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BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

भारतीय मानक मसौदा

चिकित्सा विद्युत उपकरण
भाग 2-90: श्वसन उच्च-प्रवाह चिकित्सा उपकरणों की बुनियादी सुरक्षा और आवश्यक प्रदर्शन के लिए विशेष आवश्यकताएं
[ISO 80601-2-90:2021, संशोधित]

Draft Indian Standard

Medical Electrical Equipment
Part 2-90: Particular Requirements for Basic Safety and Essential Performance of Respiratory High-Flow Therapy Equipment
[ISO 80601-2-90:2021, 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 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, 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+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 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: 2024, 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	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 80369-7:2021, Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications	IS/ISO 80369-7 : 2016, Small-Bore Connectors for Liquids and Gases in Healthcare Applications Part 7 Connectors for Intravascular or Hypodermic Applications	Non-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 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
ISO 18190:2016, Anaesthetic and respiratory equipment — General requirements for airways and related equipment	MHD/11/25375/ISO 18190:2016, Anaesthetic and respiratory equipment — General requirements for airways and related equipment	Modified
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
ISO 5359:2014+AMD1:2017	Anaesthetic and respiratory equipment — Low-pressure hose assemblies for use with medical gases
ISO 19223:2019	Lung ventilators and related equipment — Vocabulary and semantics
IEC 62570:2014	Standard practice for marking medical devices and other items for safety in the magnetic resonance environment
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 80601-2-90:2021** or kindly contact:

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Introduction

Respiratory high-flow therapy equipment has been used successfully for years with neonatal *patients*. In recent years there is more information about treating adults with *respiratory high-flow therapy equipment* when it is used as an intermediate therapy to improve oxygenation in adult critical care *patients*, respiratory care units and for palliative care. *High-flow therapy equipment* is also used in the treatment of chronic respiratory disease to reduce exacerbation, improve physiological outcomes and quality of life[30][43][44][47][1]. The use of *respiratory high-flow therapy equipment* continues to increase as it is easily set up and is well tolerated by *patients*.

Since the outbreak of COVID-19 in January of 2020, its spread has been rapid and fierce. In hospitals across the world, all kinds of *respiratory high-flow therapy equipment* have been widely used. In general, there is a trend to use more non-invasive respiratory therapy. More and more new *manufacturers* of *respiratory high-flow therapy equipment* have rapidly emerged. Neither international nor national standards are available for *respiratory high-flow therapy equipment*. With the spread of the epidemic globally, the demand for this document is clear and very urgent.

The first *respiratory high-flow therapy equipment* was constructed by the connection of a *humidifier*, air/oxygen mixer/blender, flowmeter, breathing tube and cannula. Based on the improvement in technical integration in recent years, there are several technical routes for *respiratory high-flow therapy equipment* on the market. *Respiratory high-flow therapy equipment* is not fully covered by the existing standards for *humidifiers*, gas mixers for medical use, flowmeters or *ventilators*.

This document addresses the *basic safety* and *essential performance* requirements of *respiratory high-flow therapy equipment*, including *risks* related to oxygen (e.g., fires, incorrect oxygen concentration, incorrect flow delivery, etc.).

Specifically, the following *risks* and related requirements were considered in the development of this document.

- — Contaminated air entering the *gas intake port* of the *respiratory high-flow therapy equipment*.
- — Instability of gas supply from a *high-pressure inlet*.
- — Insufficient pressure from a *high-pressure inlet*, and subsequent effects on oxygen delivered to the *patient*.
- — Insufficient oxygen being delivered to the *patient*, and related *alarm condition*.
- — *Usability* by *operators* wearing personal protective equipment (such as gloves and blurred visors), when setting up equipment, or viewing or changing settings.
- — Instability of output delivered to *patients*, necessitating frequent *operator* adjustment.
- — *Processing* of equipment, including the surface of the *enclosure* and internal *gas pathways*, particularly after use on infectious *patients*.
- — Infectious exhaled gas.
- — Overheating of *respiratory high-flow therapy equipment*.

In this document, the following print types are used:

- — requirements and definitions: roman type;
- — *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 five 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 particular 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;
- — "must" is used express an external constraint.

