BS EN IEC 60601-2-46:2024

BSI Standards Publication

Medical electrical equipment

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

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National foreword

This British Standard is the UK implementation of EN IEC 60601-2-46:2024. It is identical to IEC 60601-2-46:2023. It supersedes BS EN IEC 60601-2-46:2019, which will be withdrawn on 31 July 2027.

The UK participation in its preparation was entrusted to Technical Committee CH/62/4, Electromedical equipment.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 60601-2-46

September 2024

ICS 11.140

Supersedes EN IEC 60601-2-46:2019

English Version

Medical electrical equipment - Part 2-46: Particular requirements for the basic safety and essential performance of operating tables (IEC 60601-2-46:2023)

Appareils électromédicaux - Partie 2-46: Exigences particulières pour la sécurité de base et les performances essentielles des tables d'opération (IEC 60601-2-46:2023)

Medizinische elektrische Geräte - Teil 2-46: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Operationstischen (IEC 60601-2-46:2023)

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Comité Européen de Normalisation Electrotechnique
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European foreword

The text of document 62D/1939/CDV, future edition 4 of IEC 60601-2-46, prepared by SC 62D "Particular medical equipment, software, and systems" of IEC/TC 62 "Medical equipment, software, and systems" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 60601-2-46:2024.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2025-05-01
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2027-07-31

This document supersedes EN IEC 60601-2-46:2019 and all of its amendments and corrigenda (if any).

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The text of the International Standard IEC 60601-2-46:2023 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standard indicated:

IEC 60601-1-8:2006	NOTE	Approved as EN 60601-1-8:2007 (not modified) +A11:2017
IEC 60601-1-8:2006/A1:2012	NOTE	Approved as EN 60601-1-8:2007/A1:2013 (not modified)
IEC 60601-1-8:2006/A2:2020	NOTE	Approved as EN 60601-1-8:2007/A2:2021 (not modified)
IEC 60601-1-9:2007	NOTE	Approved as EN 60601-1-9:2008 (not modified)
IEC 60601-1-9:2007/A1:2013	NOTE	Approved as EN 60601-1-9:2008/A1:2013 (not modified)
IEC 60601-1-9:2007/A2:2020	NOTE	Approved as EN 60601-1-9:2008/A2:2020 (not modified)
IEC 60601-1-10:2007	NOTE	Approved as EN 60601-1-10:2008 (not modified)
IEC 60601-1-10:2007/A1:2013	NOTE	Approved as EN 60601-1-10:2008/A1:2015 (not modified)
IEC 60601-1-10:2007/A2:2020	NOTE	Approved as EN 60601-1-10:2008/A2:2021 (not modified)
IEC 60601-1-11:2015	NOTE	Approved as EN 60601-1-11:2015 (not modified)
IEC 60601-1-11:2015/A1:2020	NOTE	Approved as EN 60601-1-11:2015/A1:2021 (not modified)
IEC 60601-1-12:2014	NOTE	Approved as EN 60601-1-12:2015 (not modified)

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IEC 60601-1-12:2014/A1:2020	NOTE	Approved as EN 60601-1-12:2015/A1:2020 (not modified)
IEC 60601-2-35:2020	NOTE	Approved as EN IEC 60601-2-35:2021 (not modified)
IEC 60601-2-52:2009/A1:2015	NOTE	Approved as EN 60601-2-52:2010/A1:2015 (not modified)
IEC 62366-1:2015	NOTE	Approved as EN 62366-1:2015 (not modified)
IEC 62366-1:2015/A1:2020	NOTE	Approved as EN 62366-1:2015/A1:2020 (not modified)
ISO 7494-1:2018	NOTE	Approved as EN ISO 7494-1:2018 (not modified)
ISO 20342-1:2022	NOTE	Approved as EN ISO 20342-1:2022 (not modified)

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Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 Where an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cencenelec.eu.

Annex ZA of EN 60601-1:2006[1]*, applies, except as follows:*

Replace:

Publication	Year	Title	EN/HD	Year
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	EN 60601-1-3	2008
-	-		+ AC	2010
+ A1	2013		+ A1	2013
-	-		+ AC	2014
-	-		+ A11	2016
+ A2	2021		+ A2	2021
ISO 2878	2017	Rubber, vulcanized or thermoplastic - Antistatic and conductive products - Determination of electrical resistance	-	-

[1] As impacted by EN 60601-1:2006/AC:2010, EN 60601-1:2006/A1:2013, EN 60601-1:2006/A1:2013/AC:2014, EN 60601-1:2006/A12:2014, EN 60601-1:2006/A2:2021, EN 60601-1:2006/AC:2022-12 and EN 60601-1:2006/A13:2024.

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Add:

Publication	Year	Title	EN/HD	Year
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	EN IEC 60601-2-2	2018
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	EN IEC 60601-2-43	2023
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	EN IEC 60601-2-54	2024

Documents
Document Sharing Hub

Full document details: BS EN IEC 60601-2-46:2024

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

Documents
Document Sharing Hub
Full document details: BS EN IEC 60601-2-46:2024

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

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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.

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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:

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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.

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