



BSI Standards Publication

Medical electrical equipment

Part 2-80: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory insufficiency

National foreword

This British Standard is the UK implementation of EN ISO 80601-2-80:2024. It is identical to ISO 80601-2-80:2024. It supersedes BS EN ISO 80601-2-80:2019, which is withdrawn.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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English Version

Medical electrical equipment - Part 2-80: Particular
requirements for basic safety and essential performance of
ventilatory support equipment for ventilatory
insufficiency (ISO 80601-2-80:2024)

Appareils électromédicaux - Partie 2-80: Exigences
particulières pour la sécurité de base et les
performances essentielles des équipements
d'assistance ventilatoire en cas d'insuffisance
ventilatoire (ISO 80601-2-80:2024)

Medizinische elektrische Geräte - Teil 2-80: Besondere
Festlegungen für die grundlegende Sicherheit und die
wesentlichen Leistungsmerkmale von
Heimbeatmungsgeräten zur Atemunterstützung von
Patienten mit Atmungsinsuffizienz (ISO 80601-2-
80:2024)

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

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

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European foreword

This document (EN ISO 80601-2-80:2024) 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of an identical text or by endorsement, at the latest by March 2025, and conflicting national standards shall be withdrawn at the latest by March 2025.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 80601-2-80:2019.

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 80601-2-80:2024 has been approved by CEN as EN ISO 80601-2-80:2024 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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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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

This document was prepared jointly by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Respiratory devices and related equipment used for patient care*, and Technical Committee IEC/TC 62, *Medical equipment, software, and systems*, Subcommittee SC 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 80601-2-80:2018), 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, IEC 60601-1-8:2006+AMD1:2012+AMD2:2020 and IEC 60601-1-11:2015+AMD1:2020;
- clarified *maximum limited pressure* requirements;
- clarified high *airway pressure alarm condition* requirements;
- added requirements for *ventilatory support equipment system recovery*; and
- harmonization with ISO 20417, where appropriate.

ISO 80601-2-80:2024(en)

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

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

Introduction

This document specifies requirements for *ventilatory support equipment* that is intended for use in the *home healthcare environment* for *patients* who are not dependent for *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).

Varying levels of ventilatory support is often used for *patients* who have stable ventilatory needs and in some cases, changing needs as their disease worsens. This document addresses *patients* who typically have severe enough respiratory function 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. This is best characterised by *lung* functions worse than^[36]

- $FEV_1/FVC^1 < 70 \%$, or
- $FEV_1 < 50 \%$ predicted

where

FEV_1 is the forced expiratory volume in 1 s, and

FVC is the forced vital capacity.

Examples of diseases that require ventilatory support are:

- moderate to severe Chronic Obstructive Pulmonary Disease (COPD);
- moderate Amyotrophic Lateral Sclerosis (ALS)^[44];
- severe bronchopulmonary dysplasia; and
- muscular dystrophy.

Ventilatory support equipment intended for this group of *patients* typically can require *technical alarm conditions* in the event that *essential performance* is absent. The most fragile of these *patients* would likely experience injury, but not serious injury or death, with the loss of this *artificial ventilation*. For these *patients*, it is likely that ventilatory support is needed during waking hours while *patients* are moving inside or outside the home in order to facilitate mobility and functional independence in the activities of daily living.

In this document, the following print types are used:

- requirements and definitions: roman type;
- *terms defined in Clause 3 of the general standard², in this document or as noted: italic type*; and
- 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:

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

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*.

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

Medical electrical equipment

Part 2-80: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory insufficiency

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 insufficiency*, as defined in 201.3.302, 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 insufficiency* or failure, the most fragile of which would likely experience injury with the loss of this *artificial ventilation*;

— intended for *transit-operable* use; and

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

EXAMPLE 1 *Patients* with moderate to severe chronic obstructive pulmonary disease (COPD), moderate amyotrophic lateral sclerosis (ALS), severe bronchopulmonary dysplasia or muscular dystrophy.

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 *ventilator breathing system* of *ventilatory support equipment* for *ventilatory insufficiency*, where the characteristics of those *accessories* can affect the *basic safety* or *essential performance* of the *ventilatory support equipment* for *ventilatory insufficiency*.

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.

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 *accessories* intended for *ventilator-dependent patients* in the *home healthcare environment*, which are given in ISO 80601-2-72;
- *ventilatory support equipment* or *accessories* intended for *ventilatory impairment*, which are given in ISO 80601-2-79;
- sleep apnoea therapy *ME equipment*, which are given in ISO 80601-2-70;
- high-frequency jet *ventilators* (HFJVs), which are given in ISO 80601-2-87;
- high-frequency oscillatory *ventilators* (HFOVs)^[20];
- 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 insufficiency*, as defined in 201.3.302, 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*^[31] and labelling^[32] guidances 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].

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, IEC 60601-1-8:2006+AMD1:2012+AMD2:2020 and IEC 60601-1-11:2015+AMD1:2020 apply as modified in Clauses 202, 206, 208 and 211 respectively. IEC 60601-1-3:2008, 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 define *basic safety* and *essential performance* requirements, and may modify, replace or delete requirements contained in the general standard, including the collateral standards as appropriate for the particular *ME equipment* under consideration.

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

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

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

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

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

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

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

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

The term "this document" is used to make reference to the 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 particular document, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this document.