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 *respiratory high-flow therapy equipment,* as defined in 201.3.220, hereafter also referred to as *ME equipment* or *ME system,* in combination with its *accessories*:

- — intended for use with *patients* who can breathe spontaneously; and
- — intended for *patients* who would benefit from improved alveolar gas exchange; and who would benefit from receiving high-flow humidified respiratory gases, which can include a *patient* whose upper airway is bypassed.

EXAMPLE 1

Patients with Type 1 Respiratory Failure who exhibit a reduction in arterial blood oxygenation.

EXAMPLE 2

Patients who would benefit from reduced work of breathing, as needed in Type 2 Respiratory Failure, where arterial carbon dioxide is high.

EXAMPLE 3

Patients requiring humidification to improve mucociliary clearance.

Respiratory high-flow therapy equipment can be intended for use in the *home healthcare environment* or intended for use in professional healthcare facilities.

NOTE 1 In the *home healthcare environment*, the *supply mains* is often not reliable.

Respiratory high-flow therapy equipment can be:

- — fully integrated *ME equipment*; or
- — a combination of separate items forming a *ME system*.

This standard also applies to other types of respiratory equipment when that equipment includes a respiratory high-flow therapy mode.

NOTE 2 This standard and ISO 80601-2-12[14] are applicable to a critical care *ventilator* with a high-flow therapy mode.

Respiratory high-flow therapy equipment can be *transit-operable*.

This document is also applicable to those *accessories* intended by their *manufacturer* to be connected to the *respiratory high-flow therapy equipment*, where the characteristics of those *accessories* can affect the *basic safety* or *essential performance* of the *respiratory high-flow therapy equipment*.

EXAMPLE 4

Breathing sets, connectors, *humidifier*, *breathing system filter*, external electrical power source, *distributed alarm system*, *high-flow nasal cannula*, tracheal tube, tracheostomy tube, face *mask* and supra-laryngeal airway.

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 the general standard, 7.2.13 and 8.4.1.

NOTE 3 Additional information can be found in the general standard, 4.2.

This document does not specify the requirements for:

- — *ventilators* or *accessories* for *ventilator-dependent patients* intended for critical care applications, which are given in ISO 80601-2-12[14];
- — *ventilators* or *accessories* intended for anaesthetic applications, which are given in ISO 80601-2-13[15];
- — *ventilators* or *accessories* intended for the *emergency medical services environment*, which are given in ISO 80601-2-84[20];
- — *ventilators* or *accessories* intended for *ventilator-dependent patients* in the *home healthcare environment,* which are given in ISO 80601-2-72[17];
- — ventilatory support equipment or *accessories* intended for *patients* with ventilatory impairment, which are given in ISO 80601-2-79[18];
- — ventilatory support equipment or *accessories* intended for *patients* with ventilatory insufficiency, which are given in ISO 80601-2-80[19];
- — sleep apnoea therapy *ME equipment*, which are given in ISO 80601-2-70[16];
- — continuous positive airway pressure (CPAP) *ME equipment;*
- — high-frequency jet *ventilators* (HFJVs)[31], which are given in ISO 80601-2-87[21];
- — gas mixers for medical use, which are given in ISO 11195[9];
- — flowmeters, which are given in ISO 15002[11];
- — high-frequency oscillatory *ventilators* (HFOVs), which are given in ISO 80601-2-87[21]; 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 *respiratory high-flow therapy equipment,* as defined in 201.3.220, and its *accessories*.

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

NOTE 2 This document has been prepared to address the relevant International Medical Device Regulators Forum (IMDRF) *essential principles* and labelling guidances 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[26] 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 Clause 201.2 of this document.

IEC 60601-1-2:2014+AMD1:2020+AMD2:2020, IEC 60601-1-6:2010+AMD1:2013+AMD2:2020, IEC 60601-1-8:2006+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[22] does 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 define *basic safety* and *essential performance* requirements, and may modify, replace or delete requirements contained in the general standard, including the collateral standards as appropriate for the particular *ME equipment* under consideration.

A requirement of a particular standard takes priority over the general standard.

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 that 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, 211.10 in this document addresses the content of Clause 10 of the IEC 60601-1-11 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 the general standard or 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 the general standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or 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 3.154, 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, figures or tables which 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 the general standard, any applicable collateral standards and this particular document taken together.

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