BS EN ISO 80601-2-72:2023

BSI Standards Publication

Medical electrical equipment

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

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National foreword

This British Standard is the UK implementation of EN ISO 80601-2-72:2023. It is identical to ISO 80601-2-72:2023. It supersedes BS EN ISO 80601-2-72:2015, which is withdrawn.

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

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

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EUROPÄISCHE NORM

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English Version

Medical electrical equipment - Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients (ISO 80601-2-72:2023)

Appareils électromédicaux - Partie 2-72: Exigences particulières pour la sécurité de base et les performances essentielles des ventilateurs utilisés dans l'environnement des soins à domicile pour les patients ventilo-dépendants (ISO 80601-2-72:2023)

Medizinische elektrische Geräte - Teil 2-72: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Heimbeatmungsgeräten für vom Gerät abhängige Patienten (ISO 80601-2-72:2023)

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European foreword

This document (EN ISO 80601-2-72:2023) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment” the secretariat of which is held by BSI.

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of an identical text or by endorsement, at the latest by January 2024, and conflicting national standards shall be withdrawn at the latest by January 2024.

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

This document supersedes EN ISO 80601-2-72:2015.

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

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

Endorsement notice

The text of ISO 80601-2-72:2023 has been approved by CEN as EN ISO 80601-2-72:2023 without any modification.

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INTERNATIONAL STANDARD

ISO 80601-2-72

Second edition
2023-06

Medical electrical equipment —

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

Appareils électromédicaux —

Partie 2-72: Exigences particulières pour la sécurité de base et les performances essentielles des ventilateurs utilisés dans l'environnement des soins à domicile pour les patients ventilo-dépendants

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Foreword

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

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

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

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

This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Respiratory devices and related equipment used for patient care* and Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC 62D, *Electric 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).

This second edition cancels and replaces the first edition (ISO 80601-2-72:2015), which has been technically revised.

The main changes are as follows:

— added requirements for display during calibration of gas monitors;

— clarified *maximum limited pressure* requirements;

— clarified high *airway pressure alarm condition* requirements;

— added requirements for *ventilator system recovery*;

— added requirements for response to an increase in set oxygen (O_2) concentration; and

— harmonization with ISO 20417, where appropriate.

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

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Introduction

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

In referring to the structure of this document,

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

— “subclause” means a numbered subdivision of a clause (e.g. 201.7, 201.8 and 201.9 are all subclauses of Clause 201).

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

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

For the purposes of this document, the auxiliary verb:

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission;

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

— "must" is used to express an external constraint.

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

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

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

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Medical electrical equipment —

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

201.1 Scope, object, and related standards

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

201.1.1 Scope

Replacement:

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

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

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

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

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

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

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

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

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

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

NOTE 4 If a clause or subclause is specifically intended to be applicable to *ME equipment* only or to *ME systems* only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to *ME equipment* and to *ME systems*, as relevant.

Hazards inherent in the intended physiological function of *ME equipment* or *ME systems* within the scope of this document are not covered by specific requirements in this document except for the requirements specified in IEC 60601-1:2005+AMD1:2012+AMD2:2020, 7.2.13 and 8.4.1.

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

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This document does not specify the requirements for:

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

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

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

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

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

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

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

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

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

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

— oxygen therapy constant flow *ME equipment*; and

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

201.1.2 Object

Replacement:

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

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

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

NOTE 2 This document has been prepared to address the relevant *essential principles of safety and performance* of ISO 16142-1:2016 as indicated in Annex DD.

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

201.1.3 Collateral standards

Amendment (add after existing text):

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

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

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

201.1.4 Particular standards

Replacement:

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

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

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

The numbering of clauses and subclauses of this document corresponds to those of the general standard with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix "2xx" where xx is the final digits of the collateral standard document number (e.g. 202.4 addresses the content of IEC 60601-1-2, Clause 4 collateral standard, 208.4 addresses the content of IEC 60601-1-8, Clause 4 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

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

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

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

Subclauses or figures that are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.154, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

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

The term "this document" is used to make reference to IEC 60601-1:2005+AMD1:2012+AMD2:2020, any applicable collateral standards, and this document taken together.

Where there is no corresponding clause or subclause in this document, the clause or subclause of IEC 60601-1:2005+AMD1:2012+AMD2:2020 or the applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of IEC 60601-1:2005+AMD1:2012+AMD2:2020 or the applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this document.

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.

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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, *Low-pressure hose assemblies for use with medical gases*

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

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

ISO 9360-1:2000, *Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for humidifying respired gases in humans — Part 1: HMEs for use with minimum tidal volumes of 250 ml*

ISO 9360-2:2001, *Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for humidifying respired gases in humans — Part 2: HMEs for use with tracheostomized patients having minimum tidal volumes of 250 ml*

ISO 14937:2009, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

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

ISO 17664-2:2021, *Processing of health care products — Information to be provided by the* medical *device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices*

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

ISO 20417:2021, *Medical devices — Information to be supplied by the manufacturer*

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

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

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

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

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

IEC 62304:2006+AMD1:2015, *Medical device software - Software life cycle processes*

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

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IEC 81001-5-1:2021, *Health software and health IT systems safety, effectiveness and security — Part 5-1: Security — Activities in the product life cycle*

IEC Guide 115:2021, *Application of uncertainty of measurement to conformity assessment activities in the electrotechnical sector*

201.3 Terms and definitions

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

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

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

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

201.3.201
accompanying information
information accompanying or *marked* on a medical device or *accessory* for the user or those accountable for the installation, use, *processing*, maintenance, decommissioning and disposal of the medical device or *accessory*, particularly regarding safe use

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

Note 2 to entry: The *accompanying information* can consist of the label, *marking*, *instructions for use*, *technical description*, installation manual, quick reference guide, etc.

