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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 आवश्यकताएं अनुभाग 87 हाई फ्रीक्वेंसी वेंटिलेटर

[ISO 80601-2-87:2021, संशोधित]

Draft Indian Standard

Medical electrical equipment Part 2 Particular Requirements for Basic Safety and Essential Performance Section 87 High Frequency Ventilators

[ISO 80601-2-87:2021, MOD]

ICS 11.040.10

Anaesthetic, Resuscitation and Allied Equipment Sectional Committee, MHD-11	Last date for comments 10 May 2024

NATIONAL FOREWORD

(*Adoption clause will be added later*)

This Indian Standard is a modified adoption of ISO 80601-2-87: 2021 "Medical electrical equipment Part 2 Particular Requirements for Basic Safety and Essential Performance Section 87 High Frequency Ventilators".

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*
ISO 32:1977, Gas cylinders for medical use — Marking for identification of content	IS 3933: 2021, Colour Identification of Gas Cylinders and Related Equipment Intended for Medical Use	Not Equivalent
ISO 4871:1996, Acoustics — Declaration and verification of noise emission values of machinery and equipment	IS/ISO 4871: 1996, Acoustics - Declaration and Verification of Noise Emission Values of Machinery and Equipment	Identical
ISO 5356-1:2015, Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets	IS/ISO 5356-1: 2015, Anaesthetic and respiratory equipment - Conical connectors: Part 1 cones and sockets (*First Revision*)	Identical
ISO 5367:2023, Anaesthetic and respiratory equipment - Breathing sets and connectors	IS/ISO 5367: 2000, Breathing tubes intended for use with anaesthetic apparatus and ventilators	Non-Identical
ISO 7396-1:2016, Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum	IS 18466-1: 2024, Medical Gas Pipeline Systems Part 1 Pipeline Systems for Compressed Medical Gases and Vacuum	Identical
ISO 14937:2009, Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices	IS/ISO 14937 : 2009, Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development validation and routine control of a sterilization process for medical devices	Identical
ISO 16142-1:2016, Medical devices — Recognized essential principles of safety and performance of medical devices — Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards	IS/ISO 16142-1 : 2016, Medical Devices - Recognized Essential Principles of Safety and Performance of Medical Devices Part 1 General Essential Principles and Additional Specific Essential Principles for all Non-IVD Medical Devices and Guidance on the Selection of Standards	Identical

ISO 17664:2017, Processing of health care products — Information to be provided by the medical device manufacturer for the processing of 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 18562-1:2017, Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process	MHD/11/25205/ ISO 18562-1:2017, Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process	Identical
ISO 20417:2021, Medical devices — Information to be supplied by the manufacturer	MHD/14/23491/ ISO 20417:2021, Medical devices Information to be supplied by the manufacturer	Non-Identical
ISO 80369-1:2018, Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements	IS/ISO 80369-1 : 2018, Small-Bore Connectors for Liquids and Gases in Healthcare Applications Part 1 General Requirements	Identical
ISO 80601-2-84:2020, Medical electrical equipment — Part 2-84: Particular requirements for basic safety and essential performance of emergency and transport ventilators	IS 13450 (Part 2/Sec 84): 2023/ Medical Electrical Equipment Part 2 Particular Requirements for Basic Safety and Essential Performance Section 35 Ventilators for Emergency Medical Services Environment (ISO 80601-2-84: 2020, 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 Section 1 Shock (Test Ea) (*Second Revision*)	Identical
IEC 60068-2-31:2008, Environmental testing — Part 2-31: Tests — Test Ec: Rough	IS 9000 (Part 7/Sec 3): 2019/ IEC 60068-2-31: 2008, Environmental Testing Part 7 Tests Section 3 Test Ec: Rough handling shocks, primarily	Identical

handling shocks, primarily for equipment-type specimens	for equipment-types specimens (*First Revision*)	
IEC 60529:1989+AMD1:1999+ AMD2 :2013, Degrees of protection provided by enclosures (IP Code)	IS/IEC 60529 : 2001, Degrees of protection provided by enclosures (IP Code)	Non-Identical
IEC 60601-1:2005+AMD1: 2012 +AMD2:2020, Medical electrical equipment — Part 1: General requirements for basic safety and essential performance	MHD/15/22648/ IEC 60601-1:2020, Medical electrical equipment: Part 1 General requirements for basic safety and essential performance (*Third Revision*)	Identical
IEC 60601-1-10:2007+AMD1: 2020+AMD2:2020, Medical electrical equipment — Part 1-10: General requirements for basic safety and essential performance - Collateral Standard: Requirements for the development of physiologic closed-loop controllers	MHD/15/22656/ IEC 60601-1-10:2020, Medical electrical equipment: Part 1 General requirements for basic safety and essential performance, Section 10 Requirements for the development of physiologic closed-loop controllers (*First Revision*)	Identical
IEC 60601-1-11:2015+ AMD1:2020 +AMD2:2020, 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	MHD/15/22657/ IEC 60601-1-11:2020, 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 (*First Revision*)	Identical
IEC 60601-1-12:2014+AMD1: 2020, 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	IS 13450 (Part 1/Sec 12): 2024, Medical Electrical Equipment - Part 1 General Requirements for Basic Safety and Essential Performance - Section 12 Requirements for Medical Electrical Equipment and Medical Electrical Systems Intended for Use in the Emergency Medical Services Environment (IEC 60601-1-12: 2020, MOD)	Modified

