BS EN ISO 80601-2-79:2024

BSI Standards Publication

Medical electrical equipment

Part 2-79: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory impairment

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National foreword

This British Standard is the UK implementation of EN ISO 80601-2-79:2024. It is identical to ISO 80601-2-79:2024. It supersedes BS EN ISO 80601-2-79:2019, which is withdrawn.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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Appareils électromédicaux - Partie 2-79: Exigences particulières pour la sécurité de base et les performances essentielles des équipements d'assistance ventilatoire en cas de trouble ventilatoire (ISO 80601-2-79:2024)

Medizinische elektrische Geräte - Teil 2-79: Besondere Festlegungen für die grundlegende Sicherheit und die wesentlichen Leistungsmerkmale von Heimbeatmungsgeräten zur Atemunterstützung von Patienten mit Atmungsbeeinträchtigungen (ISO 80601-2-79:2024)

This European Standard was approved by CEN on 5 August 2024.

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European foreword

This document (EN ISO 80601-2-79:2024) 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of an identical text or by endorsement, at the latest by March 2025, and conflicting national standards shall be withdrawn at the latest by March 2025.

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 80601-2-79:2019.

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 80601-2-79:2024 has been approved by CEN as EN ISO 80601-2-79:2024 without any modification.

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Foreword

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

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

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

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

This second edition cancels and replaces the first edition (ISO 80601-2-79:2018), which has been technically revised.

The main changes are as follows:

— alignment with IEC 60601-1:2005+AMD1:2012+AMD2:2020, IEC 60601-1-2:2014+AMD1:2020 IEC 60601-1-6:2010+AMD1:2013+AMD2:2020 and IEC 60601-1-8:2006+AMD1:2012+AMD2:2020;

— clarified *maximum limited pressure* requirements;

— clarified high *airway pressure alarm condition* requirements; and

— harmonization with ISO 20417, where appropriate.

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

Ventilatory support is often used for *patients* who have stable ventilatory needs. This document addresses *patients* who have significant respiratory dysfunction resulting in an abnormality of a sufficient degree to be noticeable by the *patient*. This is best characterized by *lung* functions not worse than[35]:

— FEV_1/FVC[1] < 70 %; or

— 50 % ≤ FEV_1 < 80 % predicted

where

FEV_1 is the forced expiratory volume in 1 s, and

FVC is the forced vital capacity.

Examples of diseases that require *ventilation* support are:

— mild to moderate Chronic Obstructive Pulmonary Disease (COPD);

— mild to moderate neuromuscular/ amyotrophic lateral sclerosis (ALS);

— obese *patients* Obese Hypoventilation Syndrome (OHS);

— Cheyne–Stokes respiration (CSR/CSA).

CSR/CSA is an abnormal pattern of breathing characterized by progressively deeper and sometimes faster breathing, followed by a gradual decrease that results in a temporary stop in breathing called an apnoea. The pattern repeats, with each cycle usually taking 30 s to 2 min.

Cardiac *patients* with CSR/CSA might be breathless without having significant reduction in FEV_1. Reducing the work of breathing can help normalize their breathing.

This *ventilatory support equipment* is intended for *patients* who are spontaneously breathing and do not require *ventilation* for life support or intermittent periods of *ventilation* to maintain vital signs. *Ventilatory support equipment* intended for this group of *patients* typically does not require *physiological alarm conditions* as no *essential performance* exists. These *patients* can gain adequate relief from fatigue related to the work of breathing by using *ventilatory support equipment* during the night and while taking breaks during the day. This can enable a *patient* with *ventilatory impairment* to continue to move about and participate in the activities of daily living. Non-*transit-operable ventilatory support equipment* that provides ventilatory support at the bedside and beside a chair or other resting place should be adequate in this application.

In this document, the following print types are used:

— requirements and definitions: roman type;

— terms defined in *Clause 3* of the general standard[2], in this document or as noted: italic type; and

[1] This is also known as the Tiffeneau-Pinelli index.