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

[SOURCE: ISO 20417:2021, 3.2, modified — deleted note 4.]

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

Note 1 to entry: *Acknowledged* only affects *alarm signals* that are active at the time of the *operator* action.

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

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

[SOURCE: ISO 4135:2022, 3.8.1.2]

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

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

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[SOURCE: ISO 4135:2022, 3.1.4.41.1]

201.3.205
alarm condition delay
time from the occurrence of a triggering event either in the *patient*, for *physiological alarm conditions*, or in the equipment, for *technical alarm conditions*, to when the *alarm system* determines that an *alarm condition* exists

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

201.3.206
alarm limit
threshold used by an *alarm system* to determine an *alarm condition*

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

201.3.207
alarm off
state of indefinite duration in which an *alarm system* or part of an *alarm system* does not generate *alarm signals*

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

201.3.208
alarm paused
state of limited duration in which the *alarm system* or part of the *alarm system* does not generate *alarm signals*

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

201.3.209
alarm setting
alarm system configuration, including but not limited to:
– *alarm limits*;
– the characteristics of any *alarm signal* inactivation states; and
– the values of variables or parameters that determine the function of the *alarm system*

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

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

201.3.210
alarm signal generation delay
time from the onset of an *alarm condition* to the generation of its *alarm signal(s)*

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.10]

201.3.211
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*.

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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]

201.3.212
attack
attempt to destroy, expose, alter, disable, steal or gain unauthorized access to or make unauthorized use of an asset

[SOURCE: IEC 81001-5-1:2021, 3.5]

201.3.213
audio off
state of indefinite duration in which the *alarm system* or part of the *alarm system* does not generate an auditory *alarm signal*

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

201.3.214
audio paused
state of limited duration in which the *alarm system* or part of the *alarm system* does not generate an auditory *alarm signal*

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

201.3.215
BAP
quantity by which the baseline *airway pressure* is set to be positively offset from the ambient pressure

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

201.3.216
bias flow
flow that passes through the *ventilator breathing system* to the *exhaust port* but is not intended to contribute to the work of *lung* ventilation

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

201.3.217
biocompatibility
ability to be in contact with a living system without producing an unacceptable adverse effect

Note 1 to entry: 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]

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201.3.218
body temperature and pressure saturated
BTPS
ambient atmospheric pressure, at a temperature of 37 °C, and at a relative humidity of 100 %

[SOURCE: ISO 4135:2022, 3.1.1.7]

201.3.219
breathing system
pathways through which gas flows to or from the *patient* at respiratory pressures and continuously or intermittently in fluid communication with the *patient's* respiratory tract during any form of *artificial ventilation* or respiratory therapy

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

201.3.220
breathing system filter
BSF
device intended to reduce transmission of particulates, including microorganisms, in *breathing systems*

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

201.3.221
cleaning
removal of contaminants to the extent necessary for further *processing* or for *intended use*

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

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

201.3.222
connector
fitting to join two or more components

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

[SOURCE: ISO 4135:2022, 3.1.4.5]

201.3.223
continuous flow
gas flowing continuously through the *ventilator breathing system*, with a proportion intermittently passing to the *patient's lung* whenever the *airway pressure* is raised by the *ventilator* or an *operator* action, or flow is demanded by a *patient's* inspiratory effort

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

201.3.224
CPAP
continuous positive airway pressure
ventilation-mode or sleep-apnoea breathing-therapy mode in which the *patient* breathes continuously at a set *airway-pressure* level, above ambient pressure

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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 *ventilator*s 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 *ventilator*s 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.]

201.3.225
cybersecurity
state where information and systems are protected from unauthorized activities, such as access, use, disclosure, disruption, modification, or destruction to a degree that the related *risks* to violation of confidentiality, integrity, and availability are maintained at an acceptable level throughout the life cycle

[SOURCE: IEC 81001-5-1:2021, 3.30]

201.3.226
Δ inspiratory pressure
differential *airway pressure* relative to baseline *airway pressure* during an *inflation phase*

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

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201.3.227
disinfection
process to reduce the number of viable microorganisms to a level previously specified as being appropriate for a defined purpose

[SOURCE: ISO 17664-1:2021, 3.3]

201.3.228
distributed alarm system
DAS
alarm system that involves more than one item of equipment of a *ME system* intended for delivery of *alarm conditions* with technical confirmation

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

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

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

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

201.3.229
end-expiratory flow
expiratory flow at the point of initiation of an *inflation* or an inspiration

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

201.3.230
essential function
function or capability that is required to maintain *basic safety*, *essential performance*, a minimum of clinical functionality as specified by the manufacturer, and operational availability for the *medical device*

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

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

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

201.3.231
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]

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201.3.232
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]

201.3.233
expiratory phase
interval from the start of expiratory flow to the start of inspiratory flow within a *respiratory cycle*

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

201.3.234
false positive alarm condition
presence of an *alarm condition* when no valid triggering event has occurred in the *patient*, the equipment or the *alarm system*

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

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

201.3.235
firecall
method established to provide emergency access to a secure medical device

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

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

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

201.3.236
flow-direction-sensitive component
component or *accessory* through which gas flow has to be in one direction only for proper functioning or *patient* safety

[SOURCE: ISO 4135:2022, 3.1.4.15]

201.3.237
fresh gas
respirable gas delivered to a *ventilator breathing system*

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

201.3.238
gas intake port
port through which gas is drawn for use by the *patient*

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

[SOURCE: ISO 4135:2022, 3.1.4.21 modified — replaced "apposition" with "opposition".]

