



BSI Standards Publication

Medical electrical equipment

Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators

National foreword

This British Standard is the UK implementation of EN ISO 80601-2-12:2023. It is identical to ISO 80601-2-12:2023. It supersedes BS EN ISO 80601-2-12:2020, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/121/9, Lung Ventilators & Related Equipment.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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English Version

Medical electrical equipment - Part 2-12: Particular
requirements for basic safety and essential performance of
critical care ventilators (ISO 80601-2-12:2023)

Appareils électromédicaux - Partie 2-12: Exigences
particulières relatives à la sécurité de base et aux
performances essentielles des ventilateurs
pulmonaires pour utilisation en soins intensifs (ISO
80601-2-12:2023)

Medizinische elektrische Geräte - Teil 2-12: Besondere
Festlegungen für die Sicherheit einschließlich der
wesentlichen Leistungsmerkmale von
Beatmungsgeräten für die Intensivpflege (ISO 80601-
2-12:2023)

This European Standard was approved by CEN on 1 September 2023.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (EN ISO 80601-2-12:2023) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment" the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 2024, and conflicting national standards shall be withdrawn at the latest by May 2024.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 80601-2-12:2020.

Any feedback and questions on this document should be directed to the users' national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 80601-2-12:2023 has been approved by CEN as EN ISO 80601-2-12:2023 without any modification.

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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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO and IEC shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents) or the IEC list of patent declarations received (see <https://patents.iec.ch>).

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 jointly 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 third edition cancels and replaces the second edition (ISO 80601-2-12:2020), which has been technically revised.

The main changes are as follows:

- alignment with IEC 60601-1:2005+AMD1:2012+AMD2:2020, IEC 60601-1-2:2014+AMD1:2020 IEC 60601-1-6:2010+AMD1:2013+AMD2:2020 and IEC 60601-1-8:2006+AMD1:2012+AMD2:2020.
- added requirements for the display legibility for *operators* wearing personal protective equipment;
- added requirements for display during calibration of gas monitors;
- clarified *maximum limited pressure* requirements;
- clarified high *airway pressure alarm condition* requirements;
- added requirements for *ventilator system recovery*;

- added requirements and definitions for *cybersecurity*; and
- harmonization with ISO 20417, where appropriate.

A list of all parts in the ISO and 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

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 201.12 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.

In this document, the following verbal forms are used:

- “shall” indicates a requirement;
- “should” indicates a recommendation;
- “may” indicates a permission;
- “can” is used to describe a possibility or capability.

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.

Medical electrical equipment —

Part 2-12:

Particular requirements for basic safety and essential performance of critical care ventilators

201.1 Scope, object and related standards

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

201.1.1 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 critical care *ventilator* 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 2 For the purposes of this document, such an environment is referred to as a critical care environment. *Ventilators* for this environment are considered life-sustaining.

NOTE 3 For the purposes of this document, such a critical care *ventilator* can provide ventilation during transport within a *professional healthcare facility* (i.e. be a *transit-operable ventilator*).

NOTE 4 A critical care *ventilator* intended for use in transport within a *professional healthcare facility* is not considered as an *emergency medical services environment ventilator*.

- intended to be operated by a *healthcare professional operator*; and
- intended for those *patients* who need differing levels of support from *artificial ventilation* including for *ventilator-dependent patients*.

A critical care *ventilator* is not considered to use a *physiologic closed-loop-control system* unless it uses a physiological *patient* variable to adjust the *artificial 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*.

NOTE 5 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+AMD1:2012+AMD2:2020, 7.2.13 and 8.4.1.

NOTE 6 Additional information can be found in IEC 60601-1:2005+AMD1:2012+AMD2:2020, 4.2.

This document is not applicable to *ME equipment* or an *ME system* operating in a *ventilator-operational mode* solely intended for *patients* who are not dependent on *artificial ventilation*.

NOTE 7 A critical care *ventilator*, when operating in such a *ventilator-operational mode*, is not considered life-sustaining.

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:

NOTE 8 See ISO/TR 21954 for guidance on the selection of the appropriate *ventilator* for a given *patient*.

- *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;
- *ventilators* or *accessories* intended for home-care ventilatory support devices, 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;
- *continuous positive airway pressure (CPAP) ME equipment*.
- high-frequency *ventilators*, which are given in ISO 80601-2-87;

NOTE 9 A critical care *ventilator* can incorporate high-frequency jet or high-frequency oscillatory *ventilator-operational modes*.

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

NOTE 10 A critical care *ventilator* can incorporate high-flow therapy operational mode, but such a mode is only for spontaneously breathing *patients*.

- oxygen therapy constant flow *ME equipment*; and
- cuirass or “iron-lung” ventilation equipment.

201.1.2 Object

Replacement:

The object of this document is to establish *basic safety* and *essential performance* requirements for a *ventilator*, as defined in 201.3.306, 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*^[42] and labelling^[43] guidances of the International Medical Devices Regulators Forum (IMDRF) as indicated in Annex CC.

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.

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 and IEC 60601-1-8:2016+AMD1:2012+AMD2:2020 apply as modified in Clauses 202, 206 and 208 respectively.

IEC 60601-1-3, IEC 60601-1-9, IEC 60601-1-11 and IEC 60601-1-12 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 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 are 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+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 document 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, 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 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, 208 for IEC 60601-1-8, 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+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 particular 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.

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 5367:2014, *Anaesthetic and respiratory equipment — Breathing sets and connectors*

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

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*

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*

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*

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 18562-1:2023, *Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process*

ISO 20417:2021, *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 80601-2-55:2018, *Medical electrical equipment — Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors*

ISO 80601-2-74:2021, *Medical electrical equipment — Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment*

IEC 60068-2-27:2008, *Environmental testing — Part 2-27: Tests — Test Ea and guidance: Shock*

IEC 60068-2-31:2008, *Environmental testing — Part 2-31: Tests — Test Ec: Rough handling shocks, primarily for equipment-type specimens*

IEC 60068-2-64:2008+AMD1:2019, *Environmental testing — Part 2-64: Tests — Test Fh: Vibration, broadband random and guidance*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

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

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 conformance 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/>

201.3.201

accompanying information

information accompanying or *marked* on a medical device or *accessory* for the user or those accountable for the installation, use, *processing*, maintenance, decommissioning and disposal of the medical device or *accessory*, particularly regarding safe use

Note 1 to entry: The *accompanying information* shall be 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*, installation manual, quick reference guide, etc.

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

[SOURCE: ISO 20417:2021, 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 signals* that are active at the time of the *operator* action.

[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]

201.3.205**alarm condition delay**

time from the occurrence of a triggering event either in the *patient*, for *physiological alarm conditions*, or in the equipment, for *technical alarm conditions*, to when the *alarm system* determines that an *alarm condition* exists

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.2]

201.3.206**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]

201.3.207**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]

201.3.208**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]

201.3.209**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]

201.3.210**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]

201.3.211

assured inflation-type rate

number of assured *inflation-type* initiations in a specified period of time, expressed as breaths per minute

[SOURCE: ISO 19223:2019, 3.5.2.1, modified — deleted notes.]

201.3.212

attack

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

[SOURCE: IEC 81001-5-1, 3.5]

201.3.213

audio off

state of indefinite duration in which the *alarm system* or part of the *alarm system* does not generate an auditory *alarm signal*

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.12]

201.3.214

audio paused

state of limited duration in which the *alarm system* or part of the *alarm system* does not generate an auditory *alarm signal*

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.13]

201.3.215

BAP

quantity by which the baseline *airway pressure* is set to be positively offset from the ambient pressure

[SOURCE: ISO 19223:2019, 3.10.2, modified — deleted notes.]

201.3.216

bias flow

flow that passes through the *ventilator breathing system* to the *exhaust port* but is not intended to contribute to the work of *lung* ventilation

[SOURCE: ISO 19223:2019, 3.7.7, modified — deleted notes.]

201.3.217

biocompatibility

ability to be in contact with a living system without producing an unacceptable adverse effect

Note 1 to entry: A medical devices or *accessory* may produce some level of adverse effect, but that level may be determined to be acceptable when considering the benefits provided by the medical device or *accessory*.

[SOURCE: ISO 18562-1:2023, 3.6]

201.3.218

body temperature and pressure saturated

BTPS

ambient atmospheric pressure, at a temperature of 37 °C, and a relative humidity of 100 %

[SOURCE: ISO 4135:2022, 3.1.1.7]

201.3.219

breathing system

pathways through which gas flows to or from the *patient* at respiratory pressures and continuously or intermittently in fluid communication with the *patient's* respiratory tract during any form of *artificial ventilation* or respiratory therapy

[SOURCE: ISO 4135:2022, 3.6.1.1, modified — deleted notes.]

201.3.220

breathing system filter

BSF

device intended to reduce transmission of particulates, including microorganisms, in *breathing systems*

[SOURCE: ISO 23328-2:2002, 3.1]

201.3.221

cleaning

removal of contaminants to the extent necessary for further *processing* or for *intended use*

Note 1 to entry: *Cleaning* consists of the removal of adherent soil (e.g. blood, protein substances, and other debris) from the surfaces, crevices, serrations, joints and lumens of a medical device by a manual or automated *process* that prepares the items for safe handling or further *processing*.

