series. This CD draft contains the alignment as well as some updates to

the 3rd edition. National Committees are invited to submit comments at this stage.

Modification to WORKING VERSION in 2020, June 24th, modified 2021-03-30

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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.
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- 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 third edition cancels and replaces the second edition published in 2010 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, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

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

FDIS	Report on voting
62D/XXXX/FDIS	62D/XXXX/RVD

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

- 94 This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.
- 95 In this standard, the following print types are used:
- 96 – Requirements and definitions: roman type.
 - 97 – *Test specifications: italic type.*
 - 98 – Informative material appearing outside of tables, such as notes, examples and references: in smaller type.
99 Normative text of tables is also in a smaller type.
 - 100 – TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS
101 NOTED: SMALL CAPITALS.
- 102 In referring to the structure of this standard, the term
- 103 – “clause” means one of the numbered divisions within the table of contents, inclusive of all
104 subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
 - 105 – “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all
106 subclauses of Clause 7).
- 107 References to clauses within this standard are preceded by the term “Clause” followed by the
108 clause number. References to subclauses within this particular standard are by number only.
- 109 In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any
110 combination of the conditions is true.
- 111 The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC
112 Directives, Part 2. For the purposes of this standard, the auxiliary verb:
- 113 – “shall” means that compliance with a requirement or a test is mandatory for compliance with
114 this standard;
 - 115 – “should” means that compliance with a requirement or a test is recommended but is not
116 mandatory for compliance with this standard;
 - 117 – “may” is used to describe a permissible way to achieve compliance with a requirement or
118 test.
- 119 An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title
120 indicates that there is guidance or rationale related to that item in Annex AA.
- 121 A list of all parts of the IEC 60601 series, published under the general title *Medical electrical*
122 *equipment*, can be found on the IEC website.
- 123 The committee has decided that the contents of this publication will remain unchanged until the
124 stability date indicated on the IEC website under "<http://webstore.iec.ch>" in the data related to
125 the specific publication. At this date, the publication will be
- 126 • reconfirmed,
 - 127 • withdrawn,
 - 128 • replaced by a revised edition, or
 - 129 • amended.
- 130

INTRODUCTION

This particular standard concerns the BASIC SAFETY and ESSENTIAL PERFORMANCE of OPERATING TABLES. It amends and supplements IEC 60601-1:2005, IEC 60601-2:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 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.

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 standard¹⁾ 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 OPERATING TABLE top to or from the base or pedestal of an OPERATING TABLE with detachable OPERATING TABLE top.

NOTE See also 4.2 of the General Standard.

This particular standard does not apply to

- dental PATIENT chairs; Dentistry-Stationary dental units and dental patient chair – Part 1 general requirements (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)
- 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 201.3.201.

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.

¹⁾ The general standard is IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020. *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.*

180 IEC 60601-1-2 and IEC 60601-1-3 apply as modified in Clauses 202 and 203 respectively.
181 IEC 60601-1-8, IEC60601-1-9, IEC 60601-1-10, IEC 60601-1-11 and IEC 60601-1-12 do not
182 apply. All other published collateral standards in the IEC 60601-1 series apply as published.

183 **201.1.4 Particular standards**

184 *Replacement:*

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

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

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

192 The numbering of clauses and subclauses of this particular standard corresponds to that of the
193 general standard with the prefix "201" (e.g. 201.1 in this standard addresses the content of
194 Clause 1 of the general standard) or applicable collateral standard with the prefix "20x"
195 where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this
196 particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard,
197 203.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-3
198 collateral standard, etc.). The changes to the text of the general standard are specified by the
199 use of the following words:

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

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

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

206 Subclauses, figures or tables which are additional to those of the general standard are
207 numbered starting from 201.101. However, due to the fact that definitions in the general
208 standard are numbered 3.1 through 3.147, additional definitions in this standard are numbered
209 beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items
210 aa), bb), etc.

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

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

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