IEC 62366-1:2015+AMD1:2020, Medical devices — Part 1: Application of usability engineering to medical devices	IS 17922 (Part 1): 2023/ IEC 62366-1: 2015 + AMD 1: 2020, Medical Devices Part 1 Application of Usability Engineering (First *Revision*)	Identical

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*
ISO 3744:2010	Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound pressure — Engineering methods for an essentially free field over a reflecting plane
ISO 5359:2014+AMD1:2017	Anaesthetic and respiratory equipment - Low-pressure hose assemblies for use with medical gases
ISO 23328-1:2003	Breathing system filters for anaesthetic and respiratory use: — Part 1: Salt test method to assess filtration performance
ISO 23328-2:2002	Breathing system filters for anaesthetic and respiratory use: — Part 2: Non-filtration aspects
ISO 80601-2-55:2018	Medical electrical equipment — Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
ISO 80601-2-74	Medical electrical equipment — Part 2-74: Particular requirements for the basic safety and essential performance of respiratory humidifying equipment
IEC 60068-2-64:2008	Environmental testing — Part 2-64: Tests — Test Fh: Vibration, broadband random and guidance
IEC 62570:2014	Standard practice for marking medical devices and other items for safety in the magnetic resonance environment

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 80601-2-87:2021** or kindly contact:

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Introduction

In this document, the following print types are used:

- — Requirements and definitions: roman type;
- — Instructions, test specifications and terms defined in Clause 3 of the general standard, in this document or as noted: italic type;
- — Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

In referring to the structure of this document, the term

- — “clause” means one of the four numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 201 includes subclauses 201.7, 201.8, etc.);
- — “subclause” means a numbered subdivision of a clause (e.g. 201.7, 201.8 and 201.9 are all subclauses of Clause 201).

References to clauses within this document are preceded by the term “Clause” followed by the clause number. References to subclauses within this document are by number only.
In this document, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

For the purposes of this document, the auxiliary verb:

- — “shall” means that conformance with a requirement or a test is mandatory for conformance with this document;
- — “should” means that conformance with a requirement or a test is recommended but is not mandatory for conformance with this document;
- — “may” is used to describe permission (e.g. a permissible way to achieve conformance with a requirement or test);
- — "can" is used to describe a possibility or capability; and
- — "must" is used to express an external constraint.

Annex C contains a guide to the marking and labelling requirements in this document.
Annex D contains a summary of the symbols referenced in this document.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

201.1 Scope, object and related standards

Clause 1 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies, except as follows:

NOTE The general standard is IEC 60601-1:2005+AMD1:2012+AMD2:2020.

201.1.1 * Scope
Replacement:

This document applies to the basic safety and essential performance of a high-frequency ventilator (HFV) in combination with its accessories, hereafter referred to as ME equipment:

- — intended for use in an environment that provides specialized care for patients whose conditions can be life-threatening and who can require comprehensive care and constant monitoring in a professional healthcare facility;

  NOTE 1 For the purposes of this document, such an environment is referred to as a critical care environment. High-frequency ventilators for this environment are considered life-sustaining.

  NOTE 2 For the purposes of this document, such a high-frequency ventilator can provide transport within a professional healthcare facility (i.e., be a transit-operable ventilator).

  NOTE 3 A high-frequency ventilator intended for use in transport within a professional healthcare facility is not considered as a ventilator intended for the emergency medical services environment.

- — intended to be operated by a healthcare professional operator;
- — intended for those patients who need differing levels of support from artificial ventilation including ventilator-dependent patients; and
- — capable of providing more than 150 inflations/min.

There are three principal designations of HFV:

- — high-frequency percussive ventilation [HFPV, with a typical HFV frequency of (60 to 1 000) HFV inflations/min];
- — high-frequency jet ventilation [HFJV, with a typical HFV frequency of (100 to 1 500) HFV inflations/min]; and
- — high-frequency oscillatory ventilation [HFOV, with a typical HFV frequency of (180 to 1200) HFV inflations/min and typically having an active expiratory phase].