[SOURCE: ISO 17664-2:2021, 3.1, modified — replaced 'and/or' with 'or'.]

201.3.222

communicator

COM

function of the *alarm system* that generates *alarm signals* to notify an *operator* (e.g. to the presence of an *alarm condition*)

Note 1 to entry: A *communicator* can receive an *operator* response.

Note 2 to entry: An *operator* response is not limited to direct *operator* action.

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.46, modified — deleted note 3.]

201.3.223

connector

fitting to join two or more components

EXAMPLE *Connectors for low-pressure hose assembly* are any of a range of mating components intended to maintain gas specificity by the allocation of a set of different diameters to the mating *connectors* for each particular gas.

[SOURCE: ISO 4135:2022, 3.1.4.5]

201.3.224

continuous flow

gas flowing continuously through the *ventilator breathing system*, with a proportion intermittently passing to the *patient's lung* whenever the *airway pressure* is raised by the *ventilator* or an *operator* action, or flow is demanded by a *patient's* inspiratory effort

[SOURCE: ISO 19223:2019, 3.7.8, modified — deleted notes.]

201.3.225

CPAP

continuous positive airway pressure

ventilation-mode or sleep-apnoea breathing-therapy mode in which the *patient* breathes continuously at a set *airway-pressure* level, above ambient pressure

[SOURCE: ISO 19223:2019, 3.11.15, modified — deleted notes.]

201.3.226

cybersecurity

state where information and systems are protected from unauthorized activities, such as access, use, disclosure, disruption, modification, or destruction to a degree that the related *risks* to violation of confidentiality, integrity, and availability are maintained at an acceptable level throughout the life cycle

[SOURCE: IEC 81001-5-1, 3.30]

201.3.227

Δ inspiratory pressure

differential *airway pressure* relative to baseline *airway pressure* during an *inflation phase*

Note 1 to entry: In addition to its direct reference, this term or an appropriate *symbol* may be used, in context or by qualification, to designate this concept as a set quantity or a measured quantity.

Note 2 to entry: There is currently no agreed convention as to whether an inspiratory pressure is always to be expressed as an absolute quantity relative to ambient pressure or an absolute quantity for one group of *inflation-types* and relative for another. This has unacceptable *patient-safety* implications that need to be addressed in a vocabulary of *lung* ventilation. The *symbol*, Δ , is currently sometimes used as a prefix to make this distinction, and that convention has been adopted as a requirement in this document. Without a prefix, or any other indication, respiratory pressures are always to be considered to be relative to ambient pressure. The addition of a Δ prefix, is used to indicate a pressure that is relative to the set *BAP* level. In *ventilation-modes* where there is a second, higher, baseline *airway pressure*, then the prefix for a pressure relative to that higher-pressure level becomes ΔH . These prefixes are applicable to relevant terms, *symbols* and displayed values but not to *inflation-types*.

Note 3 to entry: The sum of the set *BAP* level and the Δ *inspiratory pressure* equals the inspiratory pressure. This applies to both settings and measurements of this parameter.

[SOURCE: ISO 19223:2019, 3.6.7, modified — deleted note 4.]

201.3.228

disinfection

process to inactivate viable microorganisms to a level previously specified as being appropriate for a defined purpose

[SOURCE: ISO 17664-2:2021, 3.5]

201.3.229**distributed alarm system****DAS**

alarm system that involves more than one item of equipment of a *ME system* intended for delivery of *alarm conditions* with technical confirmation

Note 1 to entry: The parts of a *distributed alarm system* can be widely separated in distance.

Note 2 to entry: A *distributed alarm system* is intended to notify *operators* of the existence of an *alarm condition*.

Note 3 to entry: For the purposes of this document, technical confirmation means that each element of a *distributed alarm system* confirms or guarantees the successful delivery of the *alarm condition* to the next element or appropriate *technical alarm conditions* are created as described in IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 6.11.2.2.1.

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.17]

201.3.230**distributed information system about alarm conditions****DIS**

system that involves more than one item of equipment in a *ME system* intended to provide information about *alarm conditions* but does not guarantee delivery of that information

Note 1 to entry: A *distributed information system about alarm conditions* is not intended to notify *operators* of the existence of an *alarm condition* as a *risk control* measure. A *distributed information system about alarm conditions* is intended to provide information about an *alarm condition* while the *operator* is aware of the existence of the *alarm condition* by an *alarm system*.

Note 2 to entry: A *distributed information system about alarm conditions* is not intended for confirmed delivery of *alarm conditions*.

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.48]

201.3.231**emergency intake**

dedicated *gas intake port* through which gas is drawn when the supply of *fresh gas* or inflating gas is insufficient or absent

[SOURCE: ISO 4135:2022, 3.4.2.3]

201.3.232**EMS environment****emergency medical services environment**

actual conditions and settings, in which *operators* interact with the *ME equipment* or *ME system*, in and around the scene of an emergency outside of a *professional healthcare facility* where a *patient* can be given medical care, basic or advanced life support as well as during professional transport to a *professional healthcare facility* or between *professional healthcare facilities*

EXAMPLE 1 Responding to and providing life support at the scene of an emergency to a *patient* reported as experiencing injury or illness in a pre-hospital setting, and transporting the *patient*, while continuing such life support care, to an appropriate *professional healthcare facility* for further care.

EXAMPLE 2 Providing monitoring, treatment or diagnosis during transport between *professional healthcare facilities*.

Note 1 to entry: For the purposes of this standard, use of equipment intended for the *EMS environment* and temporarily used in the *home healthcare environment* by emergency medical personnel is considered use in the *EMS environment*.

Note 2 to entry: For the purposes of this standard, the *operators* of equipment intended for the *EMS environment* are presumed to be professional medical personnel or personnel with relevant specialized training.

Note 3 to entry: *Professional healthcare facilities* include hospitals, physician offices, freestanding surgical centres, dental offices, freestanding birthing centres, limited care facilities, first aid rooms or rescue rooms and multiple treatment facilities.

Note 4 to entry: Emergency medical services are known by various names in different countries and regions.

Note 5 to entry: For the purposes of this standard, transport includes road, rotary and fixed-wing ambulances.

[SOURCE: IEC 60601-1-12:2014+AMD1:2020, 3.1]

201.3.233

end-expiratory flow

expiratory flow at the point of initiation of an *inflation* or an inspiration

[SOURCE: ISO 19223:2019, 3.7.6, modified — deleted notes.]

201.3.234

essential function

function or capability that is required to maintain *basic safety*, *essential performance*, a minimum of clinical functionality as specified by the *manufacturer*, and operational availability for the medical device

Note 1 to entry: *Essential functions* include, but are not limited to, the safety instrumented function (*basic safety* and *essential performance*), the control function and the availability of urgently needed functions and such allowing the *operator* to view and manipulate the medical device safely with the most urgently needed performance (operational availability). The loss of *essential function* is commonly termed loss of protection, loss of control and loss of view respectively.

Note 2 to entry: The term is derived from IEC 62443-4-2:2019, 3.1.20, and has been refined for the purpose and scope of this document.

[SOURCE: IEC/TR 60601-4-5:2021, 3.10]

201.3.235

essential principles

essential principles of safety and performance

fundamental high-level requirements that when complied with ensure a medical device is safe and performs as intended

[SOURCE: ISO 16142-1:2016, 3.3]

201.3.236

exhaust port

port of the medical equipment or device from which gas is discharged to the atmosphere during *normal use*, either directly or via an anaesthetic gas scavenging system

[SOURCE: ISO 19223:2019, 3.14.2]

201.3.237**expiratory pause**

portion of the *expiratory phase* from the end of expiratory flow to the start of inspiratory flow

[SOURCE: ISO 19223:2019, 3.4.4, modified — deleted notes.]

201.3.238**expiratory phase**

interval from the start of expiratory flow to the start of inspiratory flow within a *respiratory cycle*

[SOURCE: ISO 19223:2019, 3.4.2, modified — deleted notes.]

201.3.239**false positive alarm condition**

presence of an *alarm condition* when no valid triggering event has occurred in the *patient*, the equipment or the *alarm system*

Note 1 to entry: A *false positive alarm condition* can be caused by spurious information produced by the *patient*, the *patient*-equipment interface, other equipment or the *alarm system* itself.

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.21]

201.3.240**firecall**

method established to provide emergency access to a secure medical device

Note 1 to entry: In an emergency situation, unprivileged users can gain access to key systems to correct the problem. When a *firecall* is used, there is usually a review *process* to ensure that the access was used properly to correct a problem. These methods generally either provide a one-time use user identifier (ID) or one-time password or other suitable measures.

Note 2 to entry: Also referred to as "break glass" feature.

[SOURCE: IEC/TR 60601-4-5:2021, 3.11]

201.3.241**flow-direction-sensitive component**

component or *accessory* through which gas flow has to be in one direction only for proper functioning or *patient* safety

[SOURCE: ISO 4135:2022, 3.1.4.15]

201.3.242**fresh gas**

respirable gas delivered to a *ventilator breathing system*

[SOURCE: ISO 4135:2022, 3.1.1.16, modified — Added 'ventilator' and deleted notes.]