201.2 Normative references

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

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 5359:2014+Amd 1:2017, *Anaesthetic and respiratory equipment — Low-pressure hose assemblies for use with medical gases*

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

ISO 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*

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+AMD2:2020⁴, *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 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 115:2023, *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*.

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.

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 pressure

P_{aw}

pressure at the *patient-connection port* or at the distal *outlet* of the equipment where there is no *patient-connection port*

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

[SOURCE: ISO 4135:2022, 3.1.4.41.1]

201.3.204

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.

[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]

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]

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 indicate a pressure that is relative to the set *BAP* level. In *ventilation-modes* where there is a second, higher, baseline *airway pressure*, then the prefix for a pressure relative to that higher-pressure level becomes ΔH . These prefixes are applicable to relevant terms, *symbols* and displayed values but not to *inflation-types*.

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

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

201.3.225 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]

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".]

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

Note 1 to entry: The *gas pathway* is bounded by the 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.

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 18562-1:2024, 3.11]

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 80601-2-12:2023, 201.3.247, modified — added note.]

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

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.]

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

t_i

duration of an *inflation phase* or inspiratory phase

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

201.3.254

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.]

201.3.255

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]

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

$P_{Lim,max}$

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

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

201.3.264

maximum working pressure

$P_{W,max}$

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, 3.1.16, 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]

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 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".]

201.3.267

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 *connectors*, 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.]

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

[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.

[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

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.

[SOURCE: ISO 80601-2-12:2023, 201.3.298]

201.3.289

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]

201.3.290

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.]

201.3.291

tidal volume

V_T

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

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

201.3.292

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.]

201.3.293

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]

201.3.294

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*".]

201.3.295

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]

201.3.296

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.]

201.3.297

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.]

201.3.298

ventilator

medical device or medical electrical equipment intended to provide artificial ventilation

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

201.3.299

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.]

201.3.300

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]

201.3.301

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*).

[SOURCE: ISO 80601-2-79:2024, 201.3.300]

201.3.302

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 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 ventilatory 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*.

201.3.303

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 intended for a *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.

201.3.304

volume-control

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

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

201.4 General requirements

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

Addition:

201.4.3.101 Additional requirements for *essential performance*

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

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

Table 201.101— Distributed *essential performance* requirements

Requirement	Subclause
Providing <i>ventilation</i> at the <i>patient-connection port</i> within the <i>alarm limits</i> set by the <i>operator</i> or generation of an <i>alarm condition</i>	^a
<i>Functional connection</i> failure	201.13.2.103
Low <i>airway pressure</i>	201.12.4.101
High <i>airway pressure</i> , if provided	201.12.4.101.3
Hypoventilation	201.12.4.104
<i>Internal electrical power source</i> nears depletion	201.11.8.101
<i>System recovery</i>	201.4.3.102
Power supply failure	201.11.8.101
High leakage, if provided	201.12.4.105
^a 202.4.3.1 and 202.8.1.101 indicate methods of evaluating delivery of <i>ventilation</i> as acceptance criteria following specific tests required by this document.	

201.4.3.102 *System recovery*

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

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

NOTE 2 *Ventilatory support equipment* or a subassembly function can become disturbed by a malfunction that could jeopardize the *essential performance* of the *ventilatory support equipment*. 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 *ventilatory support equipment* 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 *ventilatory support equipment* 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 *ventilatory support equipment* shall allow spontaneous *patient* breathing in accordance with 201.103; and
- 2) the *ventilatory support equipment* 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 *ventilatory support equipment* shall be equipped with an *alarm system* to indicate *system recovery* without a cessation of *ventilation*.

- 1) The *alarm condition* for *system recovery* without a cessation of *ventilation* shall be at least *low priority*.
- 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 *ventilatory support equipment* 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 *ventilatory support equipment* 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* shall be disclosed in the *instructions for use*.

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

201.4.4 Additional requirements for *expected service life*

Amendment (add as a second paragraph):

The *manufacturer* shall:

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

Replacement (replace the compliance check):

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

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

Amendment (add prior to the compliance check):

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

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

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).

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 12,4 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 24,8 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) *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 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 *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 7396-1:2016+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 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

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*;
- 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 flowrate at a specified number of terminal outlets, in order to avoid exceeding the pipeline design flowrate, 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*,
- 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 80601-2-80 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 $\sim 95\%$) is no more than 30 % of the disclosed tolerance for the parameter being tested.

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

- c) The *manufacturer* shall disclose the measurement uncertainty 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, except as follows:

Additional subclause:

201.6.101 Additional requirements for classification of ME equipment and ME systems

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

Ventilatory support equipment shall be transit-operable.

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.

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);
 - 2) be *marked* with an indication of any limitations or adverse effects of the *accessory* on the *basic safety* or *essential performance* of the *ventilatory support equipment*, if applicable.
- 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 *ventilatory support equipment 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*.

201.7.2.18 External gas source

Amendment (add before the first dash):

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

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

NOTE In some countries, other colour coding is used.

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 *ventilatory support equipment* 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* 1) or *symbol* 7.3.1-2 (Table 201.D.2.101, *symbol* 2) of IEC 62570:2014 for 'MR Safe' *ventilatory support equipment*; or
 - ii) *symbol* 7.3.2 of IEC 62570:2014 (Table 201.D.2.101, *symbol* 3) for 'MR Conditional' *ventilatory support equipment*.
 - 2) for *ventilatory support equipment* 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* 4) for 'MR Unsafe' *ventilatory support equipment*.