



BSI Standards Publication

Medical electrical equipment

Part 2-87: Particular requirements for basic safety and essential performance of high-frequency ventilators

National foreword

This British Standard is the UK implementation of EN ISO 80601-2-87:2021. It is identical to ISO 80601-2-87:2021.

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 2-87: Particular requirements for basic safety and essential performance of high-frequency ventilators (ISO 80601-2-87:2021)

Appareils électromédicaux - Partie 2-87: Exigences particulières pour la sécurité de base et les performances essentielles des ventilateurs à haute fréquence (ISO 80601-2-87:2021)

Medizinische elektrische Geräte - Teil 2-87: Besondere Festlegungen an die Sicherheit und die wesentlichen Leistungsmerkmale von Hochfrequenz Beatmungsgeräten (ISO 80601-2-87:2021)

This European Standard was approved by CEN on 2 April 2021.

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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (EN ISO 80601-2-87:2021) 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of an identical text or by endorsement, at the latest by October 2021, and conflicting national standards shall be withdrawn at the latest by October 2021.

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.

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, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 80601-2-87:2021 has been approved by CEN as EN ISO 80601-2-87:2021 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).

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 <http://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.

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, *Electrical equipment in medical practice*, Subcommittee SC 62D, *Electromedical equipment*, 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).

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

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.

Introduction

In this document, the following print types are used:

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

In referring to the structure of this document, the term

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

References to clauses within this document are preceded by the term “Clause” followed by the clause number. References to subclauses within this document are by number only.

In this document, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

For the purposes of this document, the auxiliary verb:

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

Annex C contains a guide to the *marking* and labelling requirements in this document.

Annex D contains a summary of the *symbols* referenced in this document.

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

Medical electrical equipment —

Part 2-87: Particular requirements for basic safety and essential performance of high-frequency critical care ventilators

201.1 Scope, object and related standards

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

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

201.1.1 * Scope

Replacement:

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

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

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

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

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

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

There are three principal designations of *HFV*:

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

Additionally, *HFV* designations can be combined together or with *ventilation* at rates less than 150 *inflations/min*.

* A *high-frequency ventilator* is not considered a *physiologic closed loop-control system* unless it uses a physiological *patient* variable to adjust the *ventilation* therapy settings.

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

If a clause or subclause is specifically intended to be applicable to *ME equipment* only, or to *ME systems* only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to *ME equipment* and to *ME systems*, as relevant.

Hazards inherent in the intended physiological function of *ME equipment* or *ME systems* within the scope of this document are not covered by specific requirements in this document except in 7.2.13 and 8.4.1 of IEC 60601-1:2005.

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

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

This document does not specify the requirements for:

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

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

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

NOTE 6 An *HFV* can incorporate *EMS ventilator* capability.

- *ventilators* or *accessories* intended for *ventilator-dependent patients* in the *home healthcare environment*, which are given in ISO 80601-2-72 ^[26];
- *ventilators* or *accessories* intended for home-care ventilatory support devices, which are given in ISO 80601-2-79 ^[27] and ISO 80601-2-80 ^[28], the replacements for ISO 10651-6 ^[15];
- sleep apnoea breathing therapy *ME equipment*, which are given in ISO 80601-2-70 ^[25];
- *bi-level positive airway pressure (bi-level PAP) ME equipment*;
- *continuous positive airway pressure (CPAP) ME equipment*;

- respiratory high-flow *ME equipment*, which are given in ISO 80601-2-90:—¹; and
- cuirass or “iron-lung” *ventilation equipment*.

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

201.1.2 Object

Replacement:

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

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

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

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

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

201.1.3 Collateral standards

Amendment (add after existing text):

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

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

201.1.4 Particular standards

Replacement:

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

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

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

The numbering of clauses and subclauses of this document corresponds to those of the general standard with the prefix “201” (e.g. 201.1 in this document addresses the content of Clause 1 of

¹ Under preparation. Stage at the time of publication: ISO/DIS 80601-2-90:2020.

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

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

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

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

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

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

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

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

201.2 Normative references

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

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

Replacement:

ISO 7000:2019, *Graphical symbols for use on equipment — Registered symbols*

ISO 7010:2019, *Graphical symbols — Safety colours and safety signs — Registered safety signs*

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

Addition:

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

ISO 3744:2010, *Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound pressure — Engineering methods for an essentially free field over a reflecting plane*

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

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

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

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

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

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 16142-1:2016, *Medical devices — Recognized essential principles of safety and performance of medical devices — Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards*

ISO 17664:2017, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices*

ISO 18562-1:2017, *Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process*

ISO 20417:2020, *Medical devices — Information to be supplied by the manufacturer*

ISO 23328-1:2003, *Breathing system filters for anaesthetic and respiratory use: — Part 1: Salt test method to assess filtration performance*

ISO 23328-2:2002, *Breathing system filters for anaesthetic and respiratory use: — Part 2: Non-filtration aspects*

ISO 80369-1:2018, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

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

ISO 80601-2-84:2020, *Medical electrical equipment — Part 2-84: Particular requirements for basic safety and essential performance of emergency and transport ventilators*

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*

² Under preparation. Stage at the time of publication: ISO/DIS 80601-2-74:2020

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

IEC 60529:1989+AMD1:1999+AMD2:2013, *Degrees of protection provided by enclosures (IP Code)*

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

IEC 60601-1-10:2007+AMD1:2020+AMD2:2020, *Medical electrical equipment — Part 1-10: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers*

IEC 60601-1-11:2015+AMD1:2020+AMD2:2020, *Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

IEC 60601-1-12:2014+AMD1:2020, *Medical electrical equipment — Part 1-12: General requirements for basic safety and essential performance — Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment*

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

IEC 62570:2014, *Standard practice for marking medical devices and other items for safety in the magnetic resonance environment*

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, IEC 60601-1-2:2014+AMD1:2020, IEC 60601-1-6:2010+AMD1:2013+AMD2:2020, IEC 60601-1-8:2006+AMD1:2012+AMD2:2020 and the following apply.