201.3.243**gas intake port**

port through which gas is drawn for use by the *patient*

Note 1 to entry: Gas is drawn at a sub-ambient pressure at a *gas intake port*, in apposition to an *inlet*, at which gas is provided by a medical gas supply system.

[SOURCE: ISO 4135:2022, 3.1.4.21]

201.3.244

gas output port

port of the *ventilator* through which gas is delivered at respiratory pressures to an *operator*-detachable part of the *ventilator breathing system*

[SOURCE: ISO 19223:2019, 3.14.3]

201.3.245

gas pathway

interior surfaces, over which gases or liquids that can be inspired, in a medical device bounded by the ports through which gases or liquids enter and leave the medical device including the *patient* interface or the interior surfaces of *enclosures* that are in contact with gases or liquids that can be inspired

Note 1 to entry: *Patient* contact surfaces such as the outer surfaces of a tracheal tube or the cushion of a *mask* are evaluated according to the ISO 10993 series.

EXAMPLE 1 The *ventilator breathing system*, *inlet* filter, gas mixer, blower and internal piping.

EXAMPLE 2 Enclosed chamber of an incubator including the mattress or the inner surface of an oxygen hood.

EXAMPLE 3 The inner surfaces of breathing tubes, tracheal tubes or *masks* and mouthpieces.

[SOURCE: ISO 18562-1:2023, 3.11]

201.3.246

gas return port

port of the *ventilator* through which gas is returned at respiratory pressures through an *operator*-detachable part of the *ventilator breathing system*, from the *patient-connection port*

[SOURCE: ISO 19223:2019, 3.14.4]

201.3.247

healthcare professional

<adj> appropriately trained, knowledgeable, and skilled, providing systematic preventive, curative, promotional or rehabilitative healthcare services

201.3.248

heat and moisture exchanger

HME

device intended to retain a portion of the *patient's* expired moisture and heat, and return it to the respiratory tract during inspiration

[SOURCE: ISO 9360-1:2000, 3.1]

201.3.249

high-pressure inlet

inlet to which gas is supplied at a pressure exceeding 100 kPa above ambient

Note 1 to entry: The phrases 'low-pressure' and 'high-pressure' are used differently in various contexts, including *breathing system* pressures (typically less than 10 kPa), terminal *outlet* pressures (less than 600 kPa), manifold pressures (typically up to 3 000 kPa) and cylinder pressures (typically less than 30 000 kPa).

[SOURCE: ISO 4135:2022, 3.1.4.24]

201.3.250**home healthcare environment**

dwelling place in which a *patient* lives or other places where *patients* are present, excluding *professional healthcare facility* environments where *operators* with medical training are continually available when *patients* are present

EXAMPLE In a car, bus, train, boat or plane, in a wheelchair or walking outdoors.

Note 1 to entry: *Professional healthcare facilities* include hospitals, physician offices, freestanding surgical centres, dental offices, freestanding birthing centres, limited care facilities, first aid rooms or rescue rooms, multiple treatment facilities and emergency medical services.

Note 2 to entry: For the purpose of this collateral standard, nursing homes are considered *home healthcare environments*.

Note 3 to entry: Other places where a *patient* is present include the outdoor environment, while working and in vehicles.

[SOURCE: IEC 60601-1-11:2015+AMD1:2020, 3.1]

201.3.251**humidifier**

device that adds water in the form of droplets or vapour, or both, to the inspired gas

Note 1 to entry: This term includes vaporising, bubble-through and ultrasonic *humidifiers* and active *heat and moisture exchangers*.

[SOURCE: ISO 4135:2022, 3.7.2.1]

201.3.252**I:E ratio**

ratio of the *inspiratory time* to the expiratory time in a *respiratory cycle*

[SOURCE: ISO 19223:2019, 3.4.19, modified — deleted notes.]

201.3.253**immunity**

the ability of *ME equipment* or an *ME system* to perform without degradation in the presence of an electromagnetic disturbance

[SOURCE: IEC 60601-1-2:2014+AMD1:2020, 3.8]

201.3.254**inflation**

ventilator action intended to increase the volume of gas in the *lungs* by the application of an elevated-pressure waveform to the *patient-connection port* until a specified termination criterion is met

[SOURCE: ISO 19223:2019, 3.3.1, modified — deleted notes.]

201.3.255**inflation phase**

interval from the start of the rise in *airway pressure* resulting from the initiation of an *inflation* to the start of the expiratory flow resulting from its termination

[SOURCE: ISO 19223:2019, 3.4.10, modified — deleted notes.]

201.3.256

inflation-type

inflation characterized by its temporal delivery pattern following initiation, and its termination criteria

[SOURCE: ISO 19223:2019, 3.3.2, modified — deleted notes.]

201.3.257

information for safety

information provided to the user or *responsible organization* as a *risk control* measure

EXAMPLE 1 Warnings, precautions or contraindications.

EXAMPLE 2 *Instructions for use* of a medical device to prevent use error or avoid a *hazardous situation*

EXAMPLE 3 Explanation of a safety feature of a medical device.

Note 1 to entry: *Information for safety* may be found in any or all types of *information supplied by the manufacturer*.

Note 2 to entry: *Information for safety* can be located on the display of a medical device or *accessory*.

[SOURCE: ISO 20417:2021, 3.9]

201.3.258

information supplied by the manufacturer

information related to the identification and use of a medical device or *accessory*, in whatever form provided, intended to ensure the safe and effective use of the medical device or *accessory*

Note 1 to entry: For the purposes of this document, *e-documentation* is included in *information supplied by the manufacturer*.

Note 2 to entry: For the purposes of this document, shipping documents and promotional material are excluded from *information supplied by the manufacturer*. However, some *authorities having jurisdiction* can consider such supplemental information as *information supplied by the manufacturer*.

Note 3 to entry: The primary purpose of *information supplied by the manufacturer* is to identify the medical device and its *manufacturer*, and provide essential information about its safety, performance and appropriate use to the user or other relevant persons.

[SOURCE: ISO 20417:2021, 3.10, modified — deleted note 4.]

201.3.259

inlet

opening through which gas or other material is pushed by an elevated upstream pressure

[SOURCE: ISO 4135:2022, 3.1.4.26, modified — deleted note.]

201.3.260

inspiratory pause

interval from the end of inspiratory flow to the start of expiratory flow within a *respiratory cycle*

[SOURCE: ISO 19223:2019, 3.4.12, modified — deleted notes.]

201.3.261

inspiratory time

t_i

duration of an *inflation phase* or inspiratory phase

[SOURCE: ISO 19223:2019, 3.4.8, modified — deleted notes.]

201.3.262

inspiratory volume

V_{insp}

volume of gas delivered through the *patient-connection port* during an *inspiratory phase* or *inflation phase*

[SOURCE: ISO 19223:2019, 3.8.3, modified — deleted notes.]

201.3.263

instructions for use

IFU

portion of the *accompanying information* that is essential for the safe and effective use of a medical device or *accessory* directed to the user of the medical device

Note 1 to entry: For the purposes of this document, a user can be either a *lay* user or professional user with relevant specialized training.

Note 2 to entry: For the purposes of this document, instructions for the professional *processing* between uses of a medical device or *accessory* can be included in the *instructions for use*.

Note 3 to entry: For the purposes of this document, information indicated on a graphical user interface (GUI) is considered as appearing on the item.

Note 4 to entry: The *instructions for use*, or portions thereof, can be located on the display of a medical device or *accessory*.

Note 5 to entry: Medical devices or *accessories* that can be used safely and effectively without *instructions for use* are exempted from having *instructions for use* by some *authorities having jurisdiction*.

[SOURCE: ISO 20417:2021, 3.11, modified — deleted note 6.]

201.3.264

intelligent alarm system

alarm system that makes logical decisions based on monitored information without *operator* intervention

EXAMPLE 1 An *alarm system* that changes priority based on the rate of change of a monitored variable.

EXAMPLE 2 An *alarm system* that suppresses an *alarm condition* when a related *alarm condition* of higher priority has recently generated an *alarm signal*.

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.24]

201.3.265

latching alarm signal

alarm signal that continues to be generated after its triggering event no longer exists until stopped by deliberate *operator* action

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.26]

201.3.266

low-pressure hose assembly

assembly consisting of a flexible hose with permanently attached gas-specific *inlet* and *outlet connectors* and designed to conduct a *medical gas* at pressures less than 1 400 kPa

Note 1 to entry: The phrases 'low-pressure' and 'high-pressure' are used differently in various contexts, including *breathing system* pressures (typically less than 10 kPa), terminal *outlet* pressures (less than 1 400 kPa), manifold pressures (typically up to 3 000 kPa) and cylinder pressures (typically less than 30 000 kPa).

[SOURCE: ISO 4135:2022, 3.2.3.1]

201.3.267

lung

each of the pair of compliant organs within the ribcage (thorax), bounded by the terminal bronchiole and the visceral pleura, which during ventilation provide gas/blood interfaces that enable oxygen from the gas to pass into the blood and carbon dioxide to be removed

[SOURCE: ISO 19223:2019, 3.1.16, modified — deleted notes.]

201.3.268

marking

information, in text or graphical format, durably affixed, printed, etched (or equivalent) to a medical device or *accessory*

Note 1 to entry: For the purposes of this document, the term *marked* is used to designate the corresponding act.

