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BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

भारतीय मानक मसौदा

चिकित्सा विद्युत उपकरण
भाग 2-72: वेंटिलेटर पर निर्भर रोगियों के लिए घरेलू स्वास्थ्य देखभाल वातावरण वेंटिलेटर की बुनियादी सुरक्षा और आवश्यक प्रदर्शन के लिए विशेष आवश्यकताएं

[ISO 80601-2-72:2023, संशोधित]

Draft Indian Standard

Medical electrical equipment
Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients

[*ISO 80601-2-72:2023, MOD*]

ICS: 11.040.10

Anaesthetic, Resuscitation and Allied Equipment Sectional Committee, MHD-11	Last date for comments 25 May 2024

NATIONAL FOREWORD

(*Adoption clause will be added later*)

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 5359:2014+AMD1:2017, Low-pressure hose assemblies for use with medical gases	MHD/11/25226/ ISO 5359:2014, Anaesthetic and Respiratory Equipment Low-Pressure Hose Assemblies for Use with Medical Gases	Identical
ISO 5367, Anaesthetic and respiratory equipment - Breathing sets and connectors	MHD/11/22613/ IS 18691 : 2024/ ISO 5367 : 2023, Anaesthetic and Respiratory Equipment-Breathing Sets and Connectors (*First Revised*)	Identical
7396-1:2016+AMD1:2017, Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum	MHD/11/22279/ IS 18466-1 : 2023/ ISO 7396-1:2016, Medical Gas Pipeline Systems Part 1: Pipeline Systems for Compressed Medical Gases and Vacuum (*First Revision*)	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 17664-1:2021, Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices —	MHD/12/20835/ IS 19027 (Part 1) : 2023/ ISO 17664-1:2021, Processing of health care products Information to be provided by the medical device manufacturer for the processing of medical devices	Identical

Part 1: Critical and semi-critical medical devices	Part 1: Critical and semi critical medical devices	
ISO 17664-2:2021, Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices	MHD/12/20832/ IS 19027 (Part 2) : 2023/ ISO 17664-2:2021, Processing of health care products Information to be provided by the medical device manufacturer for the processing of medical devices Part 2: Non-critical medical devices	Identical
ISO 18562-1, Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process	MHD/11/25205, Biocompatibility evaluation of breathing gas pathways in healthcare applications Part 1: Evaluation and testing within a risk management process, (ISO 18562-1:2024, MOD)	Modified
ISO 20417, Medical devices — Information to be supplied by the manufacturer	MHD/14/23491/ IS/ISO 20417 : 2021, Medical devices Information to be supplied by the manufacturer	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 80601-2-74:2021, Medical electrical equipment — Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment	MHD/11/25364/ ISO 80601-2-74:2021, Medical electrical equipment — Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment	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/ IS 13450 (Part 1) : 2024, Medical Electrical Equipment Part 1 General Requirements for Basic Safety and Essential Performance (IEC 60601-1 : 2020, MOD)	Modified
IEC 61672-1:2013, Electroacoustics — Sound level meters — Part 1: Specifications	IS 15575 (Part 1) : 2016/ IEC 61672-1 : 2013, Electroacoustics — Sound Level Meters Part 1 Specifications *(First Revision*)	Identical
IEC 62304:2006+AMD1:2015, Medical device software - Software life cycle processes	IS/ISO 62304 : 2015, Medical Device Software — Software Life Cycle Processes	Identical

ISO 9360-1:2000, Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for humidifying respired gases in humans — Part 1: HMEs for use with minimum tidal volumes of 250 ml	MHD/11/25373/ISO 9360-1:2000, Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for humidifying respired gases in humans — Part 1: HMEs for use with minimum tidal volumes of 250 ml	Modified
ISO 9360-2:2001, Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for humidifying respired gases in humans — Part 2: HMEs for use with tracheostomized patients having minimum tidal volumes of 250 ml	MHD/11/25374/ISO 9360-2:2001, Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for humidifying respired gases in humans — Part 2: HMEs for use with tracheostomized patients having minimum tidal volumes of 250 ml	Identical
ISO 23328-1:2003, Breathing system filters for anaesthetic and respiratory use — Part 1: Salt test method to assess filtration performance	MHD/11/25381/ISO 23328-1:2003, Breathing system filters for anaesthetic and respiratory use — Part 1: Salt test method to assess filtration performance	Identical
ISO 23328-2:2002, Breathing system filters for anaesthetic and respiratory use — Part 2: Non-filtration aspects	MHD/11/25383/ISO 23328-2:2002, Breathing system filters for anaesthetic and respiratory use — Part 2: Non-filtration aspects	Modified
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 80601-2-55:2018, Medical electrical equipment — Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors	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
IEC 62570:2014	Standard practice for marking medical devices and other items for safety in the magnetic resonance environment
IEC 81001-5-1:2021	IEC 81001-5-1:2021, Health software and health IT systems safety, effectiveness and security — Part 5-1: Security — Activities in the product life cycle
IEC Guide 115:2021	Application of uncertainty of measurement to conformity assessment activities in the electrotechnical sector

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 80601-2-72:2023** or kindly contact:

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Introduction

This document specifies requirements for *lung ventilators* that are intended for use in the *home healthcare environment* for *patients* who are dependent on *ventilation* for their life support. These *ventilators* are frequently used in locations where the *supply mains* driving the *ventilator* is not reliable. These *ventilators* are often supervised by non-healthcare personnel (*lay operators*) with varying levels of training. *Lung ventilators* conforming with this standard can be used elsewhere (i.e. in healthcare facilities).