Additionally, HFV designations can be combined together or with ventilation at rates less than 150 inflations/min.
* A high-frequency ventilator is not considered a physiologic closed loop-control system unless it uses a physiological patient variable to adjust the ventilation therapy settings.

This document is also applicable to those accessories intended by their manufacturer to be connected to an HFV breathing system, or to a high-frequency ventilator, where the characteristics of those accessories can affect the basic safety or essential performance of the high-frequency ventilator.

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 7.2.13 and 8.4.1 of IEC 60601-1:2005.

NOTE 4 Additional information can be found in 4.2 of IEC 60601-1:2005+AMD1:2012.

This document is not applicable to ME equipment that is intended solely to augment the ventilation of spontaneously breathing patients within a professional healthcare facility.

This document does not specify the requirements for:

- — non-high-frequency ventilators or accessories which provide conventional ventilation for use in critical care environments, which are given in ISO 80601-2-12[23];.

NOTE 5 An HFV can incorporate conventional critical care ventilator operational modes, in which case ISO 80601-2-12 is applicable to those modes.

- — ventilators or accessories intended for anaesthetic applications, which are given in ISO 80601-2-13[24];
- — ventilators or accessories intended for the emergency medical services environment, which are given in ISO 80601-2-84, the replacement for ISO 10651-3[13];

NOTE 6 An HFV can incorporate EMS ventilator capability.

- — ventilators or accessories intended for ventilator-dependent patients in the home healthcare environment, which are given in ISO 80601-2-72[26];
- — ventilators or accessories intended for home-care ventilatory support devices, which are given in ISO 80601-2-79[27] and ISO 80601-2-80[28], the replacements for ISO 10651-6[15];
- — sleep apnoea breathing therapy ME equipment, which are given in ISO 80601-2-70[25];
- — bi-level positive airway pressure (bi-level PAP) ME equipment;
- — continuous positive airway pressure (CPAP) ME equipment;
- — respiratory high-flow ME equipment, which are given in ISO 80601-2-90:—[1]; and
- — cuirass or “iron-lung” ventilation equipment.

This document is a particular standard in the IEC 60601 series, the IEC 80601 series and the ISO 80601 series.

201.1.2 Object
Replacement:

The object of this document is to establish particular basic safety and essential performance requirements for a high-frequency ventilator, as defined in 201.3.201, and its accessories.

NOTE 1 Accessories are included because the combination of the high-frequency ventilator and the accessories needs to be adequately safe. Accessories can have a significant impact on the basic safety or essential performance of a high-frequency ventilator.

NOTE 2 This document has been prepared to address the relevant essential principles[39] and labelling[40] guidances of the International Medical Devices Regulators Forum (IMDRF) as indicated in Annex CC.

NOTE 3 This document has been prepared to address the relevant essential principles of safety and performance of ISO 16142-1:2016 as indicated in Annex DD.

NOTE 4 This document has been prepared to address the relevant general safety and performance requirements of European regulation (EU) 2017/745[38] as indicated in Annex FF.

201.1.3 Collateral standards
Amendment (add after existing text):

This document refers to those applicable collateral standards that are listed in Clause 2 of the general standard and 201.2 of this document.

IEC 60601-1-2, IEC 60601-1-6 and IEC 60601-1-8 apply as modified in Clauses 202, 206 and 208 respectively. IEC 60601-1-3[29], IEC 60601-1-9[30], IEC 60601-1-11 and IEC 60601-1-12[31] do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards
Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard, including the collateral standards, as appropriate for the particular ME equipment under consideration, and may add other basic safety or essential performance requirements.

A requirement of a particular standard takes priority over IEC 60601-1:2005+AMD1:2012+AMD2:2020 or the collateral standards.

For brevity, IEC 60601-1:2005+AMD1:2012+AMD2:2020 is referred to in this particular document as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this document corresponds to those of the general standard with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix "2xx" where xx is the final digits of the collateral standard document number (e.g. 202.4 in this document addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 208.4 in this document addresses the content of Clause 4 of the IEC 60601-1-8 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of IEC 60601-1:2005 or the applicable collateral standard is replaced completely by the text of this document.

"Addition" means that the text of this document is additional to the requirements of IEC 60601-1:2005 or the applicable collateral standard.

"Amendment" means that the clause or subclause of IEC 60601-1:2005 or the applicable collateral standard is amended as indicated by the text of this document.

Subclauses, figures or tables that are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.147, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses or figures that are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3[29], etc.

The term "this document" is used to make reference to the general standard, any applicable collateral standards and this particular document taken together.

Where there is no corresponding clause or subclause in this document, the clause or subclause of IEC 60601-1:2005+AMD1:2012 or the applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of IEC 60601-1:2005+AMD1:2012 or the applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular document.