Note 2 to entry: For the purposes of this document, *marking* is different from 'direct *marking*' as commonly described in unique device identification (UDI) standards and regulations. A UDI 'direct *marking*' is a type of *marking*.

[SOURCE: ISO 20417:2021, 3.16, modified — deleted note 3.]

201.3.269

mask

device which provides a non-invasive interface between the *patient's airway* and a *patient-connection port* or other connection to a source of respirable gas

[SOURCE: ISO 4135:2022, 3.8.6.4]

201.3.270

maximum limited pressure

$P_{lim,max}$

highest *airway pressure* that can occur during *normal use* or under *single fault condition*

[SOURCE: ISO 19223:2019, 3.13.3, modified — deleted notes.]

201.3.271

maximum working pressure

$P_{w max}$

highest *airway pressure* that can be generated by the *ventilator* during *intended use* and *normal condition*

[SOURCE: ISO 19223:2019, 3.13.4, modified — deleted notes.]

201.3.272

medical gas pipeline system

combination of a supply system, a monitoring and *alarm system* and a pipeline distribution system with terminal units for provision of medical gases or vacuum

[SOURCE: ISO 4135:2022, 3.2.1.1]

201.3.273**minimum limited pressure** $P_{\text{lim,min}}$ lowest *airway pressure* that can occur during *normal use* or under *single fault condition*Note 1 to entry: The *minimum limited pressure* can be subatmospheric.

[SOURCE: ISO 4135:2022, 3.1.4.41.4]

201.3.274**monitoring equipment**equipment or part that measures and indicates the value of a variable to the *operator*Note 1 to entry: *Monitoring equipment* includes devices that are not electrical in operation, such as a pressure gauge.

Note 2 to entry: The value can be displayed continually or intermittently.

Note 3 to entry: The *monitoring equipment* can be primarily intended for detection of an *alarm condition* or for external communication.[SOURCE: ISO 4135:2022, 3.11.1.3, modified —replaced "user" with "*operator*".]**201.3.275****operator interface**means by which the *operator* and the *ME equipment* interactNote 1 to entry: The *accompanying documents* are considered part of the *ME equipment* and its *operator interface*.Note 2 to entry: *Operator interface* includes all the elements of the *ME equipment* with which the *operator* interacts including the physical aspects of the *ME equipment* as well as visual, auditory, tactile displays and is not limited to a software interface.Note 3 to entry: For the purposes of this standard, the *manufacturer* may treat the combination of *ME equipment* and other equipment as a single *operator interface*.

Note 4 to entry: See IEC 62366-1:2015+AMD1:2020, 3.26.

[SOURCE: IEC 60601-1-6:2010+AMD2:2020, 3.1]

201.3.276**operator's position**intended position of the *operator* with respect to the *alarm signal* generating part of the *alarm system*Note 1 to entry: A *distributed alarm system* can have multiple *operator's positions*.

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.30]

201.3.277**outlet**

opening through which gas leaves a device or component

[SOURCE: ISO 4135:2022, 3.1.4.40]

201.3.278**patient-connection port**port of a *breathing system* intended for connection to an *airway device*

Note 1 to entry: The *patient-connection port* is the end of the *breathing system* proximal to the *patient*.

Note 2 to entry: The *patient-connection port* is typically a *connector* suitable for connection to an *airway device* such as a tracheal tube, tracheostomy tube, face *mask* or supralaryngeal airway.

Note 3 to entry: Current product standards typically specify that the *patient-connection port* is required to be in the form of specific standardized *connectors*, for example, a *connector* conforming to ISO 5356-1.

[SOURCE: ISO 4135:2022, 3.1.4.41, modified —deleted note 4.]

201.3.279

PEEP

positive end-expiratory pressure

<actual and measured value> respiratory pressure at the end of an *expiratory phase*

[SOURCE: ISO 19223:2019, 3.10.4, modified — deleted notes.]

201.3.280

physiological alarm condition

alarm condition arising from a monitored *patient*-related variable

EXAMPLE 1 High exhaled anaesthetic agent concentration.

EXAMPLE 2 Low exhaled *tidal volume*.

EXAMPLE 3 Low oxygen saturation measured by pulse oximetry.

EXAMPLE 4 High arterial pressure.

EXAMPLE 5 High heart rate.

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.31]

201.3.281

physiologic closed-loop control system

part of *ME equipment* or *ME system* used to adjust a physiologic variable (y) relative to a command variable (c) using a feedback variable (f)

[SOURCE: IEC 60601-1-10:2007+AMD2:2020, 3.19]

201.3.282

pressure-control

inflation-type that acts to generate a constant inspiratory pressure at a set level, after a set rise time

[SOURCE: ISO 19223:2019, 3.3.4, modified — deleted notes.]

201.3.283

primary operating function

function that involves user interaction that is related to the safety of the medical device

Note 1 to entry: Often a *primary operating function* is interacted with by a series of tasks that can be broken down into a series of user interactions.

Note 2 to entry: The concept of safety includes loss or degradation of performance resulting in an unacceptable *risk* to the *patient*, including use error that prevents the user from effectively using the medical device to achieve its intended medical purpose. In IEC 60601-1, this is referred to as *essential performance*.

[SOURCE: IEC 62366-1:2015+AMD1:2020, 3.11]

201.3.284**processing**

<preparation of medical device, *accessory*> activity to prepare a new or used medical device and *accessory* for its *intended use*

[SOURCE: ISO 20417:2021, 3.20]

201.3.285**professional healthcare facility**

facility that is continually staffed by suitably trained *healthcare professional operators*

EXAMPLE Hospitals, physician offices, freestanding surgical centres, dental offices, freestanding birthing centres, limited care facilities, first aid rooms or rescue rooms, multiple treatment facilities and emergency medical services

Note 1 to entry: There is guidance or rationale for this definition contained in Clause AA.2.

201.3.286**protection device**

part or function of *ME equipment* that, without intervention by the *operator*, protects the *patient* from hazardous output due to incorrect delivery of energy or substances

201.3.287**respiratory cycle**

complete sequence of respiratory events that leads to an increase, followed by a corresponding decrease, of gas volume in the *lung* regardless of how it is generated

[SOURCE: ISO 19223:2019, 3.4.16, modified — deleted notes.]

201.3.288**security level**

level corresponding to the required set of countermeasures and inherent *cybersecurity* properties of devices and systems for a zone or conduit based on assessment of *risk* for the zone or conduit

[SOURCE: IEC/TR 60601-4-5:2021, 3.23]

201.3.289**set rate**

number of assured *inflations* that are set to occur in a specified period of time, expressed as breaths per minute

[SOURCE: ISO 19223:2019, 3.5.1.1, modified — deleted notes and examples.]

201.3.290**single use**

<medical device, *accessory*> intended by the *manufacturer* to be used on an individual *patient* or specimen during a single *procedure* and then disposed of

Note 1 to entry: A *single use* medical device or *accessory* is not intended by its *manufacturer* to be further *processed* and used again.

[SOURCE: ISO 20417:2021, 3.26]

201.3.291**software item**

any identifiable part of a computer program, i.e., source code, object code, control code, control data, or a collection of these items

Note 1 to entry: Three terms identify the software decomposition. the top level is the software system. The lowest level that is not further decomposed is the software unit. All levels of composition, including the top and bottom levels, can be called *software items*. A *software system*, then, is composed of one or more *software items*, and each *software item* is composed of one or more software units or decomposable *software items*. The responsibility is left to the *manufacturer* to provide the definition and granularity of the *software items* and software units.

[SOURCE: IEC 62304:2006+AMD1:2015, 3.25, modified — deleted note 2.]

201.3.292

spontaneous breath rate

total number of spontaneous breaths initiated in a specified period of time, expressed as breaths per minute

[SOURCE: ISO 19223:2019, 3.5.1.3, modified — deleted notes.]

201.3.293

standard temperature and pressure dry

STPD

pressure of 101,325 kPa at a temperature of 20 °C, dry

[SOURCE: ISO 4135:2022, 3.1.1.8]

201.3.294

sterile

free from viable microorganisms

[SOURCE: ISO 20417:2021, 3.28]

201.3.295

sterilization

process used to render product free from viable microorganisms

Note 1 to entry: In a *sterilization process*, the nature of microbial inactivation is exponential and thus the survival of a microorganism on an individual item can be expressed in terms of probability. While this probability can be reduced to a very low number, it can never be reduced to zero.

[SOURCE: ISO 17664-1:2021, 3.17]

201.3.296

suction catheter

flexible tube designed for introduction into the respiratory tract or an *airway device* to remove material by suction

[SOURCE: ISO 8836:2019, 3.17]

201.3.297

symbol

graphical representation appearing on the label or associated documentation of a medical device that communicates characteristic information without the need for the supplier or receiver of the information to have knowledge of the language of a particular nation or people

Note 1 to entry: The *symbol* can be an abstract pictorial or a graphical representation, or one that uses familiar objects, including alphanumeric characters (with sufficient justification).

[SOURCE: ISO 20417:2021, 3.29]

201.3.298**system recovery**

method for fault handling via an automatic restart of *PESS* for parts of the *ME equipment* or for the complete *ME equipment*

Note 1 to entry: There is guidance or rationale for this definition contained in Clause AA.2.

