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BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

भारतीय मानक मसौदा

चिकित्सा विद्युत उपकरण

भाग 2 बुनियादी सुरक्षा और आवश्यक प्रदर्शन के लिए विशेष आवश्यकताएँ

अनुभाग 83 आवासीय प्रकाश चिकित्सा उपकरण

(IEC 60601-2-83:2019+AMD1:2022 CSV, संशोधित)

Draft Indian Standard

Medical electrical equipment

Part 2 Particular requirements for the basic safety and essential performance

Section 83 Home light therapy equipment

(IEC 60601-2-83:2019+AMD1:2022 CSV, MOD)

[ICS 11.040.60]

Electromedical, Diagnostic Imaging and Radiotherapy Equipment Sectional Committee, MHD 15	Last date for comments: 18 May, 2024

NATIONAL FOREWORD

(*Adoption clause will be added later*)

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 60601-1-2:2014, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests + AMD1:2020	IS 13450 (Part 1/Sec 2): 2023 Medical Electrical Equipment Part 1 General Requirements for Basic Safety and Essential Performance Section 2 Electromagnetic Disturbances — Requirements and Tests (IEC 60601-1-2: 2020, MOD) *(second revision)*	Modified
IEC 60601-1-6:2010, Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability + AMD1:2013 + AMD2:2020	IS 13450 (Part 1/Sec 6): 2023 Medical Electrical Equipment Part 1 General Requirements for Basic Safety and Essential Performance Section 6 Usability (IEC 60601-1-6: 2020, MOD) (*first revision*)	Modified
IEC 60601-1-11:2015, Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment + AMD1:2020	IS 13450 (Part 1/Sec 11): 2023 Medical Electrical Equipment Part 1 General Requirements for Basic Safety and Essential Performance Section 11 Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment (IEC 60601-1-11: 2020, MOD) (*first revision*)	Modified
IEC 62471: 2006, Photobiological safety of lamps and lamp systems	IS 16108: 2012 Photobiological safety of lamps and lamp systems	Identical
ISO 15223-1: 2021, Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements	IS 18105 (Part 1): 2023 Medical devices Symbols to be used with information to be supplied by the manufacturer Part 1 General requirements	Identical

ISO 3864-1:2011 Graphical symbols – Safety colours and safety signs – Part 1: Design principles for safety signs and safety markings	IS 16449 (Part 1): 2018/ISO 3864-1: 2011 Graphical Symbols — Safety Colours and Safety Signs Part 1 Design Principles for Safety Signs and Safety Markings	Identical

This standard is a modified adoption as some of the Indian Standards cross-referred (Column 2) in the table above are not identical to the referred (Column 1) International Standards.

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 part of IEC 60601 has been prepared to provide safety requirements for HOME LIGHT THERAPY EQUIPMENT, based on IEC 60601-1 and its collateral standards. This equipment is intended to be used in the HOME HEALTHCARE ENVIRONMENT and is typically used by a LAY OPERATOR, who is familiar with this environment and the specific characteristics of lamps. Some requirements of IEC 60601-1-11 are amended to better suit this type of ME EQUIPMENT and the environment in which it is used.

HOME LIGHT THERAPY EQUIPMENT provides light therapy by means of eye-mediated photobiological effects (which can be visual or non-visual) and skin-mediated photobiological effects (non-visual only). Possible applications include pain relief, psoriasis treatment, and treatment of winter depression (seasonal affective disorder, SAD).

This document is developed because IEC 60601-2-57 [2] only covers light source equipment providing light therapy by means of non-visual photobiological effects, which excludes an important group of light source equipment creating visual photobiological effects. Further, IEC 60601-2-57 focuses on radiation aspects and related markings but hardly provides any product-specific safety requirements. IEC 60335-2-113 [1] provides such specific requirements for household appliances with light sources for cosmetic and beauty care, but does not apply to equipment with medical purposes. IEC 60601-2-83 addresses all safety requirements for HOME LIGHT THERAPY EQUIPMENT and has taken over relevant requirements from [1] and [2].

This document is aligned with:

– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020;

– IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020;

– IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013 and IEC 60601-1-6:2010/AMD2:2020; and
– IEC 60601-1-11:2015 and IEC 60601-1-11:2015/AMD1:2020.

Scope

Replacement:
This part of IEC 60601 is applicable to the BASIC SAFETY and ESSENTIAL PERFORMANCE of HOME LIGHT THERAPY EQUIPMENT, intended for use in the HOME HEALTHCARE ENVIRONMENT. HOME LIGHT THERAPY EQUIPMENT is typically used by a LAY OPERATOR.
The scope of this document includes all light sources except laser.
If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

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 identical with the corresponding IEC standard. For details, please refer to IEC 60601-2-83: 2019 + AMD1: 2022 CSV or kindly contact:

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