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

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

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

201.3.201

accompanying information

information accompanying or *marked* on a *medical device* or *accessory* (3.1) 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 20417:2020, 3.2, modified — deleted note 4.]

201.3.202

airway device

device intended for use as an interface between the *patient-connection port* of a *ventilator* and the *patient's* airway, and which has no auxiliary features on which the *ventilator* is dependent for its normal operation

EXAMPLE Endotracheal tube; tracheotomy tube; face *mask*; supralaryngeal airway.

Note 1 to entry: The connection to the *patient's* airway can be at the face (non-invasive) or internal to the *patient* (invasive).

Note 2 to entry: A face *mask* that intentionally vents respiratory gas to atmosphere by means of a bleed orifice is a functional part of the *ventilator breathing system* and therefore not an *airway device*. With that arrangement, the face seal of the *mask* becomes the *patient-connection port* and there is no *patient-connection port* connector, nor an *airway device*.

Note 3 to entry: See also *patient-connection port*, *airway* and *ventilator breathing system*.

[SOURCE: ISO 19223:2019, 3.1.3]

201.3.203

airway pressure

pressure at the *patient-connection port*, relative to ambient pressure unless otherwise specified

Note 1 to entry: In addition to its direct reference, this term or its symbol P_{aw} , displayed in various character styles, is only used, in context or by qualification, to designate this concept as a measured quantity.

Note 2 to entry: The site(s) of actual measurement(s) may be anywhere in the *ventilator breathing system*, providing that the indicated value is referenced to that at the *patient-connection port*.

Note 3 to entry: This is the generic term for this fundamental concept. Post-coordinated terms, for example, peak inspiratory pressure and baseline *airway pressure*, are used in particular contexts.

Note 4 to entry: Although providing no explicit indication as to where along the *patient's* airway this pressure is measured, this term, along with its symbol, has become widely adopted as referencing the pressure at the point at which *artificial ventilation* equipment is connected to the *patient's* airway or to an *airway device*. This is the final site where a common and replicable pressure can be continuously monitored, conveniently, before breathing gas enters the *patient*.

Note 5 to entry: A pressure measured in the *patient's* airway at a site other than at the *patient-connection port* is referred to in this document as a respiratory pressure.

[SOURCE: ISO 19223:2019, 3.6.1 modified — deleted notes 6 and 7.]

201.3.204

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]

201.3.205

bi-level positive airway pressure

bi-level PAP

sleep-apnoea breathing-therapy mode in which there are two therapeutic positive pressure levels at the *patient-connection port* during the respiratory cycle

Note 1 to entry: The two levels of positive *airway pressure* (PAP) invoked by the various names that have been given to this breathing-therapy mode are typically identified by the terms IPAP (inspiratory positive *airway pressure*) and EPAP (expiratory positive *airway pressure*), with IPAP representing the set inspiratory pressure level during the *patient's* inspiratory phase and EPAP the set baseline *airway pressure* (BAP) during the *patient's* expiratory phase.

Note 2 to entry: This is the generic name for a breathing-therapy mode previously identified by the proprietary name BiPAP®8) (which is not to be confused with the proprietary name BIPAP®7), a *ventilation-mode*).

[SOURCE: ISO 19223:2019, 3.12.5, modified — deleted notes 3 and 4.]

201.3.206

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*

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

Note 2 to entry: The term *bias flow* is used to refer to an intended low-level flow that passes right through the *ventilator breathing system* with the purpose of improving the responsiveness and accuracy of the *ventilator's* control and detection systems, and of minimising the rebreathing of expired gas. It is typically only maintained during an *expiratory phase* but can be maintained throughout a respiratory cycle.

[SOURCE: ISO 19223:2019, 3.7.7]

201.3.207**biocompatibility**

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

Note 1 to entry: Medical devices 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.

[SOURCE: ISO 18562-1:2017, 3.2]

201.3.208**breathing system filter****BSF**

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

[SOURCE: ISO 4135:—, 3.6.1.4]

201.3.209**body temperature pressure, saturated****BTPS**

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

[SOURCE: ISO 4135:—, 3.1.1.7]

201.3.210**cleaning**

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

Note 1 to entry: *Cleaning* consists of the removal, usually with detergent and water, 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 and/or further *processing*.

[SOURCE: ISO 17664:2017, 3.1]

201.3.211**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

Note 1 to entry: In addition to its direct reference, this term may be used to designate this concept, in context or by qualification, as a set value.

Note 2 to entry: A constant, *continuous flow* in the inspiratory limb of the *ventilator breathing system* is commonly used in the *artificial ventilation* of neonatal and paediatric *patients*.

Note 3 to entry: The *airway pressure* can be intermittently raised to a set pressure-limited inspiratory pressure, for example, by the use of an adjustable pressure-relief valve operating in parallel with either the timed occlusions of an expiratory valve, or the manual occlusions of a normally-open *exhaust port*.

[SOURCE: ISO 19223:2019, 3.7.8, modified — deleted note 4.]

201.3.212

continuous positive airway pressure

CPAP

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

Note 1 to entry: *CPAP* is intended to maintain the *airway pressure* at its set value apart from the inevitable minor deviations that are necessary for it to perform its function. Although there are currently no tests for acceptable levels for such deviations, they are expected to neither add to nor subtract from the *patient's* perceived work of breathing to a greater extent than could be experienced during natural breathing.

Note 2 to entry: This definition excludes the use of the term to describe *ventilation*-modes where spontaneous inspirations are supported by intermittently elevated pressures other than with the intention to compensate for any actual or perceived imposed work of breathing.