In referring to the structure of this document,

— “clause” means one of the 5 numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 201 includes 201.7, 201.8, etc.); and

— “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” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission;

— "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.

Requirements in this document have been decomposed so that each requirement is uniquely delineated. This is done to support automated requirements tracking.

Scope

Replacement:

NOTE 1 There is guidance or rationale for this subclause contained in Clause AA.2.

This document applies to the *basic safety* and *essential performance* of a *ventilator* in combination with its *accessories*, hereafter referred to as *ME equipment:*

— intended for use in the *home healthcare environment;*

NOTE 2 In the *home healthcare environment*, the *supply mains* driving the *ventilator* is often not reliable.

NOTE 3 Such *ventilators* can also be used in non-critical care applications of *professional healthcare facilities.*

— intended for use by a *lay operator;* and

— intended for those *patients* who need differing levels of support from *artificial ventilation* including for *ventilator-dependent patients*.

A *ventilator* is not considered to use 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 a *ventilator breathing system* or to a *ventilator* where the characteristics of those *accessories* can affect the *basic safety* or *essential performance* of the *ventilator*.

EXAMPLE Breathing tubes, *connectors*, water traps, expiratory valve, *humidifier*, *breathing system filter*, external electrical power source, and *distributed alarm system.*

NOTE 4 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 for the requirements specified in IEC 60601-1:2005+AMD1:2012+AMD2:2020, 7.2.13 and 8.4.1.

NOTE 5 Additional information can be found in IEC 60601-1:2005+AMD1:2012+AMD2:2020, 4.2.

This document does not specify the requirements for:

— *ventilators* or *accessories* intended for critical care applications, which are given in ISO 80601-2-12;

— *ventilators* or *accessories* intended for anaesthetic applications, which are given in ISO 80601-2-13;

— *ventilators* or *accessories* intended for emergency and transport which are given in ISO 80601-2-84;

— *ventilators* or *accessories* intended for homecare ventilatory support equipment (intended only to augment the *ventilation* of spontaneously breathing *patients*), which are given in ISO 80601-2-79 and ISO 80601-2-80;

— obstructive sleep apnoea therapy *ME equipment,* which are given in ISO 80601-2-70;

— high-frequency *ventilators*, which are given in ISO 80601-2-87.

— respiratory high-flow therapy equipment, which are given in ISO 80601-2-90;

NOTE 6 An ISO 80601-2-72 *ventilator* can incorporate high-flow therapy operational mode, but such a mode is only for spontaneously breathing *patients*.

— user-powered resuscitators, which are given in ISO 10651-4;

— gas-powered emergency resuscitators, which are given in ISO 10651-5;

— oxygen therapy constant flow *ME equipment*; and

— cuirass and "iron-lung" *ventilators.*

201.1.2 Object

Replacement:

The object of this document is to establish particular *basic safety* and *essential performance* requirements for a *ventilator,* as defined in 201.3.217, and its *accessories*.

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

NOTE 1 This document has been prepared to address the relevant *essential principles*guidance of the International Medical Devices Regulators Forum (IMDRF) ahts indicated in Annex CC. [31] [32] and labelling

NOTE 2 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 3 This document has been prepared to address the relevant general safety and performance requirements of European regulation (EU) 2017/745[33] as indicated in Annex EE.

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 in 201.2 of this document.

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

IEC 60601-1-2:2014+AMD1:2020, IEC 60601-1-6:2010+AMD1:2013+AMD2:2020, IEC 60601-1-8:2016+AMD1:2012+AMD2:2020 and IEC 60601-1-11:2015+AMD1:2020 apply as modified in Clauses 202, 206, 208 and 211 respectively.
IEC 60601-1-3, IEC 60601-1-9 and IEC 60601-1-12 do not apply.

201.1.4 Particular standards

Replacement:
In the IEC 60601 series, particular standards can 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 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 addresses the content of IEC 60601-1-2, Clause 4 collateral standard, 208.4 addresses the content of IEC 60601-1-8, Clause 4 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+AMD1:2012+AMD2:2020 or the applicable collateral standard is replaced completely by the text of this document.

— "Addition" means that the text of this particular standard is additional to the requirements of IEC 60601-1:2005+AMD1:2012+AMD2:2020 or the applicable collateral standard.

— "Amendment" means that the clause or subclause of IEC 60601-1:2005+AMD1:2012+AMD2:2020 or the applicable collateral standard is amended as indicated by the text of this document.

Subclauses or figures 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 3.154, 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, etc.

The term "this document" is used to make reference to IEC 60601-1:2005+AMD1:2012+AMD2:2020, any applicable collateral standards, and this 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+AMD2:2020 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+AMD2:2020 or the applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this document.