International Standard

ISO 80601-2-90

Second edition
2026-04

Medical electrical equipment —

Part 2-90: Particular requirements for basic safety and essential performance of respiratory high-flow therapy equipment

Appareils électromédicaux —

Partie 2-90: Exigences particulières pour la sécurité de base et les performances essentielles des équipements de thérapie respiratoire à haut débit

Reference number
ISO 80601-2-90:2026(en)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives or www.iec.ch/members_experts/refdocs).

ISO and IEC draw attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO and IEC take no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO and IEC had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents and https://patents.iec.ch. ISO and IEC shall not be held responsible for identifying any or all such patent rights.

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html. In the IEC, see www.iec.ch/understanding-standards.

This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Respiratory devices and related equipment used for patient care,* and Technical Committee IEC/TC 62, *Medical equipment, software, and systems*, Subcommittee SC 62D, *Particular medical equipment, software, and systems*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 80601-2-90:2021), which has been technically revised.

The main changes are as follows:

— updated normative references;

— clarified *system recovery* requirements;

— added *cybersecurity* requirements; and

— added requirements for SpO_2 *monitoring equipment*.

A list of all parts in the ISO 80601 series and the IEC 80601 series can be found on the ISO and IEC websites.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html and www.iec.ch/national-committees.

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[29][42][43][46].[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*.

— Insufficient flow capability from a *medical gas pipeline system*, and subsequent effects on oxygen supply to other *patients* in a care area.

In this document, the following print types are used:

— requirements and definitions: roman type;

— *terms defined in Clause 3 of the general standard, in this document or as noted: italic type*;

---

[1] Numbers in square brackets refer to the Bibliography.

— 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” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission;

— "can" is used to describe a possibility or capability; and

— "must" is used 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.

Medical electrical equipment —

Part 2-90: Particular requirements for basic safety and essential performance of respiratory high-flow therapy equipment

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:

NOTE 1 There is guidance or rationale for this subclause contained in AA.2.1.

This document applies to the *basic safety* and *essential performance* of *respiratory high-flow therapy equipment,* as defined in 201.3.262, 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 is utilized in both professional healthcare facilities and the *home healthcare environment*. This standard specifically addresses *respiratory high-flow therapy equipment* for acute or infant care, predominantly found in hospitals. A separate document for long term high-flow therapy in the *home healthcare environment* is expected to be forthcoming.

Respiratory high-flow therapy equipment can be:

— fully integrated *ME equipment*; or

— a combination of separate items forming a *ME system*.

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

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

NOTE 3 This document and ISO 80601-2-72 are applicable to *ventilator* for *ventilator-dependent patients* in the *home healthcare environment* with a high-flow therapy mode.

NOTE 4 This document and ISO 80601-2-13 are applicable to an anaesthetic workstation 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.

NOTE 5 *Accessories* are assessed with the relevant clauses of this document when configured as part of *respiratory high-flow therapy equipment*.

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 6 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;

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

— *ventilators* or *accessories* intended for the *emergency medical services environment*, which are given in ISO 80601-2-84;

— *ventilators* or *accessories* intended for *ventilator-dependent patients* in the *home healthcare environment,* which are given in ISO 80601-2-72;

— ventilatory support equipment or *accessories* intended for *patients* with ventilatory impairment, which are given in ISO 80601-2-79;

— ventilatory support equipment or *accessories* intended for *patients* with ventilatory insufficiency, which are given in ISO 80601-2-80;

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

— continuous positive *airway pressure* (CPAP) *ME equipment;*

— high-frequency jet *ventilators* (HFJVs)[31], which are given in ISO 80601-2-87;

— gas mixers for medical use, which are given in ISO 11195;

— flowmeters, which are given in ISO 15002;

— high-frequency oscillatory *ventilators* (HFOVs), which are given in ISO 80601-2-87; 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 201.3.262, 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 general safety and performance requirements of European regulation (EU) 2017/745[25].

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 subclause 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 and IEC 60601-1-9 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 specifies *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.

201.2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

Clause 2 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies, except as follows:

Replacement:

IEC 61672-1:2013, *Electroacoustics — Sound level meters — Part 1: Specifications*

Addition:

ISO 32:1977, *Gas cylinders for medical use — Marking for identification of content*

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 4871:1996, *Acoustics — Declaration and verification of noise emission values of machinery and equipment*

ISO 5356-1:2015, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*

ISO 5359:2014+AMD1:2017, *Anaesthetic and respiratory equipment — Low-pressure hose assemblies for use with medical gases*

ISO 5367:2023, *Anaesthetic and respiratory equipment — Breathing sets and connectors*

ISO 7000, *Graphical symbols for use on equipment — Index and synopsis*[2]

[2] The graphical symbol collections of ISO 7000, ISO 7001, ISO 7010 and IEC 60417 can be previewed and purchased on the Online Browsing Platform (OBP), www.iso.org/obp

