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भारतीय मानक मसौदा
चिकित्सा विद्युत् उपकरण
भाग 2 बुनियादी सुरक्षा और आवश्यक प्रदर्शन के लिए विशेष आवश्यकताएं
अनुभाग 46 ऑपरेटिंग मेज
(IEC 60601-2-46: 2023, संशोधित)
(पहला पुनरीक्षण)

Draft Indian Standard

Medical Electrical Equipment
Part 2 Particular Requirements for the Basic Safety and Essential
Performance
Section 46 Operating tables
(IEC 60601-2-46: 2023, MOD)
(First Revision)

[ICS 11.140]

Electromedical, Diagnostic Imaging and Radiotherapy
Equipment Sectional Committee, MHD 15

Last date for comments:
23 February, 2024

NATIONAL FOREWORD

(Adoption clause will be added later)

This standard was originally published as IS 13450 (Part 2/Sec 46): 2020 which was an identical adoption of IEC 60601-2-46: 2016 Medical electrical equipment – Part 2-46 Particular requirements for the basic safety and essential performance of operating tables. The first revision has been taken up to align the Indian Standard with the current version of IEC 60601-2-46: 2023.

The text of IEC standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are however not identical to those used in Indian Standards. Attention is particularly drawn to the following:

- Wherever the words ‘International Standard’ appear referring to this standard, they should be read as ‘Indian Standard’; and
- Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standard also exists. The corresponding Indian Standards, which are to be substituted in their respective places, are listed below along with their degree of equivalence for the editions indicated:

<i>International Standard</i>	<i>Corresponding Indian Standard</i>	<i>Degree of Equivalence</i>
IEC 60601-1: 2005, Medical electrical equipment — Part 1: General requirements for basic safety and essential performance + AMD 1: 2012 + AMD 2: 2020	IS 13450 (Part 1): 2024 Medical Electrical Equipment Part 1 General Requirements for Basic Safety and Essential Performance (IEC 60601-1: 2020, MOD) (<i>third revision</i>)	Modified
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 + AMD1: 2013+ AMD 2: 2021	IS 13450 (Part 1/Sec 3): 2023 Medical Electrical Equipment Part 1 General Requirements for Basic Safety and Essential Performance Section 3 Radiation Protection in Diagnostic X-Ray Equipment (IEC 60601-1-3: 2021, MOD) (<i>first revision</i>)	Modified
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	IS 13450 (Part 2/Sec 2): 2024 Medical Electrical Equipment Part 2 Particular requirements for basic safety and essential performance Section 2 High frequency surgical equipment and high frequency surgical accessories (IEC 60601-2-2: 2023, MOD) (<i>first revision</i>)	Modified
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	IS 13450 (Part 2/Sec 43): 2023 Medical Electrical Equipment Part 2 Particular Requirements for Basic Safety and Essential Performance Section 43 X-ray Equipment for Interventional Procedures (IEC 60601-2-43: 2022, MOD) (<i>second revision</i>)	Modified
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	IS 13450 (Part 2/Sec 54): 2023 Medical Electrical Equipment Part 2 Particular Requirements for Basic Safety and Essential Performance Section 54 X-Ray Equipment for Radiography and Radioscopy (IEC 60601-2-54: 2022, MOD) (<i>first revision</i>)	Modified

The technical committee has reviewed the provisions of the following International Standards referred in this adopted standard and has decided that these are acceptable for use in conjunction with this standard:

<i>International Standard</i>	<i>Title</i>
ISO 2878:2017	Rubber, vulcanized or thermoplastic – Antistatic and conductive products – Determination of electrical resistance

This standard is a modified adoption as the corresponding Indian standards (Column 2) in the first table above are not identical to the referred International Standards (Column 1) as given below:

- a. IS 13450 (Part 1): 2024 is a modified adoption of IEC 60601-1: 2020. IEC 60601-1: 2020 is the consolidated version of IEC 60601-1: 2005 + AMD1: 2012 + AMD2: 2020 (Edition 3.2).
- b. IS 13450 (Part 1/Sec 3): 2023 is the modified adoption of the latest consolidated version of IEC 60601-1-3: 2021 i.e. IEC 60601-1-3: 2008 + AMD 1: 2013 + AMD 2: 2021 (Edition 2.2).
- c. IS 13450 (Part 2/Sec 2): 2024 is modified adoption of IEC 60601-2-2: 2023 which is a consolidated version of IEC 60601-2-2 : 2017 + AMD 1 : 2023 (Edition 6.1).
- d. IS 13450 (Part 2/Sec 43): 2023 is a modified adoption of IEC 60601-2-43: 2022.
- e. IS 13450 (Part 2/Sec 54): 2023 is a modified adoption of IEC 60601-2-54: 2022.

The standard also makes a reference to the BIS Certification Marking of the product, details of which are given in National Annex A.

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated, expressing the result of a test or analysis shall be rounded off in accordance with IS 2: 2022 ‘Rules for rounding off numerical values (*second revision*)’. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

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.

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.

NATIONAL ANNEX A
(National Foreword)

A-1 BIS CERTIFICATION MARKING

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act, 2016* and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.

The technical content of the document has not been enclosed as it is modified adoption of IEC standard. For details, please refer to IEC 60601-2-46: 2023 or kindly contact:

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