Note 3 to entry: Because, as used for this *ventilation*-mode, the concept of a *CPAP* level coincides with that of a baseline *airway pressure* the setting could be designated as for either concept but as the intention of the *operator* selecting this *ventilation*-mode will be to achieve a specific *CPAP* level, this becomes an acceptable admitted term to designate the set quantity.

Note 4 to entry: Although at the periphery of the spectrum of what constitutes a *ventilation*-mode, *CPAP* is included in this document because it is commonly made available on typical critical care *ventilators* for use as part of a continuum of a *patient's* treatment without the necessity to change to another device.

Note 5 to entry: It is possible for a *ventilation*-mode resembling *CPAP* to be realized on a *ventilator* by the use of CSV (continuous spontaneous *ventilation*) with the pressure-support (PS) set to 'zero' or 'none' but CSV set in this way is not equivalent to *CPAP* if its performance in response to a spontaneous inspiration is dependent on the setting of an appropriate trigger level.

Note 6 to entry: On *ventilators* equipped with ACAP, this adjunct will enable unrestricted breathing whenever *CPAP* is selected.

Note 7 to entry: *CPAP* is a Group 4b *ventilation*-mode. Because no *inflation-type* is selected this *ventilation*-mode is identical to its *ventilation*-pattern and there is no necessity to distinguish between them. The systematic *ventilation*-mode name becomes, therefore, simply, *CPAP*. On *ventilators* where *CPAP* is enabled by means of an ACAP adjunct the systematic code is *CPAP* <ACAP>.

Note 8 to entry: When used for sleep-apnoea breathing-therapy, *CPAP* is not classed as a *ventilation*-mode – it becomes a sleep-apnoea breathing-therapy mode. Although the principle clinical intention of such a therapy mode is to maintain a positive pressure in the *patient's* airway during sleep in order prevent airway obstruction by the soft tissues in the throat it has become a common practice to reduce this pressure during expiration, principally to improve *patient* acceptability. *Ventilation*-modes with this feature are typically identified with names that allude to this use of two levels of positive *airway pressure*. The generic name adopted for the designation of such a breathing-therapy mode in this document is *bi-level PAP*.

[SOURCE: ISO 19223:2019, 3.11.15, modified — deleted note 9.]

201.3.213

disinfection

process to reduce the number of viable microorganisms to a level previously specified as being appropriate for a defined purpose

[SOURCE: ISO 17664:2017, 3.3]

201.3.214**emergency intake port**

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

[SOURCE: ISO 80601-2-12:2020, 201.3.201]

201.3.215**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.

[SOURCE: ISO 80601-1-12:2014, 3.1]

201.3.216**EMS ventilator**

ventilator intended for use in the *EMS environment*

[SOURCE: ISO 80601-2-84:2020, 3.1]

201.3.217**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]

201.3.218**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]

201.3.219

expiratory phase

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

Note 1 to entry: If additional spontaneous breaths are possible, all or part of their *expiratory phases* can occur within the *expiratory phase* of an assured-inflation cycle.

Note 2 to entry: In accordance with the conceptual framework of this document, the phase between *inflations* in any respiratory cycle is the *expiratory phase* of that cycle. For *ventilators* with which there can be simultaneous respiratory cycles, it might not be clear as to which of the cycles is being referenced unless it is specifically associated with the assured-inflation cycle each time it is used. This is one of the reasons that the alternative name, *BAP phase*, has been introduced into this document; an introduction that is particularly relevant for use on *ventilators* that facilitate additional breaths in the phase between assured *inflations*. For further information regarding these concepts, see 3.10, 3.11 and 3.12.

Note 3 to entry: If the *patient* generates flow that initiates an *inflation*, the inspiratory flow for the initiated *inflation* cycle is taken as starting at the initiation of the *inflation* phase and any measurable flow in advance of that initiation becomes the trigger flow. If necessary, depending upon the level of granularity required for a specific description of this trigger flow, its duration can be considered to constitute a trigger phase. Because the change from the trigger phase to the *inflation* phase is typically optimized at a level determined by *operator* settings, in this document it is treated as having occurred during the final moments of the *expiratory phase*, unless otherwise stated.

This concept is consistent with the pragmatic view that the set *inspiratory time* should be taken to start at the same point on the pressure rise-time waveform of an *inflation*, whether it is initiated by the *ventilator* or by a *patient-trigger* event (see Figures C.3 and C.4) - also, that the main significance of the actual duration of the *expiratory phase* is as a setting that determines a maximum interval between *inflations*; an aspect that becomes much less critical whenever the patient determines a shorter interval.

If the patient generates inspiratory flow that does not cause a patient-trigger event, then its detectable commencement is treated as the initiation of the inspiratory phase of the subsequent unassisted spontaneous breath.

[SOURCE: ISO 19223:2019, 3.4.2, modified — deleted note 4.]

201.3.220

expired minute volume

volume of gas leaving the *lung* through the *patient-connection port* during all *expiratory phases*, expressed as a volume per minute

Note 1 to entry: In addition to its direct reference, this term or its symbol, V_{ME} , displayed in various character styles, is used, in context or by qualification, to designate this concept as a measured quantity.

[SOURCE: ISO 19223:2019, 3.8.9, modified —deleted note 2.]

201.3.221

fail-safe ventilation

safety provision by which the *ventilator* automatically switches to a predetermined alternative *ventilation-mode* intended to maintain *patient* safety in the event of a component, sensor or function becoming inoperable

Note 1 to entry: Such provisions could be necessitated by a *ventilator* component failure such as pressure sensor failure or a microprocessor failure.

Note 2 to entry: The automatic initiation of *fail-safe ventilation* usually generates a *technical alarm condition*.