201.3.299**technical alarm condition**

alarm condition arising from a monitored equipment-related or *alarm system*-related variable

EXAMPLE 1 An electrical, mechanical or other failure.

EXAMPLE 2 A failure of a sensor or component (unsafe voltage, high impedance, signal impedance, artefact, noisy signal, disconnection, calibration error, tubing obstruction, etc.).

EXAMPLE 3 An algorithm that cannot classify or resolve the available data.

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.36]

201.3.300**technical description**

portion of the *accompanying information* directed to the *responsible organization* and *service personnel* that is essential for preparation for the first use and safe use, maintenance or repair as well as *processing*, transport or storage for the *expected service life* of a medical device

Note 1 to entry: The *technical description* may be included in the *instructions for use*.

[SOURCE: ISO 20417:2021, 3.30, modified — replaced 'expected lifetime' with '*expected service life*' and deleted note 2.]

201.3.301**tidal volume**

V_T

volume of gas that enters and leaves the *lung* during a breath

[SOURCE: ISO 19223:2019, 3.8.1, modified — deleted notes.]

201.3.302**total respiratory rate**

number of *respiratory cycles* in a specified period of time, expressed as breaths per minute

[SOURCE: ISO 19223:2019, 3.5.1.2, modified — deleted notes.]

201.3.303**transit-operable**

<adj> term referring to transportable equipment whose *intended use* includes operation while it is being moved

EXAMPLE Transportable *ME equipment* that is body-worn, hand-held, attached to a wheelchair, or used in a car, bus, train, boat or plane.

Note 1 to entry: For the purpose of this standard, *transit-operable* use in the *home healthcare environment* can include use indoors, outdoors and in vehicles.

[SOURCE: IEC 60601-1-11:2015+AMD1:2020, 3.4]

201.3.304

validation

confirmation, through the provision of *objective evidence*, that specified requirements have been fulfilled

Note 1 to entry: The *objective evidence* needed for a *validation* is the result of a test or other form of determination such as performing alternative calculations or reviewing documents.

Note 2 to entry: The word “*validated*” is used to designate the corresponding status.

Note 3 to entry: The use conditions for *validation* can be real or simulated.

[SOURCE: ISO 9000:2015, 3.8.13]

201.3.305

ventilation-mode

specified manner in which a *ventilator* performs its ventilatory function when connected to a *patient*

[SOURCE: ISO 19223:2019, 3.11.2, modified — deleted notes.]

201.3.306

ventilator

medical device or *medical electrical equipment* intended to provide *artificial ventilation*

[SOURCE: ISO 19223:2019, 3.1.1, modified — deleted notes.]

201.3.307

ventilator breathing system

VBS

pathways through which gas flows to or from the *patient* at respiratory pressures, bounded by the port through which respirable gas enters, the *patient-connection port* and the *gas exhaust port*

Note 1 to entry: These pathways typically extend within and outside the body of the *ventilator*, with those outside being *operator-detachable*.

Note 2 to entry: The *port* of entry of a respirable gas into the *ventilator breathing system* can be inside the body of the *ventilator* and should not be confused with an external connection port into which respirable gas enters before being reduced to respirable pressures.

[SOURCE: ISO 19223:2019, 3.1.18, modified — deleted notes 3 and 4.]

201.3.308

ventilator operational-mode

way in which a *ventilator* is set to operate

EXAMPLE Standby; calibration; *ventilator breathing system* check; start-up *procedure*.

Note 1 to entry: NIV (non-invasive ventilation) also becomes an operational mode if it is selectable as an option.

Note 2 to entry: In the absence of the selection of a specific alternative *operational mode(s)*, when ventilation is started, typically after a *ventilator* setup routine, a *ventilator* will commence ventilation using its intended *ventilation-mode* and as configured by the *operator's* settings and selections.

[SOURCE: ISO 19223:2019, 3.11.1, modified — deleted note 3.]

201.3.309**ventilator-dependent**

<patient> dependent upon *artificial ventilation* in order to prevent serious deterioration of health or death

Note 1 to entry: A *ventilator-dependent patient* cannot breathe well enough to maintain life-sustaining levels of oxygen and carbon dioxide in the blood.

EXAMPLE *Patients* with Duchenne muscular dystrophy or other degenerative disease resulting in their unsupported respiratory effort being insufficient to sustain life.

[SOURCE: ISO 4135:2022, 3.1.5.19]

201.3.310**volume-control**

inflation-type that generates inspiratory flow to a selected flow-waveform, for a set *inspiratory-time*, or until the set volume has been delivered

[SOURCE: ISO 19223:2019, 3.3.3, modified — deleted notes.]

201.4 General requirements

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 4 applies, except as follows:

Addition:

201.4.3.101 Additional requirements for *essential performance*

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

Additional *essential performance* requirements are found in the subclauses listed in Table 201.101.

Table 201.101 — Distributed *essential performance* requirements

Requirement	Subclause
Delivery of ventilation at the <i>patient-connection port</i> within the <i>alarm limits</i> set by the <i>operator</i> or generation of an <i>alarm condition</i>	a
oxygen level	201.12.4.101
<i>airway pressure</i>	201.12.4.106
disconnection	201.12.4.109
<i>internal electrical power source</i> nears depletion	201.11.8.101
gas supply failure	201.13.2.102
obstruction	201.12.4.108
<i>PEEP</i>	201.12.4.107
<i>system recovery</i> , if provided	201.4.3.102
for delivered volume of greater than 50 ml, expired volume	201.12.4.103.1
for delivered volume of less than 50 ml, one of:	
CO ₂ level; or	201.12.4.104
expired volume	201.12.4.103.2
^a 202.4.3.1 and 202.8.1.101 indicate methods of evaluating delivery of ventilation as acceptance criteria following specific tests required by this document.	

201.4.3.102 *System recovery*

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

- a) Following a malfunction, the *ventilator* shall perform a *system recovery* to attempt to restore *essential performance* of the *ventilator*.

NOTE 2 A *ventilator* or a subassembly function can become disturbed by a malfunction that could jeopardize the *essential performance* of the *ventilator*. Without *system recovery*, the *patient* would have to be disconnected and connected to an alternative means of ventilation. Ventilation would thus be interrupted until an alternative means of ventilation is connected. *System recovery*, as specified in this subclause, attempts to automatically re-establish ventilation in a shorter period. If necessary, the *ventilator* can be replaced later when it is less consequential for the *patient's* therapy.

- b) *System recovery* may result in the temporary:

- 1) cessation in the ventilation of the *patient*; or
- 2) reduction in the function of *ventilator* subassemblies without impacting the ventilation of the *patient*.

EXAMPLE The temporary blanking of the display.

- c) During a *system recovery* with a cessation of ventilation:

- 1) the *ventilator* shall allow spontaneous *patient* breathing in accordance with 201.103; and
- 2) the *ventilator* shall be equipped with an *alarm system* to indicate *system recovery* with a cessation of ventilation.

- i) The *system recovery* with a cessation of ventilation *alarm condition* shall be *high priority*.
- d) During a *system recovery* without a cessation of ventilation, the *ventilator* shall be equipped with an *alarm system* to indicate *system recovery* without a cessation of ventilation.
 - 1) The *alarm condition* for *system recovery* without a cessation of ventilation shall be at least *low priority* with an auditory *alarm signal*.
- e) Following a *system recovery* without *operator* intervention, the *ventilator* shall attempt to operate with the same system configuration settings, ventilation settings and *alarm settings* as before the *system recovery*.
 - 1) If the system configuration settings, ventilation settings or *alarm settings* are different after the *system recovery*, the *ventilator* shall be equipped with an *alarm system* to indicate any change in settings.
 - 2) The change in settings *alarm condition* shall be at least *medium priority*.
- f) The duration of a *system recovery* with a cessation of ventilation should be as short as practicable to avoid an unacceptable *risk* to the *patient*.
- g) The maximum duration of a *system recovery* of ventilation shall be disclosed in the *instructions for use*.

Check conformity by inspection of the *instructions for use* and functional testing.

201.4.4 Additional requirements for *expected service life*

Amendment (add as a second paragraph):

The *manufacturer* shall:

- aa) state the probability of component failure that results in the *ventilator* needing to be taken out of service during the *expected service life* assuming that the preventative inspection, maintenance and calibration are performed according to the *accompanying documents*; and
- bb) summarize the methodology used to determine this probability.

Replacement (replace the compliance check):

Conformity is checked by inspection of the design documentation and the *risk management file*.

201.4.5 Alternative *risk control* measures or test methods for *ME equipment* or *ME system*

Amendment (add prior to the compliance check):

- aa) Subsequent revisions of dated references (new editions or amendments) may be used in substitution of a referenced document provided the *manufacturer* can demonstrate the *hazard* or *hazardous situation* addressed in the dated normative reference is adequately resolved in the subsequent revision.

201.4.6 *ME equipment* or *ME system* parts that contact the *patient*

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

Amendment (add at end of subclause):

- aa) The *VBS* or its parts or *accessories* that can come into contact with the *patient* shall be subject to the requirements for *applied parts* in accordance with this subclause.