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201.3.239
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]

201.3.240
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]

201.3.241
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]

201.3.242
healthcare professional
appropriately trained, knowledgeable, and skilled, providing systematic preventive, curative, promotional or rehabilitative healthcare services to families or communities

Note 1 to entry: This term functions as an adjective.

201.3.243
heat and moisture exchanger
HME
device intended to retain a portion of the *patient's* expired moisture and heat, and return it to the respiratory tract during inspiration

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

201.3.244
high-pressure inlet
inlet to which gas is supplied at a pressure exceeding 100 kPa above ambient

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

[SOURCE: ISO 4135:2022, 3.1.4.24]

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201.3.245
humidifier
device that adds water in the form of droplets or vapour, or both, to the inspired gas

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

[SOURCE: ISO 4135:2022, 3.7.2.1]

201.3.246
I:E ratio
ratio of the *inspiratory time* to the expiratory time in a *respiratory cycle*

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

201.3.247
immunity
the ability of *ME equipment* or an *ME system* to perform without degradation in the presence of an electromagnetic disturbance

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

201.3.248
inflation
ventilator action intended to increase the volume of gas in the *lungs* by the application of an elevated-pressure waveform to the *patient-connection port* until a specified termination criterion is met

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

201.3.249
inflation phase
interval from the start of the rise in *airway pressure* resulting from the initiation of an *inflation* to the start of the expiratory flow resulting from its termination

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

201.3.250
inflation-type
inflation characterized by its temporal delivery pattern following initiation, and its termination criteria

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

201.3.251
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.

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

201.3.252
inspiratory time
t_I
duration of an *inflation phase* or inspiratory phase

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

201.3.253
inspiratory volume
V_{insp}
volume of gas delivered through the *patient-connection port* during an *inspiratory phase* or *inflation phase*

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

201.3.254
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 20417:2021, 3.11, modified — deleted note 5.]

201.3.255
intelligent alarm system
alarm system that makes logical decisions based on monitored information without *operator* intervention

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

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

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

201.3.256
latching alarm signal
alarm signal that continues to be generated after its triggering event no longer exists until stopped by deliberate *operator* action

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

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201.3.257
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+AMD1:2020, 3.2]

201.3.258
low-pressure hose assembly
assembly consisting of a flexible hose with permanently attached gas-specific *inlet* and *outlet connectors* and designed to conduct a *medical gas* at pressures less than 1 400 kPa

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

[SOURCE: ISO 4135:2022, 3.2.3.1]

201.3.259
lung
each of the pair of compliant organs within the ribcage (thorax), bounded by the terminal bronchiole and the visceral pleura, which during *ventilation* provide gas/blood interfaces that enable oxygen from the gas to pass into the blood and carbon dioxide to be removed

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

201.3.260
manual ventilation port
port to which a manual inflating device can be connected

201.3.261
marking
information, in text or graphical format, durably affixed, printed, etched (or equivalent) to a medical device or *accessory*

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

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

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

201.3.262
mask
device which provides a non-invasive interface between the *patient's airway* and a *patient-connection port* or other connection to a source of respirable gas

[SOURCE: ISO 4135:2022, 3.8.6.4]

201.3.263
maximum limited pressure
$\boldsymbol{P}_{\mathbf{lim,max}}$
highest *airway pressure* that can occur during *normal use* or under *single fault condition*

[SOURCE: ISO 4135:2022, 3.1.4.41.3]

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201.3.264
medical gas pipeline system
combination of a supply system, monitoring and *alarm system* and a pipeline distribution system with terminal units for provision of medical gases or vacuum

[SOURCE: ISO 4135:2022, 3.2.1.1]

201.3.265
monitoring equipment
equipment or part that measures and indicates the value of a variable to the *operator*

Note 1 to entry: *Monitoring equipment* includes devices that are not electrical in operation, such as a pressure gauge.

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

Note 3 to entry: The *monitoring equipment* can be primarily intended for detection of an *alarm condition* or for external communication.

[SOURCE: ISO 4135:2022, 3.11.1.3, modified —replaced "user" with "*operator*".]

201.3.266
operator interface
means by which the *operator* and the *ME equipment* interact

Note 1 to entry: The *accompanying documents* are considered part of the *ME equipment* and its *operator interface*.

Note 2 to entry: *Operator interface* includes all the elements of the *ME equipment* with which the *operator* interacts including the physical aspects of the *ME equipment* as well as visual, auditory, tactile displays and is not limited to a software interface.

Note 3 to entry: For the purposes of this standard, the *manufacturer* may treat the combination of *ME equipment* and other equipment as a single *operator interface*.