ISO 7010, *Graphical symbols — Safety colours and safety signs — Registered safety signs*[3]

ISO 7396-1:2016+AMD1:2017, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum*

ISO 17664-1:2021, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of 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*

ISO 18190:2025, *Anaesthetic and respiratory equipment — General requirements for airways and related equipment*

ISO 18562-1:2024, *Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process*

ISO 20417:2026, *Medical devices — Information to be supplied by the manufacturer*

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 80369-2:2024, *Small-bore connectors for liquids and gases in healthcare applications — Part 2: Connectors for breathing systems and driving gases applications*

ISO 80601-2-55:2018+AMD1:2023, *Medical electrical equipment — Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors*

ISO 80601-2-61:2026, *Medical electrical equipment — Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment*

ISO 80601-2-74:2026, *Medical electrical equipment — Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment*

IEC 60601-1-11:2015+AMD1:2020, *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*

IEC 62366-1:2015+AMD1:2020, *Medical devices — Part 1: Application of usability engineering to medical devices*

IEC 62570:2025, *Standard practice for marking medical devices and other items for safety in the magnetic resonance environment*

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*

[3] The graphical symbol collections of ISO 7000, ISO 7001, ISO 7010 and IEC 60417 can be previewed and purchased on the Online Browsing Platform (OBP), www.iso.org/obp

IEC Guide 115:2023, *Application of uncertainty of measurement to conformity assessment activities in the electrotechnical sector*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005+AMD1:2012+AMD2:2020 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

NOTE An alphabetized index of defined terms is found Annex DD.

201.3.201
accompanying information
information supplied by the manufacturer with or *marked* on a medical device or *accessory* for the user or *responsible organization*, particularly regarding safe use

Note 1 to entry: The *accompanying information* is regarded as part of the medical device or *accessory*.

Note 2 to entry: The *accompanying information* can consist of the label, *marking*, *instructions for use*, *technical description*, information shown on the packaging or graphical *user* interface (GUI), installation manual, quick reference guide, etc and can address the installation, use, *processing*, *maintenance* and disposal of the medical device or *accessory*.

Note 3 to entry: *Accompanying information* is not necessarily a written or printed document but can involve auditory, visual, or tactile materials and multiple media types (e.g. CD-ROM, DVD-ROM, USB stick, website).

[SOURCE: ISO 20417:2026, 3.2, modified — deleted note 4.]

201.3.202
acknowledged
state of an *alarm system* initiated by *operator* action, where the auditory *alarm signal* associated with a currently active *alarm condition* is inactivated until the *alarm condition* no longer exists or until a predetermined time interval has elapsed

Note 1 to entry: *Acknowledged* only affects *alarm signal*s that are active at the time of the *operator* acti*on.*

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.37]

201.3.203
airway device
device intended to provide a *gas pathway* to and from the *patient's* airway

[SOURCE: ISO 4135:2022, 3.8.1.2]

201.3.204
airway pressure
p_{aw}
pressure at the *patient-connection port* or at the distal *outlet* of the equipment where there is no *patient-connection port*

Note 1 to entry: The *airway pressure* can be derived from pressure measurements made anywhere within the equipment.

[SOURCE: ISO 4135:2022, 3.1.4.41.1, modified — added letter symbol.]

201.3.205
alarm limit
threshold used by an *alarm system* to determine an *alarm condition*

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.3]

201.3.206
alarm off
state of indefinite duration in which an *alarm system* or part of an *alarm system* does not generate *alarm signals*

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.4]

201.3.207
alarm paused
state of limited duration in which the *alarm system* or part of the *alarm system* does not generate *alarm signals*

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.5]

201.3.208
alarm setting
alarm system configuration, including but not limited to:
– *alarm limits*;
– the characteristics of any *alarm signal* inactivation states; and
– the values of variables or parameters that determine the function of the *alarm system*

Note 1 to entry: Some algorithmically-determined *alarm settings* can require time to be determined or re-determined.

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.8]

201.3.209
artificial ventilation
intermittent elevation of the pressure in the *patient's airway* relative to that in the *lungs* by external means with the intention of augmenting, or totally controlling, the *ventilation* of a *patient*

EXAMPLE Means used to provide *artificial ventilation* are manual resuscitation; mouth-to-mouth resuscitation; automatic *ventilation*; mechanical *ventilation*.

Note 1 to entry: Common classifications of areas of application of *artificial ventilation* are: emergency; transport; home-care; anaesthesia; critical care; rehabilitation.

Note 2 to entry: Classifications used to denote means used for *artificial ventilation* include: positive-pressure; negative-pressure; gas-powered; *operator*-powered; electrically-powered.

Note 3 to entry: Negative-pressure *ventilation* elevates the relative pressure in the airway by intermittently lowering the pressure in the *lungs*.

[SOURCE: ISO 19223:2019, 3.1.10]

201.3.210
attack
attempt to destroy, expose, alter, disable, steal or gain unauthorized access to or make unauthorized use of an asset