Addition:

201.4.11.101 Additional requirements for pressurized gas input

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

201.4.11.101.1 Overpressure requirement

- a) A *ventilator* with a pressurized gas input shall:
- 1) operate and meet the requirements of this document throughout its *rated* range of input pressure; and
 - 2) not cause an unacceptable *risk* under the *single fault condition* of 1 000 kPa.
- b) A *ventilator* with a maximum *rated* input pressure in excess of 600 kPa shall not cause an unacceptable *risk* under the *single fault condition* of twice the maximum *rated* input pressure.

NOTE 1 Internal pressure regulators can be required to accommodate the *single fault condition* of maximum input pressure as well as the *rated* range of input pressure.

NOTE 2 Under the *single fault condition* of overpressure, it is desirable for gas to continue to flow to the *VBS*. Under this condition, the flowrate from the *ventilator* is likely to be outside of its specification.

Check conformity by functional testing in *normal use* and under *normal condition* with the most adverse operating settings, by functional testing in *single fault condition* and inspection of the *risk management file* for risks associated with overpressure conditions.

201.4.11.101.2 Compatibility requirement for *medical gas pipeline systems*

If the *ventilator* is intended to be connected to a *medical gas pipeline system* conforming with ISO 7396-1:2016+AMD1:2017 then:

- a) the *rated* range of input pressure shall cover the range specified in ISO 7396-1:2016+AMD1:2017; and

NOTE Taking account of requirements for over-pressure and under-pressure, this corresponds to a range 280 kPa to 600 kPa.

- b) under *normal condition*,
- 1) the maximum input flowrate required by the *ventilator* for each gas shall not exceed 60 l/min averaged over 10 s, measured at the *gas intake port* with an input pressure of 280 kPa; and
 - 2) any transient input flowrate shall not exceed 200 l/min averaged over 3 s,

or:

- 3) the *accompanying documents* shall disclose:

- i) the maximum input flowrate required by the *ventilator* for each gas at a pressure of 280 kPa averaged over 10 s, measured at the *gas intake port*;
- ii) the maximum transient input flowrate averaged for 3 s required by the *ventilator* for each gas at a pressure of 280 kPa, measured at the *gas intake port*; and
- iii) a warning to the effect that this ventilator is a high-flow device and should only be connected to a pipeline installation designed using a diversity factor that allows for the indicated high flow at a specified number of terminal *outlets*, in order to avoid exceeding the pipeline design flow, thereby minimising the *risk* that the ventilator interferes with the operation of adjacent equipment.

Check conformity by functional testing in *normal use* and under *normal condition* with the most adverse operating settings and by inspection of the *accompanying documents*.

EXAMPLE Highest driving gas consumption under worst-case settings for *set rate* and *tidal volume* within the *rated* range for *inlet* pressure.

201.5 General requirements for testing of *ME equipment*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 5 applies, except as follows:

Addition:

201.5.101 Additional requirements for general requirements for testing of *ME equipment*

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

201.5.101.1 *Ventilator* test conditions

- a) For testing, the *ventilator*
 - 1) shall be connected to gas supplies as specified for *normal use*,
 - 2) except that industrial grade oxygen and air may be substituted for the equivalent medical gas, as appropriate, unless otherwise stated.

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

- b) When using substitute gases, care should be taken to ensure that the test gases are oil-free and appropriately dry.

201.5.101.2 Gas flowrate and leakage specifications

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

All requirements for gas flowrate, volume and leakage in this document,

- a) are expressed at *STPD*,
- b) except for those associated with the *VBS*, which are expressed at *BTPS*.

Correct all test measurements to STPD or BTPS, as appropriate.

201.5.101.3 Ventilator testing errors

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

a) For the purposes of this document, acceptance criteria for declared tolerances of testing shall use:

- 1) *procedure 1* (calculation of uncertainty of measurement) from IEC Guide 115:2021, 4.4.2; or
- 2) *procedure 2* (accuracy method) from IEC Guide 115:2021, 4.4.3.

NOTE 2 This is a change from previous revisions of this document, which required tolerances to be adjusted by subtracting measurement uncertainty from disclosed tolerance values to determine acceptance criteria.

b) Test equipment and methods shall be selected and controlled to ensure that the uncertainty (with coverage factor $k = 2$, for confidence of $\sim 95\%$) is no more than 30% of the disclosed tolerance for the parameter being tested.

EXAMPLE If the *manufacturer* wishes to claim a tolerance for delivered volume of $\pm(10 \text{ ml} + 10 \% \text{ of set volume})$ then the uncertainty of the measurement cannot exceed $\pm(3 \text{ ml} + 3 \% \text{ of set volume})$.

c) The *manufacturer* shall disclose the measurement uncertainty for each disclosed tolerance in the *technical description*.

Check conformity by inspection of the *technical description*.

201.6 Classification of ME equipment and ME systems

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 6 applies.

201.7 ME equipment identification, marking and documents

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 7 applies, except as follows:

Addition:

201.7.1.101 Information to be supplied by the manufacturer

- a) The *information supplied by the manufacturer* of a ventilator and its *accessories* shall conform with ISO 20417:2021.
- b) In applying ISO 20417:2021, the terms in this document and those in IEC 60601-1:2005+AMD1:2012+AMD2:2020 shall be used as follows.
 - 1) The term "*accompanying information*" shall assume the same meaning as *accompanying documents*.
 - 2) The term "*medical device*" shall assume the same meaning as *ME equipment*.
 - 3) The term "*user*" shall assume the same meaning as *operator*.
 - 4) The term "*patient*" shall include animals.

Check conformity by application of ISO 20417:2021.

201.7.2.3 Consult accompanying documents

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

Replacement:

The *ventilator* shall be marked with the *safety sign* for the mandatory action: “follow instructions for use”, ISO 7010-M002 (see IEC 60601-1:2005+AMD1:2012+AMD2:2020, Table D.2, *safety sign* 10).

Addition:

201.7.2.4.101 Additional requirements for accessories

a) *Accessories* supplied separately shall:

- 1) fulfil the *marking* requirements of ISO 20417:2021, 6.1.1 c); and
- 2) be marked with an indication of any limitations or adverse effects of the *accessory* on the *basic safety* or *essential performance* of the *ventilator*, if applicable. See also 201.7.2.101.

b) If *marking* the *accessory* is not practicable, this information may be placed in the *instructions for use*.

Check conformity by inspection, inspection of the *risk management file* for any limitations or adverse effects of the *accessory*, if applicable, and where necessary, inspection of the *instructions for use*.

201.7.2.18 External gas source

Amendment (add before the first dash):

- aa) the gas name or chemical *symbol* in accordance with ISO 5359:2014+AMD1:2017;
- bb) the *rated* range of gas pressure;
- cc) for oxygen gas inputs, the *rated* range of oxygen concentration;
- dd) gas-specific colour coding in accordance with ISO 32:1977, if colour coding is used.

EXAMPLE Colour coding to match the colour of the flexible hose or a gas cylinder intended to be attached to the *connector of an inlet*.

NOTE In some countries, other colour coding is used.

Addition:

201.7.2.101 Additional requirements for marking on the outside of ME equipment or ME equipment parts

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

- a) If applicable, *operator-accessible ME equipment*, parts or *accessories* shall have *clearly legible markings* of the following
 - 1) for a *ventilator* intended to be used in the magnetic resonance (MR) environment, in accordance with IEC 62570:2014:

- i) *symbol 7.3.1-1* (Table 201.D.2.101, *symbol 3*) or *symbol 7.3.1-2* (Table 201.D.2.101, *symbol 4*) of IEC 62570:2014 for an 'MR Safe' ventilator; or
 - ii) *symbol 7.3.2* of IEC 62570:2014 (Table 201.D.2.101, *symbol 5*) for an 'MR Conditional' ventilator.
- 2) for a ventilator not intended for use in the magnetic resonance (MR) environment, in accordance with IEC 62570:2014 *symbol 7.3.3* (Table 201.D.2.101, *symbol 6*) for an 'MR Unsafe' ventilator.
- 3) for *flow-direction-sensitive components* that are *operator-removable* without the use of a *tool*, an arrow indicating the direction:
- i) of the flow; or
 - ii) of inspiratory flow if exposed to inspiratory and expiratory flow.
- b) If applicable, *operator-accessible ME equipment*, parts or *accessories* shall have *clearly legible markings* of the following on or adjacent to the following items:
- 1) a warning not to obstruct the *gas intake port*; and
- EXAMPLE 1 WARNING: Gas intake – Do not obstruct
- i) A *symbol* or *safety sign* evaluated in accordance with to IEC 62366-1 as *information for safety* may be used.
- 2) an arrow indicating the intended direction of gas flow:
- i) for the *gas output port*; and
 - 1) *Symbol 0795* of ISO 7000 (Table 201.D.2.101, *symbol 2*) may be used for *gas output port*.
 - ii) for the *gas return port*.
 - 1) *Symbol 0794* of ISO 7000 (Table 201.D.2.101, *symbol 1*) may be used for the *gas return port*.
- 3) for a sampling gas *inlet*, either with the text "Gas sample" or the *Symbol* ISO 7000-0794, (Table 201.D.2.101, *symbol 1*).