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

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

201.3.267
outlet
opening through which gas leaves a device or component

[SOURCE: ISO 4135:2022, 3.1.4.40]

201.3.268
patient-connection port
port of a *breathing system* intended for connection to an *airway device*

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

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

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

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

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201.3.269
PEEP
positive end-expiratory pressure
<actual and measured value> respiratory pressure at the end of an *expiratory phase*

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

201.3.270
physiologic closed-loop control system
part of *ME equipment* or *ME system* used to adjust a physiologic variable relative to a command variable using a feedback variable

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

201.3.271
pressure-control
inflation-type that acts to generate a constant inspiratory pressure at a set level, after a set rise time

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

201.3.272
processing
<preparation of medical device, *accessory*> activity to prepare a new or used medical device and *accessory* for its *intended use*

[SOURCE: ISO 20417:2021, 3.20]

201.3.273
professional healthcare facility
facility that is continually staffed by suitably trained *healthcare professional operators*

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

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

201.3.274
protection device
part or function of *ME equipment* that, without intervention by the *operator*, protects the *patient* from hazardous output due to incorrect delivery of energy or substances

201.3.275
respiratory cycle
complete sequence of respiratory events that leads to an increase, followed by a corresponding decrease, of gas volume in the *lung* regardless of how it is generated

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

201.3.276
security level
level corresponding to the required set of countermeasures and inherent *cybersecurity* properties of devices and systems for a zone or conduit based on assessment of *risk* for the zone or conduit

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

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201.3.277
set rate
number of assured *inflations* that are set to occur in a specified period of time, expressed as breaths per minute

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

201.3.278
single use
<medical device, *accessory*> intended by the *manufacturer* to be used on an individual *patient* or specimen during a single *procedure* and then disposed of

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

[SOURCE: ISO 20417:2021, 3.27]

201.3.279
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.]

201.3.280
spontaneous breath rate
total number of spontaneous breaths initiated in a specified period of time, expressed as breaths per minute

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

201.3.281
standard temperature and pressure dry
STPD
pressure of 101,325 kPa at a temperature of 20 °C, dry

[SOURCE: ISO 4135:2022, 3.1.1.8]

201.3.282
sterile
free from viable microorganisms

[SOURCE: ISO 20417:2021, 3.29]

201.3.283
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.

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

201.3.284
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]

201.3.285
symbol
graphical representation appearing on the label or associated documentation of a medical device that communicates characteristic information without the need for the supplier or receiver of the information to have knowledge of the language of a particular nation or people

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

[SOURCE: ISO 20417:2021, 3.30]

201.3.286
system recovery
method for fault handling via an automatic restart of *PESS* for parts of the *ME equipment* or for the complete *ME equipment*

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

201.3.287
technical alarm condition
alarm condition arising from a monitored equipment-related or *alarm system*-related variable

EXAMPLE 1 An electrical, mechanical or other failure.

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

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

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

201.3.288
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 lifetime of a medical device

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

[SOURCE: ISO 20417:2021, 3.30, modified — deleted note 2.]

201.3.289
tidal volume
$\boldsymbol{V_T}$
volume of gas that enters and leaves the *lung* during a breath

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

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201.3.290
total respiratory rate
number of *respiratory cycles* in a specified period of time, expressed as breaths per minute

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

201.3.291
transit-operable
<adj> term referring to transportable equipment whose *intended use* includes operation while it is being moved

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

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

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

201.3.292
use scenario
specific sequence of tasks performed by a specific *operator* in a specific use environment and any resulting response of the *ME equipment*

[SOURCE: IEC 62366-1:2015+AMD1:2020, 3.22, modified — replaced "user" with "*operator*" and "medical device" with "*ME equipment*".]

201.3.293
validation
confirmation, through the provision of *objective evidence*, that the requirements for a specific *intended use* or 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]

201.3.294
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.]

201.3.295
ventilation-mode
specified manner in which a *ventilator* performs its ventilatory function when connected to a *patient*

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

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201.3.296
ventilator
medical device or *medical electrical equipment* intended to provide *artificial ventilation*

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

201.3.297
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.]

201.3.298
ventilator-dependent
<*patient*> dependent upon *artificial ventilation* in order to prevent serious deterioration of health or death

Note 1 to entry: A *ventilator-dependent patient* cannot breathe well enough to maintain life-sustaining levels of oxygen and carbon dioxide in the blood. For the purposes of this document, dependent means the loss of therapy can require immediate medical intervention.

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

201.3.299
volume-control
inflation-type that generates inspiratory flow to a selected flow-waveform, for a set *inspiratory-time*, or until the set volume has been delivered

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

201.4 General requirements

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

Addition:

201.4.3.101 Additional requirements for *essential performance*

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

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

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Table 201.101 — Distributed *essential performance* requirements

Requirement	Subclause
Delivery of *ventilation* at the *patient-connection port* within the *alarm limits* set by the *operator* or	[a]
generation of an *alarm condition*	
airway pressure	201.12.4.102
continuing positive-pressure	201.12.4.110
functional connection failure	201.13.2.103
high *airway pressure*	201.12.4.106
high leakage	201.12.4.111
hypoventilation	201.12.4.109
internal electrical power source nears depletion	211.8.4.101
low expired volume[b], if provided	201.12.4.103
obstruction	201.12.4.107
oxygen levels[c], if provided	201.12.4.101
system recovery	201.4.3.102
tidal volume	201.12.1.105

[a] 202.4.3.1 and 202.8.1.101 indicate methods of evaluating delivery of *ventilation* as acceptance criteria following specific tests required by ISO 80601 series.