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— informative material appearing outside of tables, such as notes, examples and references: in smaller type; normative text of tables is also in a smaller type;

In referring to the structure of this document, the term:

— "clause" means one of the five numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 201 includes subclauses 201.7, 201.8); 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 particular document are by number only.

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

For the purposes of this document, the auxiliary verb:

— "shall" indicates a requirement;

— "should" indicates a recommendation;

— "may" indicates a permission;

— "can" indicates 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.

[2] The general standard is IEC 60601-1:2005+AMD1:2012+AMD2:2020, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

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Medical electrical equipment

Part 2-79:
Particular requirements for the basic safety and essential performance of ventilatory support equipment for ventilatory impairment

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 *ventilatory support equipment,* as defined in 201.3.302, for *ventilatory impairment*, as defined in 201.3.300, hereafter also referred to as *ME equipment,* in combination with its *accessories*:

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

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

NOTE 3 Such *ventilatory support equipment* can also be used in professional health care facilities.

— intended for use by a *lay operator*;

— intended for use with *patients* who have *ventilatory impairment*, the most fragile of these *patients*, would not likely experience injury with the loss of this *artificial ventilation*; and

— not intended for *patients* who are dependent on *artificial ventilation* for their immediate life support.

EXAMPLE 1 *Patients* with mild to moderate chronic obstructive pulmonary disease (COPD).

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

This document is also applicable to those *accessories* intended by their *manufacturer* to be connected to the *breathing system* of *ventilatory support equipment* for *ventilatory impairment*, where the characteristics of those *accessories* can affect the *basic safety* or *essential performance* of the *ventilatory support equipment* for *ventilatory impairment*.

EXAMPLE 2 Breathing sets, *connectors*, water traps, expiratory valve, *humidifier*, *breathing system filter*, external electrical power source, *distributed alarm system.*

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.

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

NOTE 4 Additional information can be found in IEC 60601-1:2005+AMD1:2012+AMD2:2020, 4.2.

NOTE 5 See ISO/TR 21954 for guidance on the selection of the appropriate *ventilator* for a given *patient*.

This document does not specify the requirements for:

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

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

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

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

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

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

— high-frequency jet *ventilators* (HFJVs)[33], which are given in ISO 80601-2-87;

— high-frequency oscillatory *ventilators* (HFOVs)[22];

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

NOTE 6 *Ventilatory support equipment* 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 or “iron-lung” *ventilation* equipment.

201.1.2 Object

IEC 60601-1:2005+AMD1:2012+AMD2:2020, 1.2 is replaced by:

The object of this document is to establish particular *basic safety* and *essential performance* requirements for *ventilatory support equipment,* for ventilatory impairment, as defined in 201.3.300, and its *accessories*.

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

NOTE 1 This document has been prepared to address the relevant International Medical Device Regulators Forum (IMDRF) *essential principles*[37] and labelling[38] guidances as indicated in Annex CC.

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NOTE 2 This document has been prepared to address the relevant *essential principles of safety and performance* of ISO 16142-1:2016[10] 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[39].

201.1.3 Collateral standards

IEC 60601-1:2005+AMD1:2012+AMD2:2020, 1.3 applies with the following addition:

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

IEC 60601-1-2:2014+AMD1:2020, IEC 60601-1-6:2010+AMD1:2013+AMD2:2020, and IEC 60601-1-11:2015+AMD1:2020 apply as modified in Clauses 202, 206 and 211 respectively. IEC 60601-1-3, IEC 60601-1-9 and IEC 60601-1-12 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

IEC 60601-1:2005+AMD1:2012+AMD2:2020, 1.4 is replaced by:

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

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

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

The numbering of clauses and subclauses of this document corresponds to that of the general standard with the prefix “201” (e.g. 201.1 in this document addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix “2xx”, where xx is the final digits of the collateral standard document number (e.g. 202.4 in this document addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 211.10 in this document addresses the content of Clause 10 of the IEC 60601-1-11 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

“Replacement” means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this document.