EXAMPLE 2 Input to a diverting respiratory gas monitor integrated into the EMS ventilator.

Check conformity by inspection.

201.7.4.3 Units of measurement

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

IEC 60601-1:2005+AMD1:2012+AMD2:2020, 7.4.3 applies, except as follows:

Amendment (add to the bottom as a new row in Table 1):

All gas volume, flowrate and leakage specifications:

- aa) shall be expressed at STPD; except for those associated with the VBS which
- bb) shall be expressed at BTPS.

201.7.9.2.1 General

Amendment (add as the fifth bullet following the first paragraph):

— the intended position of the *operator*;

Addition:

201.7.9.2.1.101 Additional general requirements

The *instructions for use* shall disclose the following:

- a) the intended range of *tidal volume*.

Check conformity by inspection.

201.7.9.2.2.101 Additional requirements for warnings and safety notices

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

- a) The *instructions for use* shall include:

- 1) a warning statement to the effect of “Warning: Do not cover the ventilator or place in a position that affects proper operation”, including applicable examples.

EXAMPLE 1 **WARNING:** Do not position next to a curtain that blocks the flow of cooling air, thereby causing the equipment to overheat, thereby interfering with patient ventilation.

EXAMPLE 2 **WARNING:** Do not block the gas intake port or emergency intake, thereby interfering with patient ventilation.

- 2) a warning statement to the effect of “Warning: Always have immediate access to an alternative means of ventilation, which is ready for use, in order to reduce the possibility of patient death or serious deterioration of health.”

EXAMPLE 3 **WARNING:** Failure to have an alternative means of ventilation such as a self-inflating, manually-powered resuscitator (as specified in ISO 10651-4:2023) with mask can result in patient death if the ventilator fails.

- 3) a warning statement to the effect of “WARNING: Do not add any attachments or accessories to the ventilator that contravene the *instructions for use* of the ventilator or accessory, as the ventilator might not function correctly, leading to the risk of patient death or serious deterioration of health.”

- b) If applicable, the *instructions for use* shall include the following:

- 1) a warning statement to the effect of “Warning: The ventilator shall not be used in a hyperbaric chamber. Such use might cause the ventilator to not function correctly, causing patient death or serious deterioration of health.”
- 2) a warning statement to the effect of “Warning: The ventilator shall not be used with nitric oxide. Such use might cause the ventilator to not function correctly, causing patient death or serious deterioration of health.”
- 3) a warning statement to the effect of “Warning: The ventilator shall not be used with inlet gases, which are not specified for use (e.g. helium or mixtures with helium). Such use might cause the ventilator to not function correctly, causing patient death or serious deterioration of health.”
- 4) a warning statement to the effect of “Warning: The ventilator accuracy can be affected by the gas added to the ventilator breathing system by use of a pneumatic nebuliser.”

- 5) a warning statement to the effect of “Warning: It is the responsibility of the responsible organization to ensure that the oxygen source is compatible with the rated range of pressure, flowrate and oxygen concentration as marked on the ventilator and indicated in the instructions for use as this can affect the performance of the ventilator that can consequently result in patient death or serious deterioration of health.”
- 6) a warning statement to the effect of “Warning: When using nebulisation or humidification, breathing system filters and heat and moisture exchangers can require more frequent replacement to prevent increased resistance and blockage.

Check conformity by inspection.

201.7.9.2.8.101 Additional requirements for start-up *procedure*

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

NOTE 2 A start-up *procedure* includes a pre-use functional test that is used to determine whether the *ventilator* is ready for use.

- a) The *instructions for use* shall disclose a method by which the following can be functionally tested by the *healthcare professional operator* to determine if they are operating correctly:
 - 1) the assembled *VBS*;
 - 2) switchover to and operation from the *internal electrical power source*; and
 - 3) all of the *alarm signals*, including the *alarm signals* from any *distributed alarm systems*.
- b) Portions of this test method may:
 - 1) be automatically performed by the *ventilator*; or
 - 2) require *healthcare professional operator* action.

EXAMPLE Combination of the power-on self-test routines and *healthcare professional operator* action.

Check conformity by inspection of the *instructions for use*.

201.7.9.2.9.101 Additional requirements for operating instructions

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

The *instructions for use* shall disclose

- a) a listing of the following pressures:
 - 1) the range of *maximum limited pressure* ($P_{\text{lim,max}}$);
 - 2) if provided, the *rated* range to which the *maximum working pressure* ($P_{\text{w max}}$) can be set, if adjustable;
 - 3) the means by which the *maximum working pressure* is accomplished;

EXAMPLE 1 Pressure cycling, pressure limiting, pressure generation.

- 4) a statement that airway pressure can be subatmospheric during the expiratory phase for a ventilator that can generate subatmospheric pressure in the expiratory phase, if applicable;
 - 5) the *minimum limited pressure* at the *patient-connection port*, for *ventilators* that can generate subatmospheric pressure in the *expiratory phase*.
- b) the *rated* range of the following characteristics of the assembled *operator-detachable* parts of the *VBS*, over which the accuracies of set and monitored volumes and pressures are maintained:
- 1) inspiratory *gas pathway* resistance,
 - 2) expiratory *gas pathway* resistance, and
 - 3) *VBS* compliance.
 - i) These specifications may be presented in ranges.
 - ii) The accuracies of set and monitored volumes may be presented as a function of these characteristics.
- NOTE Compliance and resistance can be non-linear. These characteristics might need to be specified over a range (e.g. at 15 l/min, 30 l/min, 60 l/min and the maximum flowrate or the maximum pressure).
- c) the conditions under which the *ventilator* maintains the accuracy of controlled and displayed variables as disclosed in the *instructions for use*.
- EXAMPLE 2 Acceptable range of water level in a *humidifier*.
- EXAMPLE 3 Interval of calibration of a flow sensor.
- d) an explanation of the meaning of the IP classification *marked* on the *ME equipment*.
- e) an indication as to whether the *ventilator* is intended for non-invasive ventilation.
- EXAMPLE 4 This ventilator is intended for use with mask ventilation.
- f) a cross reference between the *manufacturer-specific* naming of the *ventilator's ventilation-modes* and the *ventilation-mode* systematic coding scheme in Annex E of ISO 19223:2019.

Check conformity by inspection.

201.7.9.2.12 *Cleaning, disinfection, and sterilization*

Amendment: (add after normal use)

or in *single fault condition*

Amendment: (add after bulleted list)

- aa) The *instructions for use* shall identify which portions of the *gas pathways* through the *ventilator* can become contaminated with body fluids or by contaminants carried by expired breathing gases during both *normal condition* and *single fault condition*.

Addition:

201.7.9.2.14.101 Additional requirements for *accessories*, supplementary equipment, used material

- a) The *instructions for use* of the *ventilator* shall identify:
 - 1) at least one set of *accessories*; and
 - 2) if applicable, the *ME equipment* necessary for the *ventilator's intended use*.
- b) If applicable, the *instructions for use* of the *ventilator* shall disclose:
 - 1) any restrictions on the positioning of components within the *ventilator breathing system*; and
EXAMPLE Where such components are *flow-direction-sensitive components*.
 - 2) any reasonably foreseeable adverse effect of any recommended *accessory* on the *essential performance* or *basic safety* of the *ventilator* (additional requirements are found in 201.16).

Check conformity by inspection of the *instructions for use* and inspection of the *risk management file* for any adverse effect of any recommended *accessory*.

201.7.9.2.16.101 Additional requirements for reference to the *technical description*

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

Where the *technical description* is supplied as a separate document from the *instructions for use*, then the *instructions for use* shall:

- a) list the contents of the *technical description*; and
- b) wherever appropriate, provide a cross reference to the additional information available in the *technical description*.

Check conformity by inspection.

201.7.9.3.1.101 Additional general requirements

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

- a) The *technical description* shall disclose:
 - 1) a summary description of the filtering or smoothing techniques for measured or computed variables that are displayed or used for control necessary for the *operator* to form a mental model of the operation of the *ventilator*;
 - 2) a pneumatic diagram of the *ventilator*, including a diagram for *operator-detachable* parts of the *ventilator breathing system* either supplied or recommended in the *instructions for use*; and
 - 3) a summary description of the means of initiating and terminating the *inflation phase* in each *ventilation-mode* of the *ventilator*.
- b) If applicable, the *technical description* shall disclose
 - 1) the essential technical characteristics of each recommended *breathing system filter*.

EXAMPLE Dead space and resistance.

Check conformity by inspection.

201.7.9.3.101 Additional requirements for the *technical description*

The *technical description* shall disclose:

- a) a description of a *procedure* for checking the function of the *alarm system* for each of the *alarm conditions*, other than *system recovery*, specified in this document, if not performed automatically during start-up; and
- b) which checks are performed automatically.

Check conformity by inspection of the *technical description*.

201.8 Protection against electrical *hazards* from *ME equipment*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 8 applies.