[SOURCE: ISO 19223:2019, 3.7.7]

201.3.222

flow-direction-sensitive component

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

[SOURCE: ISO 4135:—, 3.1.4.13]

201.3.223

gas intake port

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

[SOURCE: ISO 4135:—, 3.1.4.19]

201.3.224

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]

201.3.225

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 18562-1:2017, 3.5]

201.3.226

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]

201.3.227

healthcare professional

individual with appropriate training, knowledge and skills who provides preventive, curative, promotional or rehabilitative healthcare services in a systematic way to people, families or communities

[SOURCE: ISO 4135:—, 3.1.6.2]

201.3.228

high-frequency ventilator

HFV

ME equipment intended to provide *ventilation* of the *lungs* of the *patient* when connected to the airway of the *patient* using a *rate* greater than 150 *inflations/min*

Note 1 to entry: Inflation rates are specified as per minute solely when differentiating from conventional-rate *ventilation*. All normative requirements regarding *HFV* are written using inflation rates per second.

201.3.229

HFV breathing system

pathways through which gas flows to or from the *HFV* and to or from the *patient*

201.3.230

HFV frequency

number of *HFV inflations* that are set to occur in a specified period of time, expressed as *HFV inflations* per second

201.3.231

HFV inflation

periodic *ventilator* action intended to increase the volume of gas in the *lungs*

201.3.232

HFV volume

volume of gas delivered through the *patient-connection port* or at the distal outlet of the jet system during an *HFV inflation*

Note 1 to entry: The effective volume delivered to the *lung* can be significantly smaller than the *HFV volume*. The leakage of uncuffed tracheal tubes and even small changes in resistance or compliance of the respiratory system (e.g. due to secretions in the airways, through the use of a different *HFV breathing system* or tracheal tube) can change the volume delivered to the *lung*.

Note 2 to entry: The achievable *HFV volume* depends characteristically on the *HFV frequency*. In general, lower *HFV frequencies* permit higher *HFV volumes*.

Note 3 to entry: The *HFV volume* significantly influences CO₂ elimination.

201.3.233

high-pressure inlet

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

[SOURCE: ISO 4135:—, 3.1.4.22]

201.3.234

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, 3.1]

201.3.235

humidifier

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

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

[SOURCE: ISO 80601-2-74:—, 201.3.214]

201.3.236

I:E ratio

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

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

Note 2 to entry: By mathematical convention, a colon or a slash is used to designate a ratio between two values so the addition of the word 'ratio' is not strictly necessary. However, its addition is widely practiced and is considered to add to the readability of descriptive texts and lists, but in this document, its use is optional.

[SOURCE: ISO 19223:2019, 3.4.19]

201.3.237

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

Note 1 to entry: The elevation of the *airway pressure*, above the *PEEP* of the previous phase, during an *inflation* and in the absence of total airway obstruction, generates an inspiratory flow that will either assist or totally control the *inflation* of the *patient's lungs*. This action relieves some of or all the *patient's* work of breathing.

Note 2 to entry: If the *inflation* is pressure-regulated and the inspiratory phase is set to extend beyond the inspiratory-flow time, then the *lungs* are held distended until the *inflation* is terminated. During this inspiratory pause, concurrent breathing can be possible, to the extent determined by the specific *ventilation*-mode selected and whether an ACAP adjunct is provided.

Note 3 to entry: Although, typically, there will be more than one *inflation*-termination criterion, for *patient*-safety reasons, these will always include time-termination, intended as either a primary or secondary means.

Note 4 to entry: If an *inflation* is intended to be terminated by means additional to time, this should be indicated, at least in the *instructions for use*, employing the *inflation-type* systematic naming and coding tables.

Note 5 to entry: The elevated pressure waveform is implemented by either a flow-regulation function or a pressure-regulation function.

Note 6 to entry: This is a context-sensitive term designating an intermittent elevated-pressure *ventilator* parameter, as distinct from a negative-pressure *ventilator inflation* or a *lung inflation* resulting solely from a *patient's* inspiratory effort. When used in its defined context, the preferred term is used by itself but in cases of possible ambiguity, the qualified form, 'positive-pressure inflation', should be used.

Note 7 to entry: The admitted term ventilator inspiration is included to facilitate translation into languages that do not have a translation for the word, *inflation*, as it is used in this context.

[SOURCE: ISO 19223:2019, 3.3.1, modified —deleted note 8.]

201.3.238

inflation-type

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

Note 1 to entry: *Inflation-types* are designated in this document by their property-class common names, wherever possible. They are more precisely designated by the systematic coding scheme, which uses the abbreviations of the common names, where available, but which also often includes designators of additional properties and designates *inflation-types* with no common name yet attributed to them.

Note 2 to entry: A group of *inflation-types* that might be selected for a specific purpose is sometimes given a purpose-class name, but such a name is not an alternative name for that *inflation-type*. As an example, a *pressure-control inflation-type* might be selected to serve as the assured *inflation* within a *ventilation*-mode, but that only makes it the assured 'inflation-type'; a name that identifies its function within a *ventilation*-mode as being assured to be delivered at least at the *set rate* but that does not change its *pressure-control* characteristics.

[SOURCE: ISO 19223:2019, 3.3.2, modified —deleted note 3.]

201.3.239

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 the 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 20417:2020, 3.9]

201.3.240

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 20417:2020, 3.10, modified — deleted note 4.]

201.3.241

inspiratory time

duration of an *inflation* phase or inspiratory phase

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

Note 2 to entry: The symbol, t_i , displayed in various character styles, is typically used to designate the *inspiratory time* setting, particularly where space is limited, such as on user interfaces.

[SOURCE: ISO 19223:2019, 3.4.8, modified —deleted notes 3 and 4.]