“Addition” means that the text of this document is additional to the requirements of the general standard or applicable collateral standard.

“Amendment” means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this document.

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

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

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

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

201.2 Normative references

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

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

Replacement:

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

Addition:

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

ISO 7396-1:2016/Amd 1:2017, *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 18562-1:2024, *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*

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

ISO 80369-1:—[3], *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

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[4], *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

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

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

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

201.3 Terms and definitions

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

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

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

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

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.]

[3] Under preparation. Stage at the time of publication: ISO/FDIS 80369-1:2024.

[4] There exists a consolidated edition 3.2(2020) including IEC 60601-1:2005, its Amendment 1:2012 and its Amendment 2:2020.

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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 pressure
$\boldsymbol{P}_{\mathbf{aw}}$
pressure at the *patient-connection port* or at the distal *outlet* of the equipment where there is no *patient-connection port*

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

[SOURCE: ISO 4135:2022, 3.1.4.41.1]

201.3.204
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]

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

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

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

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

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

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

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

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

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

201.3.209
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]

201.3.210
artificial ventilation
intermittent elevation of the pressure in the *patient's airway* relative to that in the *lungs* by external means with the intention of augmenting, or totally controlling, the *ventilation* of a *patient*

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

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

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

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

[SOURCE: ISO 19223:2019, 3.1.10]

201.3.211
assured inflation-type rate
number of assured *inflation-type* initiations in a specified period of time, expressed as breaths per minute

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

[SOURCE: ISO 19223:2019, 3.5.2.1, modified — deleted note 2.]

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]

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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
biocompatibility
ability of a medical device, *accessory* or material to perform with an appropriate host response in a specific application

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

[SOURCE: ISO 18562-1:2024, 3.6]

201.3.217
body temperature and pressure saturated
BTPS
ambient atmospheric pressure, at a temperature of 37 °C, and a relative humidity of 100 %

[SOURCE: ISO 4135:2022, 3.1.1.7]

201.3.218
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.]

201.3.219
breathing system filter
BSF
device intended to reduce transmission of particulates, including microorganisms, in *breathing systems*

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

201.3.220
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'.]

201.3.221
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]

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201.3.222
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

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.

[SOURCE: ISO 19223:2019, 3.11.15, modified — deleted notes 6 to 9.]

201.3.223
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]

201.3.224
Δ inspiratory pressure
differential *airway pressure* relative to baseline *airway pressure* during an *inflation phase*

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

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

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

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

201.3.225
disinfection
process to inactivate viable microorganisms to a level previously specified as being appropriate for a defined purpose

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

201.3.226
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]

201.3.227
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.]

201.3.228
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]

201.3.229
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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201.3.230
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]

201.3.231
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.]

201.3.232
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]

201.3.233
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]

201.3.234
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]

201.3.235
fresh gas
respirable gas delivered to a *ventilator breathing system*

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

201.3.236
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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201.3.237
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]

201.3.238
gas pathway
interior surfaces, over which gases or liquids that can be inspired pass

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.

Note 1 to entry: The *gas pathway* is bounded by the fluid ports through which gases or liquids enter the medical device. This can include the *patient* interface or the interior surfaces of *enclosures* that are in contact with gases or liquids that can be inspired.

Note 2 to entry: The *gas pathway* can include some surfaces in the expiratory pathway.

Note 3 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.

[SOURCE: ISO 18562-1:2024, 3.11, modified — replaced “ports” with “fluid ports”.]

201.3.239
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]

201.3.240
healthcare professional
<adj> appropriately trained, knowledgeable, and skilled, providing systematic preventive, curative, promotional or rehabilitative health care services

Note 1 to entry: The *healthcare professional operator* is the supervising clinician or the *healthcare professional* responsible for the treatment of a *patient* on *ventilatory support equipment*.

