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BUREAU OF INDIAN STANDARDS

भारतीय मानक मसौदा

चिकित्सा विद्युत उपकरण
भाग 2-55: श्वसन गैस मॉनिटर की बुनियादी सुरक्षा और आवश्यक प्रदर्शन के लिए विशेष आवश्यकताएं
[ISO 80601-2-55:2018, संशोधित]

Draft Indian Standard

Medical electrical equipment
Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
[ISO 80601-2-55:2018, MOD]

ICS: 11.040.10

Anaesthetic, Resuscitation and Allied Equipment Sectional Committee, MHD-11	Last date for comments 14 August 2024

NATIONAL FOREWORD

(*Adoption clause will be added later*)

Amendment 1 published in 2023 to ISO 80601-2-55:2018 is given at the end of this publication.

The text of ISO 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'
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 Standards also exist. 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+AMD1:2012+AMD2:2020, Medical electrical equipment — Part 1: General requirements for basic safety and essential performance, Clause 2 applies, except as follows:	MHD/15/22648/ 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, Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic disturbances — Requirements and tests	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 60601-1-6:2010+Amd 1:2013, Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability	IS 13450 (Part 1/Sec 6) : 2024, 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 60601-1-8:2006+Amd 1:2012, Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	IS 13450 (Part 1/Sec 8) : 2024, Medical Electrical Equipment Part 1 General Requirements for Basic Safety and Essential Performance Section 8 General Requirements, Tests and Guidance for Alarm Systems in Medical Electrical Equipment and Medical Electrical Systems (IEC 60601-1-8 : 2020, MOD) (First Revision)	Modified
ISO 7000, Graphical symbols for use on equipment — Registered symbols	IS 16450 : 2023/ ISO 7000:2019, Graphical Symbols for Use on Equipment — Registered Symbols (First Revision)	Identical
ISO 7010, Graphical symbols — Safety colours and safety signs — Registered safety signs	IS 16451 : 2023/ ISO 7010 : 2019, Graphical Symbols — Safety Colours and Safety Signs — Registered Safety Signs (First Revision)	Identical
ISO 14937:2009, Sterilization of health care products — General requirements for characterization of a	IS/ISO 14937 : 2009, Sterilization of Health Care Products — General Requirements for Characterization	Identical

sterilizing agent and the development, validation and routine control of a sterilization process for medical devices	of a Sterilizing Agent and the Development, Validation and Routine Control of a Sterilization Process for Medical Devices	
ISO 15223-1:2016, Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements	IS/ISO 15223-1 : 2016/ ISO 15223-1 : 2016, Medical Devices — Symbols to be Used with Medical Device Labels, Labelling and Information to be Supplied Part 1 General Requirements (Second Revision)	Identical
ISO 17664, Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices	IS/ISO 17664 : 2017, Processing of Health Care Products — Information to be provided by the Medical Device Manufacturer for the Processing of Medical Devices	Identical
ISO 80369 (all parts), Small bore connectors for liquids and gases in healthcare applications ISO 80369-1:2018	IS/ISO 80369-1 : 2018, Small-Bore Connectors for Liquids and Gases in Healthcare Applications Part 1 General Requirements	
IEC 80369-5:2016 ISO 80369-6 : 2016 ISO 80369-7 : 2016	IS/IEC 80369-5 : 2016, Small-bore connectors for liquids and gases in healthcare applications Part 5 Connectors for limb cuff inflation applications	
ISO 80369-20: 2015	IS/ISO 80369-6 : 2016, Small bore connectors for liquids and gases in healthcare applications Part 6 Connectors for neuraxial applications	Identical
	IS/ISO 80369-7 : 2016, Small-Bore Connectors for Liquids and Gases in Healthcare Applications Part 7 Connectors for Intravascular or Hypodermic Applications	
	IS 17964 (Part 20) : 2023/ ISO 80369-20: 2015, Small-bore connectors for liquids and gases in healthcare applications Part 20: Common test methods	

ISO 80601-2-13:2011+Amd 1:2015 and Amd 2:—, Medical electrical equipment — Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation	IS 13450 (Part 2/Sec 13) : 2024, Medical Electrical Equipment Part 2 Particular Requirements for the Basic Safety and Essential Performance Section 13 Anaesthetic Workstation (ISO 80601-2-13 : 2022, MOD)	Modified
IEC 60068-2-27:2008, Environmental testing — Part 2-27: Tests — Test Ea and guidance: Shock	IS 9000 (Part 7/Sec 1) : 2018/ IEC 60068-2-27 : 2008, Basic environmental testing procedures for electronic and electrical items: Part 7 impact test: Sec 1 shock (Test Ea) (Second Revision)	Identical
IEC 60529:1989+Amd 1:1999 and Amd 2:2013, Degrees of protection provided by enclosures (IP code)	IS/IEC 60529 : 2001, Degrees of protection provided by enclosures (IP Code)	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	IS 13450 (Part 1/Sec 11) : 2024, 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

The technical committee responsible for the preparation of this standard has reviewed the provisions of following mentioned International Standards and has decide that they are acceptable for use in conjunction with this standard:

International Standard/ Other Publication	*Title*
IEC 60068-2-64:2008	Environmental testing — Part 2-64: Test methods — Test Fh: Vibration, broad band random and guidance
IEC 60601-1-12:2014	Medical electrical equipment — Part 1-12: General requirements for basic safety and essential performance — Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment
IEC 62570:2014	Standard practice for marking medical devices and other items for safety in the magnetic resonance environment

ISO 80369-2:2024	Small-bore connectors for liquids and gases in healthcare applications — Part 2: Connectors for respiratory applications
ISO 80369-3:2016	Small-bore connectors for liquids and gases in healthcare applications — Part 3: Connectors for enteral applications
ISO 80369-3:2016/Amd 1:2019	Small-bore connectors for liquids and gases in healthcare applications — Part 3: Connectors for enteral applications — Amendment 1

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 shall be rounded off in accordance with IS 2: 2022 'Rules for rounding off numerical values (*revised*)'.

This standard also makes a reference to the BIS Certification Marking of the product. Details of which is given in National Annex A.

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 BIS 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 ISO standard. For details, please refer to **ISO 80601-2-55:2018** or kindly contact:

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SCOPE

IEC 60601-1:2005+Amd 1:2012, 1.1 is replaced by:

This document specifies particular requirements for the BASIC SAFETY and ESSENTIAL PERFORMANCE of a RESPIRATORY GAS MONITOR (RGM), hereafter referred to as ME EQUIPMENT, intended for CONTINUOUS OPERATION for use with a PATIENT.

This document specifies requirements for

— anaesthetic gas monitoring,

— carbon dioxide monitoring, and

— oxygen monitoring.

NOTE 1 An RGM can be either stand-alone ME EQUIPMENT or integrated into other equipment, e.g. an anaesthetic workstation or a ventilator.

This document is not applicable to an RGM intended for use with flammable anaesthetic agents.

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.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this document are not covered by specific requirements in this document except in IEC 60601-1:2005+Amd 1:2012, 7.2.13 and 8.4.1.

NOTE 2 Additional information can be found in IEC 60601-1:2005+Amd 1:2012, 4.2.