[b] If $etCO_2$ monitoring or high leakage is not in use.

[c] If a control for the setting of the inspiratory oxygen concentration is provided.

201.4.3.102 *System recovery*

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

a) Following a malfunction, which causes loss or degradation of *essential performance*, the *ventilator* shall attempt to perform a *system recovery* with the intention of restoring the *essential performance* of the *ventilator*.

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

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

1) cessation in the *ventilation* of the *patient*; or

2) reduction in the function of *ventilator* subassemblies without impacting the *ventilation* of the *patient.*

EXAMPLE The temporary blanking of the display.

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

1) the *ventilator* shall allow spontaneous *patient* breathing in accordance with 201.103; and

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2) the *ventilator* shall be equipped with an *alarm system* to indicate *system recovery* with a cessation of *ventilation*.

   i) The *system recovery* with a cessation of *ventilation alarm condition* shall be *high priority*.

d) During a *system recovery* without a cessation of *ventilation*, the *ventilator* shall be equipped with an *alarm system* to indicate *system recovery* without a cessation of *ventilation*.

1) The *system recovery* without a cessation of *ventilation alarm condition* shall be at least *low priority.*

2) A *low priority system recovery* without a cessation of *ventilation alarm condition* need not have an auditory *alarm signal*.

e) Following a *system recovery* without *operator* intervention, the *ventilator* shall attempt to operate with the same system configuration settings, *ventilation* settings and *alarm settings* as before the *system recovery*.

1) If the system configuration settings, ventilation settings or *alarm settings* are different after the *system recovery*, the *ventilator* shall be equipped with an *alarm system* to indicate any change in settings.

2) The change in settings *alarm condition* shall be at least *medium priority*.

f) The duration of a *system recovery* with a cessation of *ventilation* should be as short as practicable to avoid an unacceptable *risk* to the *patient*.

g) The maximum duration of a *system recovery* of ventilation shall be disclosed in the *instructions for use*.

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

201.4.4 Additional requirements for *expected service life*

Amendment (add as a second paragraph):

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

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

bb) summarize the methodology used to determine this probability.

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

Amendment (add prior to the compliance check):

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

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

Amendment (add at end of 4.6 prior to the compliance check):

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NOTE 100 There is guidance or rationale for this subclause contained in Clause AA.2.

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

201.4.10.2 *Supply mains* for *ME equipment* and *ME systems*

Replacement of the tenth dash as follows.

NOTE 100 There is guidance or rationale for this subclause contained in Clause AA.2.

— For operation from:

1) 12 V d.c. *supply mains*

   i) the *rated* range shall include at least 11,6 V to 15,1 V, and

   ii) the *ME equipment* shall maintain *basic safety* and *essential performance* during and following a 30 s dip to 10 V.

2) 24 V d.c. *supply mains*

   i) the *rated* range shall include at least 23,2 V to 30,3 V, and

   ii) the *ME equipment* shall maintain *basic safety* and *essential performance* during and following a 30 s dip to 20 V.

3) other d.c. *supply mains*

   i) a d.c. voltage (as measured by a moving coil meter or equivalent method) having a peak-to-peak ripple not exceeding 10 % of the average value.

Additional subclauses:

201.4.11.101 Additional requirements for pressurized gas input

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

201.4.11.101.1 Overpressure requirement

a) A *ventilator* with a *high-pressure inlet* 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) If the *ventilator* has a maximum *rated* input pressure in excess of 600 kPa, the *ventilator* 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 needed to accommodate the *single fault condition* of maximum input pressure, as well as the *rated* range of input pressure.

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

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

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+AMD1:2017, then

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

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

b) under *normal condition*,

1) the maximum 10 s average input flow required by the *ventilator* for each gas shall not exceed 60 l/min at a pressure of 280 kPa, measured at the *gas intake port*, and

2) the transient input flow shall not exceed 200 l/min averaged for 3 s

or

3) the *accompanying documents* shall disclose the following:

i) the maximum 10 s average input flow required by the *ventilator* for each gas at a pressure of 280 kPa, measured at the *gas intake port*;

ii) the maximum transient input flow averaged for 3 s required by the *ventilator* for each gas at a pressure of 280 kPa, measured at the *gas intake port*;

iii) a warning to the effect that this ventilator is a high-flow device and should only be connected to a pipeline installation designed using a diversity factor that allows for the indicated high flow at a specified number of terminal outlets, in order to avoid exceeding the pipeline design flow, thereby minimizing the risk that the ventilator interferes with the operation of adjacent equipment.

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

EXAMPLE The highest driving gas consumption, the highest *fresh gas* delivery, and, if provided, the highest *rated* gas consumption at any gas power supply output under worst-case settings for *set rate* and *tidal volume* and worst-case *medical gas pipeline system* conditions within the *rated* range for inlet pressure.

201.5 General requirements for testing of *ME equipment*

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

Addition:

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

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

201.5.101.1 *Ventilator* test conditions

a) For testing, the *ventilator*

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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

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

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

a) are expressed at *STPD*,

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

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

201.5.101.3 *Ventilator* testing errors

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

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

1) *procedure* 1 (calculation of uncertainty of measurement) from IEC Guide 115:2021, 4.4.2; or

2) *procedure* 2 (accuracy method) from IEC Guide 115:2021, 4.4.3.