201.3.242

inspiratory volume

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

Note 1 to entry: In addition to its direct reference, this term or its symbol, V_i , displayed in various character styles, may only be used, in context or by qualification, to designate this concept as a measured quantity.

Note 2 to entry: This is the concept designated by 'delivered volume', in ISO 4135:2001,3.4.2; a term that has not been widely adopted to date. It is a concept relevant to where measurements of volume made close to the *patient-connection port*, such as is typically the case with self-contained, multi-parameter *patient* monitors, as distinct from the redefined delivered volume, which is applicable to *ventilators* where the inspiratory flow is determined or measured within the body of the *ventilator*. The closer site of measurement means that this quantity only differs from the actual volume entering the *lung* by the amount of any volume loss occurring at the connection to the *patient's* airway.

[SOURCE: ISO 19223:2019, 3.8.3, modified —deleted note 3.]

201.3.243

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

Note 4 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 20417:2020, 3.11, modified — deleted note 5.]

201.3.244

lay

<adj> term referring to non-professional or professional without relevant specialized training

EXAMPLE *Lay operator, lay responsible organization.*

[SOURCE: IEC 60601-1-11:2015, 3.2]

201.3.245

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

Note 1 to entry: In specific reference to the pair of these organs, in this document the inflection '*lungs*' is used.

Note 2 to entry: In accordance with what has become common practice in the absence of a more suitable term, this term in its singular form is also used in this document to reference the connected, respiratory-gas containing cavities within the respiratory system, consisting of the airway and the *lungs*. Examples of this common practice in applications that are outside the scope of this document are: lung function; lung disease; lung compliance; lung mechanics; test lung. Other established examples are lung ventilator; lung elastance; lung protective strategy.

Note 3 to entry: Although there are no such references in this document, if in the application of this document a need arises to refer to just 'one of the *lungs*' then, in order to avoid any possible ambiguity, it should always be identified as such, or as the 'left *lung*' or 'right *lung*'.

[SOURCE: ISO 19223:2019, 3.1.16, modified —deleted note 4.]

201.3.246

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 20417:2020, 3.10, modified — deleted note 3.]

201.3.247

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:—, 3.8.6.4]

201.3.248

maximum limited pressure

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

Note 1 to entry: In addition to its direct reference as a requirement, this term is only used, in context or by qualification, to designate this concept as a set quantity.

Note 2 to entry: As with all unqualified *airway pressures*, this limited pressure is that at the *patient-connection port* and relative to ambient pressure.

Note 3 to entry: As this is the highest-level precaution against excessive pressures being applied to the *patient's* airway this pressure limit is typically preset by the *manufacturer* but can be made adjustable by the *responsible organization* to a lower pressure level.

[SOURCE: ISO 19223:2019, 3.13.3]

201.3.249

mean airway pressure

mean value of the pressure as measured at the *patient-connection port* or at the distal outlet of the jet system during high-frequency *ventilation*

201.3.250

medical gas pipeline system

complete system which comprises a supply system, a monitoring and alarm system and a distribution system with terminal units at the points where medical gases or vacuum are required

[SOURCE: ISO 7396-1:2016, 3.36]

201.3.251

minimum limited pressure

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

Note 1 to entry: The *minimum limited pressure* can be sub-atmospheric.

[SOURCE: ISO 4135:—, 3.1.4.39.4]

201.3.252

monitoring equipment

medical electrical equipment or part that continuously or continually measures and indicates the value of a variable to the *operator*

[SOURCE: ISO 4135:—, 3.11.1.2]

201.3.253

patient-connection port

port of a *ventilator breathing system* intended for connection to an *airway device*

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

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

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

Note 4 to entry: In *ventilators* designed to provide NIV (non-invasive *ventilation*) and where the *ventilation* function is dependent upon a design feature of a component that connects the *ventilator* to the *patient's* airway, then the *patient-connection port* typically becomes the contact line of the seal to the *patient's* face and there is no *patient-connection-port* connector.

[SOURCE: ISO 19223:2019, 3.14.5, modified — deleted note 5.]

201.3.254

patient variable

patient attribute, characteristic, quantity or condition that is measured

EXAMPLE A *patient variable* can be a measure of body chemistry (e.g. electrolytes or blood glucose value), a physical property (e.g. body temperature, electrophysiologic characteristic, hemodynamic quantity), or a pharmaceutical concentration.

[SOURCE: IEC 60601-1-10: 2007+AMD1:2015+AMD2:2020, 3.29]

201.3.255

physiologic closed-loop control system

PCLCS

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+AMD1:2015+AMD2:2020, 3.19]

201.3.256

*** pressure amplitude**

magnitude of the pressure swing during high-frequency *ventilation*, as measured at the *patient-connection port* or at the distal outlet of the jet system during high-frequency *ventilation*

201.3.257

pressure-control

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

Note 1 to entry: After the set rise time, the set inspiratory pressure is typically maintained by means of a pressure-regulation function.

Note 2 to entry: If the *patient* makes an inspiratory effort during a *pressure-control inflation*, this will result in a corresponding increase in inspiratory flow, although not necessarily an increased delivered volume.

Note 3 to entry: If the *patient* makes an expiratory effort during a *pressure-control inflation*, the inspiratory pressure could rise above that set, which might cause immediate termination of the *inflation*. The addition of ACAP enables concurrent unrestricted expiration without termination.

[SOURCE: ISO 19223:2019, 3.3.4, modified — deleted note 4.]

201.3.258

processing

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

[SOURCE: ISO 20417:2017, 3.20]

201.3.259

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.

[SOURCE: ISO 80601-2-12:2020, 201.3.209]

201.3.260

protection device

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

[SOURCE: ISO 4135:—, 3.1.4.47, modified — replaced 'medical device' with '*me equipment*' and 'user' with '*operator*'.]