[SOURCE: ISO 80601-2-12:—, 201.3.247, modified — added note 1 to entry.]

201.3.241
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]

201.3.242
high-pressure inlet
inlet to which gas is supplied at a pressure exceeding 100 kPa above ambient

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

[SOURCE: ISO 4135:2022, 3.1.4.24]

201.3.243
home healthcare environment
dwelling place in which a *patient* lives or other places where *patients* are present, excluding professional healthcare facility environments where *operators* with medical training are continually available when *patients* are present

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

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

Note 2 to entry: Nursing homes are considered *home healthcare environments*.

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

[SOURCE: IEC 60601-1-11:2015+AMD1:2020, 3.1, modified — deleted "For the purpose of this collateral standard,".]

201.3.244
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]

201.3.245
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.]

201.3.246
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]

201.3.247
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.]

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201.3.248
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.]

201.3.249
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.]

201.3.250
information supplied by the manufacturer
information related to the identification and use of a medical device or *accessory*, in whatever form provided, intended to ensure the safe and effective use of the medical device or *accessory*

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

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

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

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

201.3.251
inlet
opening through which gas or other material is pushed by an elevated upstream pressure

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

201.3.252
inspiratory pressure
airway pressure during an inspiratory or *inflation phase*

[SOURCE: ISO 19223:2019, 3.6.2, modified — deleted notes.]

201.3.253
inspiratory time
$\boldsymbol{t}_{\mathbf{I}}$
duration of an *inflation phase* or inspiratory phase

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

201.3.254
inspiratory volume
$\boldsymbol{V}_{\mathbf{insp}}$
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.]

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201.3.255
instructions for use
IFU
portion of the *accompanying information* that is essential for the safe and effective use of a medical device or *accessory* directed to the user of the medical device

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

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

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

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

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

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

201.3.256
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]

201.3.257
lay
lay person
<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]

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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
$P_{\mathrm{Lim,max}}$
highest *airway pressure* that can occur during *normal use* or under *single fault condition*

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

201.3.264
maximum working pressure
$P_{\mathrm{W,max}}$
highest *airway pressure* that can be generated by the *ventilator* during *intended use* and *normal condition*

Note 1 to entry: This information is usually documented in the *instructions for use* as it is valuable in determining if a *ventilator* is suitable for use with *patients* with an impaired *lung*.

Note 2 to entry: This maximum pressure is typically determined by the *manufacturer*.

[SOURCE: ISO 19223:2019, 3.13.4, modified — deleted note 3.]

201.3.265
medical gas pipeline system
combination of a supply system, a monitoring and *alarm system* and a pipeline distribution system with terminal units for provision of medical gases or vacuum

[SOURCE: ISO 4135:2022, 3.2.1.1]

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201.3.266
monitoring equipment
equipment or part that measures and indicates the value of a variable to the *operator*

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

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

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

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

201.3.267
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]

201.3.268
outlet
opening through which gas leaves a device or component

[SOURCE: ISO 4135:2022, 3.1.4.40]

201.3.269
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 *connector*s, for example, a *connector* conforming to ISO 5356-1.

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

201.3.270
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.]

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201.3.271
physiological alarm condition
alarm condition arising from a monitored *patient*-related variable

EXAMPLE 1 High exhaled anaesthetic agent concentration.

EXAMPLE 2 Low exhaled *tidal volume*.

EXAMPLE 3 Low oxygen saturation measured by pulse oximetry.

EXAMPLE 4 High arterial pressure.

EXAMPLE 5 High heart rate.

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

201.3.272
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]

201.3.273
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.]

201.3.274
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]

201.3.275
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

201.3.276
rebreathing
inhalation of expired gas mixture from which carbon dioxide may or may not have been removed

[SOURCE: ISO 4135:2022, 3.1.5.12]

201.3.277
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.]

201.3.278
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

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

201.3.279
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.]