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

EXAMPLE If the *manufacturer* wishes to claim a tolerance for *tidal volume* of ±(10 ml +10 % of set volume) then the uncertainty of the measurement cannot exceed ±(3 ml +3 % of set volume).

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

Check conformity by inspection of the *technical description*.

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

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

201.7 *ME equipment* identification, *marking*, and documents

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

Addition:

201.7.1.101 *Information to be supplied by the manufacturer*

a) The *information supplied by the manufacturer* of a *ventilator* and its *accessories* shall conform with ISO 20417:2021.

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b) In applying ISO 20417:2021, the terms in this document and those in IEC 60601-1:2005+AMD1:2012+AMD2:2020 shall be used as follows.

1) The term "*accompanying information*" shall assume the same meaning as *accompanying documents*.

2) The term "*medical device*" shall assume the same meaning as *ME equipment*.

3) The term "*user*" shall assume the same meaning as *operator*.

4) The term "*patient*" shall include animals.

Check conformity by application of ISO 20417:2021.

201.7.2.3 Consult *accompanying documents*

Replacement:

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

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

Additional subclauses:

201.7.2.4.101 Additional requirements for *accessories*

a) *Accessories* supplied separately shall:

1) fulfil the requirements of ISO 20417:2021, 6.1.1 c); and

2) be *marked* with an indication of any limitations or adverse effects of the *accessory* on the *basic safety* or *essential performance* of the *ventilator*, if applicable. See also 201.7.2.101.

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

NOTE The *manufacturer* of the *accessory* can be the *ventilator manufacturer* or another entity ("third-party manufacturer", healthcare provider or durable medical equipment provider) and all these entities are expected to ensure conformity with this requirement. Additional requirements are found in 201.102.

Check conformity by inspection and inspection of the *risk management file* for any limitations or adverse effects of the *accessory*.

Additional subclauses:

201.7.2.18 Additional requirements for external gas source

Amendment (add before the first dash):

If provided with a control for the setting of the inspiratory oxygen concentration, adjacent to each input *connector*, the *ME equipment* shall be *marked* with:

a) the gas name or chemical *symbol* in accordance with ISO 5359:2014+AMD1:2017, if applicable;

b) the *rated* range of gas pressure;

c) for oxygen gas inputs, the *rated* range of oxygen concentration;

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d) gas-specific colour coding in accordance with ISO 32:1977, if colour coding is used;

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

NOTE In some countries, other colour coding is used.

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

a) If applicable, *operator*-accessible *ME equipment,* parts or *accessories* shall have *clearly legible markings* of the following.

1) for a *ventilator* intended to be used in the magnetic resonance (MR) environment, in accordance with IEC 62570:2014:

i) *symbol* 7.3.1-1 (Table 201.D.2.101, *symbol* 3) or *symbol* 7.3.1-2 of IEC 62570:2014 (Table 201.D.2.101, *symbol* 4) for an 'MR Safe' *ventilator*; or

ii) *symbol* 7.3.2 of IEC 62570:2014 (Table 201.D.2.101, *symbol* 5) for an 'MR Conditional' *ventilator.*

2) for a *ventilator* not intended for use in the magnetic resonance (MR) environment, in accordance with IEC 62570:2014 *symbol* 7.3.3 (Table 201.D.2.101, *symbol* 6) for an 'MR Unsafe' *ventilator.*

3) an arrow indicating the intended direction of gas flow:

i) for the *gas output port*; and

I) *Symbol* 0795 of ISO 7000 (Table 201.D.2.101, *symbol* 1) may be used.

ii) for the *gas return port*.

II) *Symbol* 0794 of ISO 7000 (Table 201.D.2.101, *symbol* 2) may be used.

4) for *flow-direction-sensitive components* that are *operator*-removable without the use of a *tool*, an arrow indicating the direction:

i) of the flow; or

ii) of inspiratory flow if exposed to inspiratory and expiratory flow.

b) If applicable, *operator*-accessible *ME equipment,* parts or *accessories* shall have *clearly legible markings,* on or adjacent to the following items:

1) for a *gas intake port*, a warning not to obstruct the *gas intake port*.

EXAMPLE WARNING: Gas Intake – Do not obstruct.

i) A *symbol* or *safety sign* evaluated in accordance with to IEC 62366-1 as *information for safety* may be used.

Check conformity by inspection.

201.7.4.2 Control devices

Amendment (add after the second dash):

aa) The *marking* of the trigger sensitivity control shall be such that the minimum (least *patient* effort) and the maximum (greatest *patient* effort) trigger sensitivity settings are self-evident to the *operator*.

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bb) The *marking*, if numeric, shall

1) use the lowest number to represent the setting for the least *patient* effort; and

2) not only be numeric.

201.7.4.3 Units of measurement

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

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

aa) All gas volume, flow, and leakage specifications:

1) shall be expressed at *STPD*; except for those associated with the *VBS*, which

2) shall be expressed at *BTPS*.

bb) The unit of *airway pressure* measurement shall be capable of being configured to be expressed in hPa.