201.3.261

recruitment manoeuvre

temporary increase in the *mean airway pressure* provided during *artificial ventilation*, with or without a momentary pause of the *artificial ventilation*, intended to open the *lungs*

Note 1 to entry: A *recruitment manoeuvre* is used to reduce atelectasis.

Note 2 to entry: A *recruitment manoeuvre* may pause either conventional *ventilation* or the oscillation.

201.3.262

safety sign

sign giving a general safety message, obtained by a combination of a colour and geometric shape and which, by the addition of a graphical *symbol*, gives a particular safety message

[SOURCE: ISO 20417:2020, 3.21]

201.3.263

set rate

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

Note 1 to entry: In the absence of suitable standardization, *manufacturers* have devised their own abbreviations to denote the various terms relating to respiratory rate for use on user interfaces, where space is often limited, and in user manuals. In the case of *set rate*, it has become widely established custom and practice, when used in context

and without further qualification, to adopt the abbreviation, “Rate”, displayed in various character styles. With the introduction of the term assured *inflation* in this document the adoption of the abbreviation AR displayed in various character styles, to represent assured rate, would be appropriate as an alternative for this purpose.

Note 2 to entry: The *set rate* can be determined by the *operator* either by a direct setting, or indirectly by means of an algorithm (see Example 4).

Note 3 to entry: The *set rate* assures the *operator* that *inflations* of the selected assured *inflation-type* will be delivered at intervals (in minutes) not exceeding, on average, the reciprocal of the *set rate*, although the actual interval between any two successive *inflations* might not be constant.

Note 4 to entry: The deprecated symbol, *f*, and the term that it represents, frequency, are deprecated as synonyms for set rate in this document. Although having similar meanings, rate is the term more usually used in reference to the number of instances occurring in a certain period of time, with no inference that the interval between these instances is constant, whereas frequency has more of the connotation of occurring at constant intervals.

EXAMPLE 1 With an assist/control (A/C) *ventilation-mode*, the *set rate* is the assured minimum *ventilator-initiated inflation* rate; with any *patient-initiated (assist) inflations* the total respiratory rate becomes higher.

EXAMPLE 2 With an IMV (intermittent mandatory *ventilation*) mode, the *set rate* is the rate at which the assured *inflations* are initiated.

EXAMPLE 3 With a SIMV (synchronized intermittent mandatory *ventilation*) mode, the *set rate* is the average rate at which the assured *inflations* are initiated.

EXAMPLE 4 With one means of achieving a MMV (minimum minute volume) *ventilation-mode*, the mode-control algorithm automatically adjusts the *set rate* downwards from its initial setting, as necessary to maintain the set minute volume as a minimum.

[SOURCE: ISO 19223:2019, 3.5.1.1, modified — deleted note 4.]

201.3.264

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 20417:2020, 3.26]

201.3.265

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.]

201.3.266**spontaneous breath rate**

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

Note 1 to entry: In addition to its direct reference, this term, and its symbol, RR_{spont} , displayed in various character styles, is only used, in context or by qualification, to designate this concept as a measured quantity.

Note 2 to entry: The *spontaneous breath rate* is the difference between the total respiratory rate and the *ventilator-initiated inflation* rate.

Note 3 to entry: The detection of the beginning and end of a breath is dependent on the sensitivity of the *ventilator* sensors and the thresholds of the detection algorithms. For further information concerning the reliability of using the *patient-triggered* rate as a measure of the *spontaneous-breath rate*.

Note 4 to entry: Because there is no dependent action required, as is the case with assisted breaths, the counting of an unassisted spontaneous breath can be delayed until its inspiratory phase has terminated, thereby allowing a higher level of discrimination between actual breaths and spurious events.

Note 5 to entry: Many legacy *ventilators* display and log the *spontaneous breath rate* as the unassisted breath rate plus the supported breath rate. While true for CSV modes, this practice does not include the spontaneous breaths that can initiate assured *inflations*, for example, in assist/control (A/C) *ventilation* and SIMV modes, making the *spontaneous breath rate* measurement dependent on the *ventilation*-mode that has been selected. This practice is considered to be misleading and is not supported in this document. The admitted term ISO *spontaneous-breath rate* has been included for use where it is necessary to highlight this distinction as, for example, was necessary in ISO/IEEE 11073-10101 [16].

[SOURCE: ISO 19223:2019, 3.5.1.3, modified — deleted note 6.]

201.3.267**standard temperature and pressure, dry****STPD**

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

[SOURCE: ISO 4135:—, 3.1.1.7]

201.3.268**sterile**

free from viable microorganisms

[SOURCE: ISO 20417:2020, 3.28]

201.3.269**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 17664:2017, 3.17]

201.3.270

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]

201.3.271

symbol

graphical representation appearing on the label and/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 20417:2020, 3.29]

201.3.272

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 20417:2020, 3.30, modified — deleted note 2.]

201.3.273

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, 3.4]

201.3.274

use error

user action or lack of user action while using the medical device that leads to a different result than that intended by the *manufacturer* or expected by the user

Note 1 to entry: *Use error* includes the inability of the user to complete a task.

Note 2 to entry: *Use errors* can result from a mismatch between the characteristics of the user, user interface, task, or use environment.

Note 3 to entry: Users might be aware or unaware that a *use error* has occurred.

Note 4 to entry: An unexpected physiological response of the *patient* is not by itself considered *use error*.

Note 5 to entry: A malfunction of a medical device that causes an unexpected result is not considered a *use error*.

[SOURCE: IEC 62366-1:2015, 3.6, modified — deleted note 6.]

201.3.275

validation

confirmation, through the provision of *objective evidence* that the requirements for a specific *intended use* of application 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]

201.3.276

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.]

201.3.277

ventilation

cyclical movement of a respirable gas into and out of the *lungs*

Note 1 to entry: This might be by external or spontaneous means, or by a combination of both.