201.3.280
single use
<medical device, *accessory*> intended by the *manufacturer* to be used on an individual *patient* or specimen during a single *procedure* and then disposed of

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

[SOURCE: ISO 20417:2021, 3.26]

201.3.281
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.]

201.3.282
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.]

201.3.283
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]

201.3.284
sterile
free from viable microorganisms

[SOURCE: ISO 20417:2021, 3.28]

201.3.285
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]

201.3.286
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]

201.3.287
symbol
graphical representation appearing on the label or associated documentation of a medical device that communicates characteristic information without the need for the supplier or receiver of the information to have knowledge of the language of a particular nation or people

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

[SOURCE: ISO 20417:2021, 3.29]

201.3.288
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]

201.3.289
technical description
portion of the *accompanying information* directed to the *responsible organization* and *service personnel* that is essential for preparation for the first use and safe use, maintenance or repair as well as *processing* transport or storage for the *expected service life* of a medical device

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

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

201.3.290
tidal volume
$\boldsymbol{V}_{\mathrm{T}}$
volume of gas that enters and leaves the *lung* during a breath

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

201.3.291
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.]

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201.3.292
transit-operable
<adj> term referring to transportable equipment whose *intended use* includes operation while it is being moved

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

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

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

201.3.293
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*".]

201.3.294
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]

201.3.295
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.]

201.3.296
ventilation-mode
specified manner in which a *ventilator* performs its ventilatory function when connected to a *patient*

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

201.3.297
ventilator
medical device or *medical electrical equipment* intended to provide *artificial ventilation*

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

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201.3.298
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.]

201.3.299
ventilator-dependent
<*patient*> dependent upon *artificial ventilation* in order to prevent serious deterioration of health or death

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

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

[SOURCE: ISO 4135:2022, 3.1.5.19]

201.3.300
ventilatory impairment
respiratory impairment
clinically significant respiratory dysfunction resulting in an abnormality of a sufficient degree to be noticeable by the *patient*

Note 1 to entry: *Patients* with *ventilatory impairment* exhibit a minimal level of illness acuity, fragility, or instability. Their dependence on the *ventilatory support equipment* to maintain adequate gas exchange is minimal. Without such support as needed, these *patients* would likely experience some difficulty with activities that they might normally pursue and this might interfere with daily living. Without ventilatory support as needed, these *patients* are likely to experience short periods of abnormal *lung* gas exchange which can result in them becoming more sedentary.

EXAMPLE *Patients* with mild to moderate chronic obstructive pulmonary disease (COPD).

Note 2 to entry: *Ventilatory support equipment* for *ventilatory impairment* is suitable for use where *physiological alarm condition* monitoring is usually not required because the absence or degradation of the ventilatory support is not likely to cause injury to the *patient* (i.e. *ventilatory support equipment* for *ventilatory impairment* has no *essential performance*).

201.3.301
ventilatory insufficiency
respiratory insufficiency
degradation in respiratory function severe enough to prohibit certain activities that the *patient* might normally pursue, and to interfere with daily living; occurring in association with measurements of respiratory mechanics or gas exchange that are markedly abnormal

Note 1 to entry: *Patients* with *ventilatory insufficiency* exhibit an illness acuity, fragility or instability level up to and including a moderate to severe degradation in respiratory function. Their dependence on the *ventilatory support equipment* to maintain adequate gas exchange can range from minimal to moderate dependence. Without

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such support, the most fragile of these *patients* would likely be prohibited from certain activities that they might normally pursue and this would likely interfere with their daily living. The most fragile of these *patients* would likely experience injury with the loss of this *artificial ventilation*.

EXAMPLE *Patients* with moderate to severe chronic obstructive pulmonary disease (COPD), amyotrophic lateral sclerosis (ALS), severe bronchopulmonary dysplasia and muscular dystrophy.