201.9 Protection against *mechanical hazards* of *ME equipment* and *ME systems*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 9 applies, except as follows:

Addition:

201.9.6.2.1.101 Additional requirements for audible acoustic energy

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

- a) The A-weighted sound pressure level emitted by the *ventilator* shall be:
 - 1) measured in accordance with ISO 4871:1996 and ISO 3744:2010 using engineering method grade 2; and
 - 2) disclosed in the *instructions for use*.
- b) The A-weighted sound power level shall be:
 - 1) calculated in accordance with 8.2.5 and 8.6 of ISO 3744:2010; and
 - 2) disclosed in the *instructions for use*.
- c) Check conformity with the following test:
 - 1) Place the *ventilator* on the sound-reflecting plane and attach the least favourable *VBS* from those indicated in the *instructions for use*.

NOTE 1 The least favourable *VBS* configuration can vary by *ventilation-mode*, *inflation-type* and flow pattern, as applicable.

- 2) If a *humidifier* is provided with the *ventilator*, include the *humidifier* filled to the least favourable level in the test.

- 3) Configure the test lung with the compliance and resistance components whose values are indicated in Table 201.102.
 - i) Acoustically isolate the test lung by a suitable means so that any noise caused by the test lung does not interfere with the sound measurement of the *ventilator*.
 - ii) Connect the *patient-connection port* to the test lung.
- 4) Set the *ventilator* to the least favourable *ventilation-mode*, *inflation-type* and flow pattern, as applicable, that generates ventilation as indicated in Table 201.102.

NOTE 2 The least favourable *ventilation-mode*, *inflation-type* and flow pattern can vary by VBS configuration.

Table 201.102 — Test conditions for acoustic tests

Adjustable parameter	Test condition		
	For a <i>ventilator</i> intended to provide <i>tidal volume</i>		
	$V_T \geq 300 \text{ ml}$	$300 \text{ ml} \geq V_T \geq 50 \text{ ml}$	$V_T \leq 50 \text{ ml}$
<i>Tidal volume</i> , V_T^a	500 ml	150 ml	30 ml
<i>Set rate</i>	10 breaths/min	20 breaths/min	30 breaths/min
<i>I:E ratio</i>	1:2	1:2	1:2
<i>BAP</i>	10 hPa (10 cmH ₂ O)	10 hPa (10 cmH ₂ O)	10 hPa (10 cmH ₂ O)
Linear resistance, $R^{b[49][66][69]}$	5 hPa·(l/s) ⁻¹ ±10 %	20 hPa·(l/s) ⁻¹ ±10 %	50 hPa·(l/s) ⁻¹ ±10 %
Isothermal Compliance, C^b	50 ml·hPa ⁻¹ ±10 %	20 ml·hPa ⁻¹ ±10 %	1 ml·hPa ⁻¹ ±10 %
^a V_T is measured by means of a pressure sensor at the test lung, where $V_T = C (P_{\max} - P_{\min})$, and V_T is the volume delivered to the test lung C is the isothermal compliance of the test lung $P_{\max}$ is the maximum pressure measured in the test lung $P_{\min}$ is the minimum pressure measured in the test lung. ^b The accuracy for C and R applies over the ranges of the measured parameters. NOTE There is guidance or rationale for this table contained in Clause AA.2.			

- 5) Using a microphone of the sound level meter, conforming with the requirements of type 1 instruments specified in IEC 61672-1:2013, measure the maximum time-weighted sound pressure level using frequency weighting A and the time weighting F of the sound level meter (i.e. $L_{AF\max}$) at 10 positions in a hemisphere with a radius from the geometric centre of the *ventilator* in a free field over a reflecting plane as specified in 8.1.1 of ISO 3744:2010. Average the values in conformity with 8.2.2 of ISO 3744:2010.
- 6) Calculate the A-weighted sound pressure level averaged over the measurement surface in accordance with 8.2.2 of ISO 3744:2010.
- 7) Calculate the A-weighted sound power level in accordance with 8.6 of ISO 3744:2010.
- 8) Confirm that the criteria for background noise specified in 4.2 of ISO 3744:2010 are fulfilled.
- 9) Ensure that the average measured sound pressure level is less than that disclosed in the *instructions for use*.
- 10) Ensure that the sound power level is less than that disclosed in the *instructions for use*.

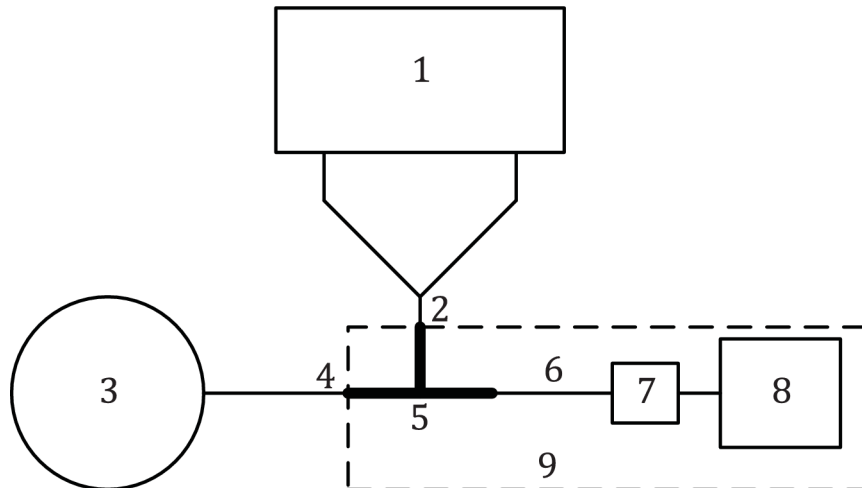
201.9.101 Additional requirements for suction procedures

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

- a) The *instructions for use* shall disclose recommended ventilation settings for use with a closed *suction catheter*.
- b) A *ventilator* shall continue to function as intended after the use of a closed *suction catheter*:
 - 1) for each *ventilation-mode* with the lowest *tidal volume* of each intended *tidal volume* range indicated in the *instructions for use*; and
 - 2) using the *VBS* configuration with the lowest compliance of those indicated in the *instructions for use*.

NOTE 1 For the purposes of this requirement, *pressure-control* based ventilation with a volume target is considered a form of *volume-control*.

- c) Check conformity by inspection of the *instructions for use* and with the following test:
 - 1) Connect a suction system, as shown in Figure 201.101, leaving the *patient-connection port* of the closed *suction catheter* adaptor open to air and the *ventilator* disconnected. Use a closed *suction catheter* of minimum inside diameter of 2,95 mm (French (Charriere) equivalent size 14 F).
 - 2) Adjust the suction equipment as follows:
 - i) Close the flow control valve and adjust the vacuum regulator of the suction equipment to an occluded vacuum of 200 hPa (204 cmH₂O) below ambient atmospheric pressure.
 - ii) Open and set the flow control valve to give a free air flow (suction flow) of:
 - I) 30 l/min, for a *ventilator* intended to provide *tidal volume*, $V_T \geq 300$ ml;
 - II) 15 l/min, for a *ventilator* intended to provide *tidal volume*, $300 \text{ ml} \geq V_T \geq 50$ ml; and
 - III) 5 l/min, for a *ventilator* intended to provide *tidal volume*, $V_T \leq 50$ ml.
 - 3) Disable the suction flow without affecting the flow control valve setting.
 - 4) Connect the *ventilator* as shown in Figure 201.101 using the lowest compliance *VBS* indicated in the *instructions for use* for the intended *tidal volume* range.
 - 5) Connect a test lung to the *patient-connection port* of the closed *suction catheter* adaptor. Use a test lung with compliance:
 - i) 10 ml/hPa ± 10 %, for a *ventilator* intended to provide *tidal volume*, $V_T \geq 300$ ml;
 - ii) 3 ml/hPa ± 10 %, for a *ventilator* intended to provide *tidal volume*, $300 \text{ ml} \geq V_T \geq 50$ ml; and



Key

- 1 ventilator under test
- 2 patient-connection port of VBS before adding the closed suction catheter adaptor
- 3 test lung
- 4 patient-connection port of VBS after adding the closed suction catheter adaptor
- 5 closed suction catheter adaptor
- 6 14 Fr closed suction catheter conforming with ISO 8836:2019
- 7 flow control valve (can be incorporated in 8)
- 8 suction equipment conforming with ISO 10079-1:2022 or ISO 10079-3:2022
- 9 suction system

Figure 201.101 — Typical closed suctioning test setup

- iii) 0,5 ml/hPa $\pm$ 10 %, for a ventilator intended to provide tidal volume, $V_T \leq 50$ ml.
- 6) Do not enable any special suction procedure ventilator operational mode and retract the closed suction catheter.
- 7) Perform any compliance correction as indicated in the instructions for use.
- 8) Select a volume-control inflation-type with the following settings:
 - i) minimum tidal volume for the intended tidal volume range;
 - ii) set rate: 10 breaths/min; and
 - iii) trigger: off or, if not so equipped, at the most insensitive method and setting.
- 9) Wait until stability is achieved.
- 10) Advance the closed suction catheter between 1 cm and 2 cm beyond the patient-connection port.
- 11) Enable the suction flow, without affecting the flow control valve setting, and maintain for 30 s.

NOTE 2 Some alarm conditions might become active. This is an expected possibility.

- 12) Terminate the suction flow by closing the suction equipment valve and retract the suction catheter.

NOTE 3 Retracting the suction catheter into its supplied sleeve can be important to seal the gas pathway and reduce gas leakage.