[SOURCE: ISO 19223:2019, 3.1.9, modified — deleted note 2.]

201.3.278

ventilator

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

Note 1 to entry: In cases of possible ambiguity the full term, *lung ventilator*, should be used.

Note 2 to entry: See also *ventilation*.

[SOURCE: ISO 19223:2019, 3.1.1]

201.3.279

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 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.]

201.3.280

ventilator-dependent

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 Duchennes Muscular Dystrophy or other degenerative disease resulting in their unsupported respiratory effort being insufficient to sustain life.

[SOURCE: ISO 4135:—, 3.1.5.20]

201.3.281

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

Note 1 to entry: The selected inspiratory-flow waveform is typically that of a constant flow at a set value or of a decreasing flow pattern, sometimes after a set rise time. The constant flow is maintained for the duration of the *inflation* phase by means of a flow-regulation function.

Note 2 to entry: The flow-regulation function typically either maintains the set inspiratory flow or maintains an *inflation-to-inflation* adjusted inspiratory flow with the intention that the set volume is delivered in the set time, particularly when compensating for *ventilator breathing system* characteristics or an airway leak.

[SOURCE: ISO 19223:2019, 3.3.3, modified — deleted note 3.]

201.4 General requirements

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

201.4.3 *Essential performance*

Addition:

201.4.3.101 * Additional requirements for *essential performance*

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

201.4.4 Additional requirements for expected service life

Amendment (add as a second paragraph):

In the *risk management file*, the *manufacturer* shall:

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

Table 201.101 — Distributed essential performance requirements

Requirement	Subclause
Delivery of <i>ventilation</i> at the <i>patient-connection port</i> or at the distal outlet of the jet system within the <i>alarm limits</i> set by the <i>operator</i>	a
or generation of an <i>alarm condition</i>	
disconnection	201.12.4.109
gas supply failure	201.13.102
<i>HFV volume</i> , if provided	201.12.4.105
<i>internal electrical power source</i> nears depletion	201.11.8.101
<i>mean airway pressure</i>	201.12.4.102 201.12.4.103
obstruction	201.12.4.108
oxygen level	201.12.4.101
<i>pressure amplitude</i> , if provided	201.12.4.104
^a Subclause 202.8.1.101 indicates methods of evaluating delivery of <i>ventilation</i> as acceptance criteria following specific tests required by this document.	

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

Amendment (add at end of subclause):

- aa) The *HFV breathing system* or its parts or *accessories* that can come into contact with the *patient* shall be subject to the requirements for *applied parts* according to this subclause.

Addition:

201.4.11.101 * Additional requirements for pressurized gas input**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 *HFV breathing system*. Under this condition, the flowrate from the *ventilator* is likely to be outside of its specification.

Check conformance 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.

201.4.11.101.2 Compatibility requirement

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

- a) the *rated* range of input pressure shall cover the range specified in ISO 7396-1:2016; and
- 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 at a pressure of 280 kPa, measured at the *gas intake port*; 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 10 s average input flowrate required by the *ventilator* for each gas at a pressure of 280 kPa, 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-flowrate 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 conformance 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 *HFV frequency* and *HFV volume* and worst-case gas pipeline conditions within the *rated* range for inlet pressure.

201.5 General requirements for testing of ME equipment

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

Addition:

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

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.
- 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

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

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

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

201.5.101.3 * *Ventilator* testing errors

- a) For the purposes of this document, declared tolerances shall be adjusted by the measurement uncertainty.
- b) The *manufacturer* shall disclose the measurement uncertainty for each disclosed tolerance in the *technical description*.

Check conformance by inspection of the instructions for use and the technical description.

201.6 Classification of *ME equipment* and *ME systems*

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

201.7 *ME equipment* identification, marking and documents

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

Addition:

201.7.1.101 *Information to be supplied by the manufacturer*

The *information supplied by the manufacturer* of a *ventilator* and its accessories shall conform with ISO 20417:2020.

In applying ISO 20417:2020, the terms in this document and those in IEC 60601-1:2005+A1:2012+A2:2020 shall be used as follows.

- a) The term "*accompanying information*" shall assume the same meaning as *accompanying documents*.
- b) The term "*medical device*" shall assume the same meaning as *ME equipment*.

- c) The term "*user*" shall assume the same meaning as *operator*.
- d) The term "*patient*" shall include animals.

Check conformance by application of ISO 20417:2020.

201.7.2.3 * Consult accompanying documents

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 and Technical Corrigendum 1, Table D.2, Number 10).

Addition:

201.7.2.4.101 Additional requirements for accessories

- a) *Accessories* supplied separately shall:
 - 1) fulfil the requirements of 201.102.1; 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 201.7.2.17.101 and 201.7.2.101.
- b) If *marking* the *accessory* is not practicable, this information may be placed in the *instructions for use*.

Check conformance by inspection and inspection of the risk management file for any limitations or adverse effects of the accessory, 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;
- bb) the *rated* range of gas pressure;
- cc) for oxygen gas inputs, the *rated* range of oxygen concentration;
- dd) gas-specific colour-coding conforming 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 inlet connector.

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

- a) The *ME equipment*, parts or *accessories* shall have *clearly legible markings* including
 - 1) an arrow indicating the intended direction of gas flow:

- i) for the *gas output port*; and
 - ii) for the *gas return port*.
 - 2) *Symbol* ISO 7000-0794 (Table 201.D.2.101, *symbol* 1) or *symbol* ISO 7000-0795 (Table 201.D.2.101, *symbol* 2) may be used.
- b) 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,
 - 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 for an 'MR Safe' *ventilator*, or
 - ii) *Symbol* 7.3.2 of IEC 62570 (Table 201.D.2.101, *symbol* 5) for an 'MR Conditional' *ventilator*,
 in conforming with IEC 62570:2014.
 - 2) an arrow indicating the direction of the flow for *flow-direction-sensitive components* that are *operator-removable* without the use of a *tool*.
 - 3) a warning not to obstruct the *gas intake port*.