Note 2 to entry: *Ventilatory support equipment* for *respiratory insufficiency* is suitable for use where some *physiological alarm condition* monitoring is required to prevent the absence or degradation of the ventilatory support, which in turn could cause the compromise of the health of the *patient*.

[SOURCE: ISO 80601-2-80:2024, 201.3.302]

201.3.302
ventilatory support equipment
ME equipment, suitable for domiciliary use without continuous professional supervision, intended to augment or provide *ventilation* of the *lungs* of a *patient* who is not *ventilator-dependent*

Note 1 to entry: *Ventilatory support equipment* is a type of *ventilator*, but is not a *ventilator* for *ventilator-dependent patient*.

Note 2 to entry: A *patient* suitable for *ventilatory support equipment* requires a narrow spectrum of *ventilation* modalities and monitoring for appropriate management.

[SOURCE: ISO 80601-2-80:2024, 201.3.303]

201.3.303
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 1 There is guidance or rationale for this subclause contained in Clause AA.2.

a) For the purposes of this document, *ventilatory support equipment for ventilatory impairment* is considered not to have *essential performance.* Notwithstanding this fact, when this document refers to *essential performance* as acceptance criteria, the continuous pressure shall be evaluated.

b) The method of subclauses 202.4.3.1 and 202.8.1.101 may be used to evaluate continuous pressure as an acceptance criterion following specific tests required by this document.

NOTE 2 A continuous pressure mode is often referred to as a *continuous positive airway pressure* (*CPAP*) mode.

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

Amendment (add prior to the compliance check):

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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):

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 (i.e., 4.6 of the general standard).

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) *Ventilatory support equipment* 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.

NOTE 1 Internal pressure regulators can be necessary 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 *ventilatory support equipment* is likely to be outside of its specification.

b) If the *ventilatory support equipment* has a maximum *rated* input pressure in excess of 600 kPa, the *ventilatory support equipment* shall not cause an unacceptable *risk* under the *single fault condition* of twice the maximum *rated* input pressure.

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 *ventilatory support equipment* is intended to be connected to a *medical gas pipeline system* conforming with ISO 7396-1+AMD1:2017, then

a) the *rated* range of input pressure shall cover the range specified in ISO 7396-1+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 flowrate required by the *ventilatory support equipment* for each gas shall not exceed 60 l/min at a pressure of 280 kPa, measured at the *high-pressure inlet*, and

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2) the transient input flowrate 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 flowrate required by the *ventilatory support equipment* for each gas at a pressure of 280 kPa, measured at the *high-pressure inlet*,;

   ii) the maximum transient input flowrate averaged for 3 s required by the *ventilatory support equipment* for each gas at a pressure of 280 kPa, measured at the *high-pressure inlet*,; and

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

Additional subclauses:

201.5.101 Additional requirements for the 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 *Ventilatory support equipment* test conditions

a) For testing, the *ventilatory support equipment*:

   1) shall be connected to gas supplies as specified for *normal use*;

   2) except that industrial grade oxygen and air may be substituted for the equivalent medical gas, as appropriate, unless otherwise stated;

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

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

NOTE 2 This subclause is only applicable to *ventilatory support equipment* intended to be connected to a gas supply in *normal use* (e.g. *medical gas pipeline system* or medical gas cylinder).

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*,

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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 *Ventilatory support equipment* testing errors

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

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

1) evaluation of uncertainty of measurement from IEC Guide 115:2023, 4.1.1 and 4.1.2; and

2) simple acceptance method from IEC Guide 115:2023, 4.3.

NOTE 2 Previous revisions of ISO 80601-2-79 required tolerances to be adjusted by subtracting measurement uncertainty from disclosed tolerance values to determine acceptance criteria.

b) Test equipment and methods shall be selected and controlled to ensure that the measurement 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 *instructions for use* and 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:

Additional subclauses:

201.7.1.101 *Information to be supplied by the manufacturer*

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

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

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

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

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

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

Check conformity by application of ISO 20417:2021.

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