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BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

भारतीय मानक मसौदा

चिकित्सा विद्युत् उपकरण

भाग 2 बुनियादी सुरक्षा और आवश्यक प्रदर्शन के लिए विशेष आवश्यकताएं

अनुभाग 6 माइक्रोवेव थेरेपी उपकरण की बुनियादी सुरक्षा और आवश्यक प्रदर्शन के लिए विशेष आवश्यकताएं

(IEC 60601-2-6: 2022, संशोधित)

(पहला पुनरीक्षण)

Draft Indian Standard

Medical Electrical Equipment

Part 2 Particular Requirements for Basic Safety and Essential Performance

Section 6 Particular requirements for the basic safety and essential performance of microwave therapy equipment

(IEC 60601-2-6: 2022, MOD)

(First Revision)

[ICS 11.040.60]

Electromedical, Diagnostic Imaging and Radiotherapy Equipment Sectional Committee, MHD 15	Last date for comments: 29 February, 2024

NATIONAL FOREWORD

(*Adoption clause will be added later*)

This standard was originally published as IS 13450 (Part 2/Sec 6): 2018 which was an identical adoption of IEC 60601-2-6: 2012 'Medical electrical equipment 2-6: Particular requirements for the basic safety and essential performance of microwave therapy equipment'. The first revision has been brought out to align the Indian Standard with the consolidated version of IEC 60601-2-6:2012+AMD1:2016+AMD2:2022.

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:

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'; and
b) 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:

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
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) (*third revision*)	Modified
IEC TR 60878:2015, Graphical symbols for electrical equipment in medical practice	IS 2032 (Part 19): 2023/ IEC TR 60878: 2015 Graphical Symbols Used in Electrotechnology Part 19 Electrical Equipment in Medical Practice (*first revision*)	Identical

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).

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

The minimum safety requirements specified in this particular standard are considered to provide for a practical degree of safety in the operation of microwave therapy equipment.

This particular standard amends and supplements IEC 60601-1, *Medical electrical equipment – Part 1: General requirements for safety and essential performance*, hereinafter referred to as the general standard (see 201.1.4).

The requirements are followed by specifications for the relevant tests.

A "Particular guidance and rationale" section giving some explanatory notes, where appropriate, about the more important requirements is included in Annex AA.

Clauses or subclauses for which there are explanatory notes in Annex AA are marked with an asterisk (*).

It is considered that a 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, this annex does not form part of the requirements of this standard.

201.1 Scope, object and related standards

Clause 1 of the general standard1 applies, except as follows:

201.1.1 * Scope

Replacement:

This International Standard specifies requirements for the safety of MICROWAVE THERAPY EQUIPMENT used in medical practice, as defined in 201.3.204.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for MICROWAVE THERAPY EQUIPMENT as defined in 201.3.204.

[201.3.204

MICROWAVE THERAPY EQUIPMENT

MEDICAL ELECTRICAL EQUIPMENT for the treatment of the PATIENT by means of a propagated electromagnetic field in the frequency range of more than 300 MHz but not exceeding 30 GHz]

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.

IEC 60601-1-2 applies as modified in Clause 202. IEC 60601-1-3 and IEC 60601-1-12 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

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 60601-2-6: 2022 or kindly contact:

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