201.7.9.2.1 General

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

— the intended position of the *operator*;

Additional subclauses:

201.7.9.2.1.101 Additional general requirements

a) Separate *instructions for use* shall be provided for:

1) the *lay operator*; and

2) the supervising clinician or the *healthcare professional operator.*

b) Unless otherwise indicated in this document, the *manufacturer* may choose in which *instructions for use* to place the information required by this document based on *risk management* and *usability* considerations.

c) The supervising clinician or the *healthcare professional operator instructions for use* shall include the information contained in the *lay operator instructions for use*.

d) The *instructions for use* shall disclose the following:

1) the intended range of *tidal volume*.

Check conformity by inspection of the *instructions for use*, the *risk management file*, and *usability engineering file*.

201.7.9.2.2.101 Additional requirements for warnings and safety notices

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

The *instructions for use* shall include the following.

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a) A warning statement to the effect of "WARNING: To prevent death or serious injury, monitor the patient and the ventilator regularly in order to determine the need to provide emergency ventilation when an alarm sounds or the ventilator malfunctions."

b) A warning statement to the effect of "WARNING: Do not cover the ventilator or place in a position that affects proper operation", including applicable examples.

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

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

c) A warning statement to the effect of "WARNING: Always have immediate access to an alternative means of ventilation, which is ready for use, to avoid patient death or serious injury."

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

d) A warning statement to the effect of "WARNING: Do not add any attachments or accessories to the ventilator that contravene the instruction for use of the ventilator or accessory, as the ventilator might not function correctly which consequently can result in patient death."

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

e) If the *instructions for use* include a *VBS* configuration with a *BSF* exposed to the humidity from nebulisation or humidification, a warning statement to the effect of "WARNING: When using nebulisation or humidification, the breathing system filter will require more frequent replacement to prevent increased resistance or blockage."

NOTE 3 There is guidance or rationale for this subclause contained in Clause AA.2.

f) A warning statement to the effect of "WARNING: Do not use the ventilator at an altitude above (insert maximum *rated* altitude) or outside a temperature of [insert *rated* temperature range]. Using the ventilator outside of this temperature range or above this altitude can affect the ventilator performance which consequently can result in patient death."

g) A warning statement to the effect of "WARNING: Do not connect the ventilator to the battery of a battery-powered wheelchair unless the connection is listed in the instruction for use of the ventilator or wheelchair as this can affect the ventilator performance which can consequently result in patient death."

NOTE 4 There is guidance or rationale for this subclause contained in Clause AA.2.

h) A warning statement to the effect of "WARNING: When using the ventilator in a carrying case, only use a carrying case that is listed in the instructions for use to prevent adverse ventilator performance which can consequently result in patient death."

i) A warning statement to the effect of "WARNING: To reduce the likelihood of disconnection and to prevent adverse ventilator performance, use only accessories compatible with the ventilator. Compatibility is determined by reviewing the instructions for use of either the ventilator or the accessories".

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j) If applicable, a warning statement to the effect of "WARNING: The ventilator accuracy can be adversely affected by the gas added by the use of a pneumatic nebuliser."

k) If applicable, a warning statement to the effect of "WARNING: Unintentional leaks cause indicated volume and expired CO_2 values to differ from actual patient values."

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

201.7.9.2.8.101 Additional requirements for start-up *procedure*

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

NOTE 2 For the purposes of this document, a start-up *procedure* is a pre-use functional test that is used to determine whether the *ventilator* is ready for use.

a) The *instructions for use* for the *lay operator* shall disclose a method by which the following can be functionally tested to determine if they are operating correctly:

   1) the assembled breathing tubes and related *accessories;*

   2) the switchover to and operation from the *internal electrical power source*; and

   3) all of the *alarm signals*, including the *alarm signals* from *distributed alarm systems*.

b) Portions of these test methods may:

   1) be performed automatically by the *ventilator*; or

   2) require *operator* action.

   EXAMPLE 1 Combination of the power-on self-test routines and *operator* actions that functionally check the *alarm signals*.

c) The specifications of any required *accessories* or test equipment needed to perform these tests shall be disclosed in the *instructions for use* for the *lay operator*.

   EXAMPLE 2 Volume, resistance, and compliance of the test lung necessary to perform the tests.

d) The *instructions for use* for the supervising clinician or the *healthcare professional operator* shall disclose a method by which all functions and settings necessary for *normal use* can be functionally tested to determine if they are operating correctly.

e) Portions of this test method may:

   1) be performed automatically by the *ventilator*; or

   2) require *operator* action.

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

201.7.9.2.9.101 Additional requirements for operating instructions

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

201.7.9.2.9.101.1 *Lay operator* operating instructions

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

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The *instructions for use* intended for the *lay operator* shall include the following:

a) the conditions under which the *ventilator* maintains the accuracy of controlled and displayed variables as disclosed in the *instructions for use*;

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

EXAMPLE 2 Interval of calibration of a flow sensor.

b) an explanation of the meaning of the IP classification *marked* on the *ME equipment;*

c) an indication as to whether the *ventilator* is intended for non-invasive *ventilation*;

EXAMPLE 3 *Mask ventilation*.

d) a description of how at least the following *alarm conditions* can be tested:

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

1) high leakage;

2) *internal electrical power source* nears depletion;

3) low *airway pressure*;

4) low inspiratory pressure;

5) obstruction;

6) power failure of external mains;

