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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 33 चिकित्सा निदान के लिए चुंबकीय अनुनाद उपकरण

(IEC 60601-2-33: 2022, संशोधित)

(पहला पुनरीक्षण)

Draft Indian Standard

Medical Electrical Equipment

Part 2 Particular Requirements for the Basic Safety and Essential Performance

Section 33 Magnetic resonance equipment for medical diagnosis

(IEC 60601-2-33: 2022, MOD)

(First Revision)

[ICS 11.040.55]

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 33): 2018 which was an identical adoption of IEC 60601-2-33: 2015 Medical electrical equipment – Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis. The first revision has been taken up to align the Indian Standard with the current version of IEC 60601-2-33: 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 60601-1-2: 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): 2024 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: 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 60695-11-10: 2013, Fire hazard testing – Part 11-10: Test flames – 50 W horizontal and vertical flame test methods	IS/IEC 60695-11-10: 2013 Fire hazard testing Part 11 Test Flames Sec 10 50 W Horizontal and vertical flame test methods	Identical
IEC 61672-1: 2013, Electroacoustics – Sound level meters – Part 1: Specifications	IS 15575 (Part 1): 2016/IEC 61672-1 Electroacoustics – Sound level meters Part 1 Specifications (*first revision*)	Identical
IEC 61672-2: 2013, Electroacoustics – Sound level meters – Part 2: Pattern evaluation tests	IS 15575 (Part 2): 2023/IEC 61672-2: 2017 Electroacoustics Sound level meters Part 2: Pattern evaluation tests (*second revision*)	Identical

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:

International Standard	*Title*
IEC 62570: 2014	Standard practice for marking devices and other items for safety in the magnetic resonance environment

ISO 3746: 2010	Acoustics – Determination of sound power levels and sound energy levels of noise sources using sound pressure – Survey method using an enveloping measurement surface over a reflecting plane
ISO 9614-1	Acoustics – Determination of sound power levels of noise sources using sound intensity – Part 1: Measurement at discrete points
NEMA MS 4	Acoustic noise measurement procedure for diagnostic magnetic resonance equipment
NEMA MS 8	Characterization of the Specific Absorption Rate (SAR) for magnetic resonance imaging systems
NEMA MS 14	Characterization of radiofrequency (RF) coil heating in magnetic resonance imaging systems

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/Sec 2): 2024 is a modified adoption of IEC 60601-1-2: 2020 which is a consolidated version of IEC 60601-1-2: 2014 + AMD1: 2020 (Edition 4.1).
b. 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).

In this text, reference is made to IEC 61672-2: 2013. IS 15575 (Part 2): 2023 is the identical adoption of IEC 61672-2: 2017 which is the consolidated version of IEC 61672-2: 2013+AMD1: 2017.

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 International Standard addresses technical aspects of medical diagnostic MR EQUIPMENT and MR SYSTEMS, necessary to ensure the safety of PATIENTS, and to address electromagnetic field (EMF) exposure concerns for MR WORKERS involved with the operation, development, manufacturing, installation, and servicing of MR EQUIPMENT and MR SYSTEMS. Annex AA provides rationales for requirements and limit values including references to peer-reviewed publications used to establish the content of this document.

Exposure limits for PATIENTS and for MR WORKERS are selected to protect them from transient adverse health effects and from unacceptable RISK. In addition, scientific consensus today is that no experimental or theoretical basis exists to expect long-term adverse health effects in humans from (repeated) EMF exposures.

Organizational aspects related to safety of operating the MR EQUIPMENT are the task of the RESPONSIBLE ORGANIZATION. This task includes, but is not limited to:

– qualification of staff for decisions that are related to safety;

– adequate training of staff;

– definition of medical responsibility; including

- rules for screening the PATIENT for contraindications or for conditions that can affect
- acceptable exposure;
- rules for ROUTINE MONITORING, and for MEDICAL SUPERVISION of the PATIENT during the MR EXAMINATION;
- rules for access to and oversight of the MR ENVIRONMENT, and for hearing protection;

– demarcating, maintaining and controlling access to the B_0 HAZARD AREA and the MR ENVIRONMENT, including

- screening of any person entering this environment;
- confirming that no materials or equipment entering this environment pose a HAZARD.

– emergency procedures for (rapid) removal of the PATIENT who is in the B_0 HAZARD AREA ;

– emergency procedures related to a potential QUENCH of a superconductive magnet, when applicable;

– rules to minimize and to limit the exposure of MR workers to EMF;

– establishing and ensuring adequate preventive maintenance;

– evaluation and implementation of local regulations.

This fourth edition aligns with IEC 60601-1: 2005, IEC 60601-1: 2005/AMD1: 2012 and IEC 60601-1: 2005/AMD2: 2020 and the associated updates of the collateral standards.

Scope

Replacement:

This document applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MAGNETIC RESONANCE (MR) EQUIPMENT and MAGNETIC RESONANCE (MR) SYSTEMS.

NOTE Where ME EQUIPMENT and ME SYSTEMS are used in the clause headings, this is to be understood to indicate MR EQUIPMENT and MR SYSTEMS.

This document does not cover the application of MR EQUIPMENT beyond the INTENDED USE.

If a clause or subclause is specifically intended to be applicable to MR EQUIPMENT only, or to MR 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 MR EQUIPMENT and to MR SYSTEMS, as relevant.

This document does not formulate additional specific requirements for MR EQUIPMENT or MR SYSTEMS used in INTERVENTIONAL MR EXAMINATIONS.

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 60601-2-33: 2022 or kindly contact:

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