EXAMPLE WARNING: Gas Intake – Do not obstruct

- i) A *symbol* evaluated according to IEC 62366-1 as *information for safety* may be utilized.
- Check conformance by inspection.*

201.7.4.3 * Units of measurement

IEC 60601-1:2005+AMD1:2012, 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
- bb) those associated with the *HFV breathing system* which shall be expressed at *BTPS*.

Addition:

201.7.9.2.1.101 Additional general requirements

The *instructions for use* shall disclose

- a) if the *ventilator*, its parts or *accessories* are intended for *single use*, information on known characteristics and technical factors known to the *manufacturer* that could pose a *risk* if the *ventilator*, its parts or *accessories* would be reused.
- b) the intended range of *patient* weight.

Check conformance by inspection.

201.7.9.2.2.101 * Additional requirements for warnings and safety notices

The *instructions for use* shall include

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

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 port, thereby interfering with patient ventilation.

- b) * a warning statement to the effect that “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 **WARNING:** Failure to have an alternative means of ventilation such as a self-inflating, manually powered resuscitator (as specified in ISO 10651-4^[14]) with a mask can result in patient death if the ventilator fails.

- c) * a warning statement to the effect that “WARNING: Do not add any attachments or accessories to the ventilator that are not listed as intended for use in combination with the ventilator in 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.”

If applicable, the *instructions for use* shall include

- d) * a warning statement to the effect that “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.”

- e) * a warning statement to the effect that “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.”

- f) * a warning statement to the effect that “Warning: The ventilator shall not be used with inlet gases that 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.”

- g) * a warning statement to the effect that “Warning: The ventilator accuracy can be affected by the gas added to the breathing system by use of a pneumatic nebuliser.

- h) * a warning statement to the effect that “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.”

- i) * a warning statement to the effect that “Warning: When using nebulization or humidification, breathing system filters and heat and moisture exchangers can require more frequent replacement to prevent increased resistance and blockage.”

Check conformance by inspection.

201.7.9.2.8.101 * Additional requirements for start-up procedure

NOTE A start-up *procedure* includes a pre-use functional test that is used to determine if 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 the *ventilator* operates correctly:
 - 1) the assembled *HFV breathing system*;
 - 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 conformance by inspection of the instructions for use.

201.7.9.2.9.101 * Additional requirements for operating instructions

The *instructions for use* shall disclose

- a) a listing of the following pressures:
 - 1) *maximum limited pressure* ($P_{Lim,max}$); and
 - 2) *minimum limited pressure* ($P_{Lim,min}$), for an *HFV* that can generate subatmospheric pressure in the *expiratory phase*.
- b) * the *rated range* of all characteristics of the assembled *operator-detachable parts* of the *HFV breathing system* required to maintain the accuracies of set and monitored *HFV volumes* and pressures, for example:
 - 1) *inspiratory gas pathway resistance*,
 - 2) *expiratory gas pathway resistance*, and
 - 3) *HFV breathing system compliance*.
 - i) These specifications may be presented in ranges.
 - ii) The accuracies of set and monitored *HFV 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 maximum flowrate or the maximum pressure.

- c) the conditions under which the *ventilator* maintains the accuracy of controlled and displayed variables.

EXAMPLE 1 Acceptable range of water level in a *humidifier*.

EXAMPLE 2 Interval of calibration of a flow sensor.

- d) a description of any degradation in accuracy of monitored values with frequency.

EXAMPLE 3 Impaired accuracy of an *HFV volume* monitor at higher frequency due to the time response of a flow transducer.

- e) an explanation of the meaning of the IP classification *marked* on the *ME equipment*.

- f) whether or not the *HFV* is intended for use with closed suctioning.

- g) whether or not the *HFV* is intended for use with nitric oxide and helium.

- h) whether or not the *HFV*

1) is intended for use with nebulized medications, and if so,

2) any constraints.

EXAMPLE Intended for use only with nebulizers or medical drug inhaler that inject droplets without adding carrier gas such as an ultrasonic nebulizer.

- i) when *fail-safe ventilation* is initiated.

- j) the settings of *fail-safe ventilation*.

Check conformance 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 include a statement to the effect that antistatic or electrically conductive hoses or tubing are not to be used in the *HFV breathing system*.
- b) If applicable, the *instructions for use* of the *ventilator* shall disclose:

- 1) any restrictions on the positioning of components within or connected to the *HFV breathing system*; and

EXAMPLE Where such components are *flow-direction-sensitive components*.

- 2) any adverse effect of any recommended *accessory* on the *essential performance* or *basic safety* of the *ventilator* (additional requirements are found in 201.4.11.101 and 201.16).

Check conformance by inspection and inspection of the risk management file for any adverse effect of any recommended accessory.

201.7.9.3.1.101 * Additional general requirements

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 summary description of the algorithm for how the *mean airway pressure* is calculated; and
- 3) a pneumatic diagram of the *ventilator*, including a diagram for *operator-detachable parts* of the *HFV breathing system* either supplied or recommended in the *instructions for use*.

b) If applicable, the *technical description* shall disclose:

- 1) a summary description of the algorithm for how the *pressure amplitude* is calculated, including the averaging period;
- 2) a summary description of the algorithm for how the *HFV volume* is calculated, including the averaging period; and
- 3) the essential technical characteristics of each recommended *breathing system filter*.

EXAMPLE Deadspace and resistance.

Check conformance 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* specified in this document, if not performed automatically during start-up; and
- b) which checks are performed automatically.

Check conformance by inspection of the technical description.

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

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