7) power failure of external DC power

e) a description of how the following *alarm conditions*, if provided, can be tested:

1) low expired volume;

2) oxygen levels

f) a description of a means to determine the operation time of the *internal electrical power source*;

g) a description of how to connect and test the connection of a *distributed alarm system.*

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

201.7.9.2.9.101.2 Supervising clinician or *healthcare professional operator* operating instructions

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

a) The *instructions for use* intended for the supervising clinician or the *healthcare professional operator* shall include a detailed description of the function of all *ventilation-modes* provided by the *ventilator*, including but not limited to, the following items:

1) working principle of each of the *ventilator's ventilation-modes* including waveforms;

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2) methods for controlling the cycling;

3) parameter settings;

4) range of parameter settings;

5) any limitation of parameter settings;

6) a description of how at least the following *alarm conditions*, if included, can be tested:

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

i) continuing positive-pressure;

ii) *tidal volume*;

iii) high *airway pressure*;

iv) high expiratory volume;

v) hypoventilation; and

vi) low expiratory volume.

b) The *instructions for use* intended for the supervising clinician or the *healthcare professional operator* shall include the *rated* range of the following characteristics of the assembled *operator*-detachable parts of the *VBS*, over which the accuracies of set and monitored volumes and pressures are maintained:

1) inspiratory *gas pathway* resistance;

2) expiratory *gas pathway* resistance;

3) compliance.

4) These specifications may be presented in ranges.

5) The accuracies of set and monitored volumes may be presented as a function of these characteristics.

NOTE 3 Compliance and resistance can be nonlinear. These characteristics might need to be specified over a range (e.g. at 15 l/min, 30 l/min, 60 l/min, maximum flowrate, or the maximum pressure).

c) If applicable, *instructions for use* intended for the supervising clinician or the *healthcare professional operator* shall disclose

1) the essential technical characteristics of each recommended *breathing system filter*, and

EXAMPLE Dead space and resistance.

2) a statement as to whether any portion of the gas supplied to a *high-pressure inlet* is supplied to the *patient.*

d) For a *ventilator* that is not provided with a control for the setting of the inspiratory oxygen concentration, the length of time required for an increase of oxygen concentration in the *tidal*

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volume from room air to reach 90 % of the stable achievable delivered oxygen concentration shall be disclosed in the *instructions for use*.

1) The time shall be reported separately, as appropriate, for each *VBS* configuration (insertion point of oxygen into the *VBS*) and at *tidal volume* range indicated in the *instructions for use* when the oxygen source is greater than 99 % oxygen.

2) The *instructions for use* shall indicate that when the oxygen source is from an oxygen concentrator, the time can be significantly longer.

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

201.7.9.2.12 *Cleaning*, *disinfection*, and *sterilization*

Amendment: (add after normal use)

and *single fault condition*

Amendment: (add after bulleted list)

e) The *instructions for use* shall identify any portions of the *gas pathways* through the *ventilator* that can become contaminated with body fluids or by microbial material conveyed by the expired gases during both *normal condition* and *single fault condition*.

Additional subclauses:

201.7.9.2.13.101 Additional requirements for maintenance

The *instructions for use* shall disclose the following:

a) a description of periodic visual safety inspections that should be performed by the *operator*;

b) the *internal electrical power source* care and maintenance *procedures*, including instructions for recharging and replacement.

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

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

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

a) The *instructions for use* of the *ventilator* shall identify:

1) at least one set of *accessories*;

2) if applicable, the *ME equipment* necessary for the *ventilator's intended use*; and

3) all *accessories* that the *ventilator manufacturer* claims are compatible.

b) If applicable, the *instructions for use* of the *ventilator* shall disclose the following.

1) Any restrictions on the positioning of components within the *ventilator breathing system.*

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*.

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

201.7.9.3.1.101 Additional general requirements

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

The *technical description* shall disclose the following:

a) summary description of the filtering and smoothing techniques for all measured and computed variables that are displayed or used for control;

b) interdependence of control functions;

c) pneumatic diagram of the *ventilator*, including a diagram for *operator*-detachable parts of the *ventilator breathing system* either supplied or recommended in the *instructions for use*;

d) summary description of the means of initiating and terminating the *inflation phase* while in each *ventilation-mode*;

e) means by which the continuing pressure *alarm condition* is detected and a summary description of the detection algorithm; and

f) statement to the effect that the responsible organization needs to ensure the compatibility of the ventilator and all of the parts and accessories intended to be used to connect to the patient prior to use.

Check conformity by inspection of the *technical description*.

201.7.9.3.101 Additional requirements for the *technical description*

a) The *technical description* shall disclose a description of a method for checking the function of the *alarm system* for each of the *alarm conditions* specified in Table 201.101, except *system recovery*, if not performed automatically during start-up.

b) The *technical description* shall disclose which checks are performed automatically.

Check conformity by inspection of the *technical description*.

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

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

201.9 Protection against mechanical hazards of ME equipment and ME systems

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

Additional subclause:

201.9.4.3.101 Additional requirements for instability from unwanted lateral movement

a) A *transit-operable ventilator* shall include a means by which the *ventilator* can be easily immobilized without the use of a *tool* to prevent unwanted movement during transport while in use.

EXAMPLE 1 Means to attach during transport in a personal vehicle, in an ambulance, or on a wheelchair.

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