BS EN ISO 80601-2-84:2023

BSI Standards Publication

Medical electrical equipment

Part 2-84: Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services environment

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National foreword

This British Standard is the UK implementation of EN ISO 80601-2-84:2023. It is identical to ISO 80601-2-84:2023. It supersedes BS EN 794-3:1998+A2:2009 and BS EN ISO 80601-2-84:2020, which are withdrawn.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 2-84: Exigences particulières relatives à la sécurité de base et aux performances essentielles des ventilateurs utilisés dans l'environnement des services médicaux d'urgence (ISO 80601-2-84:2023)

Medizinische elektrische Geräte - Teil 2-84: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Notfall- und Transportbeatmungsgeräten (ISO 80601-2-84:2023)

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

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European foreword

This document (EN ISO 80601-2-84:2023) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment” the secretariat of which is held by BSI.

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of an identical text or by endorsement, at the latest by May 2024, and conflicting national standards shall be withdrawn at the latest by May 2024.

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

This document supersedes EN 794-3:1998+A2:2009.

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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 62D, *Particular medical equipment, software, and systems,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 80601-2-84:2020), which has been technically revised. The main changes are as follows:

— alignment with IEC 60601-1:2005+AMD1:2012+AMD2:2020, IEC 60601-1-2:2014+AMD1:2020, IEC 60601-1-6:2010+AMD1:2013+AMD2:2020, IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, and IEC 60601-1-12:2014+AMD1:2020;

— added requirements for a *responsible organization* log

— added requirements for the display legibility for *operators* wearing personal protective equipment;

— added requirements for display during calibration of gas monitors;

— clarified *maximum limited pressure* requirements;

— added requirements for *ventilator system recovery*;

— added requirements and definitions for *cybersecurity*; and

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— 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

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, etc.);

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

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

In this document, the following verbal forms are used:

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission;

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

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

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

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

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

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Medical electrical equipment —

Part 2-84: Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services environment

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 an *EMS ventilator* in combination with its *accessories*, hereafter also referred to as *ME equipment:*

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

— intended to be operated by a *healthcare professional operator*;

— intended for use in the *EMS environment*; and

— intended for invasive or non-invasive *ventilation*.

NOTE 2 An *EMS ventilator* can also be used for transport within a *professional healthcare facility*.

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

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

NOTE 3 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.

This document does not specify the requirements for the following:

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

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

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

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

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

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

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

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

— *continuous positive airway pressure* (*CPAP*) *ME equipment*.

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

— high-frequency oscillatory *ventilators* (HFOVs)[44], which are given in ISO 80601-2-87.

NOTE 6 An *EMS ventilator* can incorporate high-frequency jet or high-frequency oscillatory *ventilation-modes*.

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

NOTE 7 An *EMS ventilator* can incorporate high-flow therapy operational mode, but such a mode is only for spontaneously breathing *patients*.

— oxygen therapy constant flow *ME equipment*.

— cuirass or “iron-lung” *ventilators*.

201.1.2 Object

Replacement:

The object of this particular document is to establish *basic safety* and *essential performance* requirements for an *EMS ventilator,* as defined in 201.3.228, and its *accessories*.

Accessories are included because the combination of the *EMS ventilator* and the *accessories* needs to have acceptable *risk*. *Accessories* can have a significant impact on the *basic safety* or *essential performance* of an *EMS ventilator*.

NOTE 1 This document has been prepared to address the relevant *essential principles*[38] and labelling[39] guidances of the International Medical Devices Regulators Forum (IMDRF) as indicated in Annex CC.

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

NOTE 3 This document has been prepared to address the relevant general safety and performance requirements of European regulation (EU) 2017/745[40].

201.1.3 Collateral standards

Amendment (add at the end of the subclause):

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

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

IEC 60601-1-2:2014+AMD1:2020, IEC 60601-1-6:2010+AMD1:2013+AMD2:2020, IEC 60601-1-8:2016+AMD1:2012+AMD2:2020 and IEC 60601-1-12:2014+AMD1:2020 apply as modified in Clauses 202, 206, 208 and 212 respectively.

IEC 60601-1-3, IEC 60601-1-9, and IEC 60601-1-11 do not apply.

All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

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

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

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

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

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

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

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

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

Subclauses or figures that are additional to those of a collateral standard are numbered starting from 20x, where “x” is the number of the collateral standard (e.g. 202 for IEC 60601-1-2, 208 for IEC 60601-1-8, etc.).

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

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

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IEC 60601-1:2005+AMD1:2012+AMD2:2020 or the applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular document.

201.2 Normative references

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

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

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

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

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

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

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

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

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

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

ISO 10524-1:2018, *Pressure regulators for use with medical gases — Part 1: Pressure regulators and pressure regulators with flow-metering devices*

ISO 10524-3:2019, *Pressure regulators for use with medical gases — Part 3: Pressure regulators integrated with cylinder valves (VIPRS)*

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

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

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

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

ISO 19054:2005+AMD1:2016, *Rail systems for supporting medical equipment*

ISO 19223:2019, *Lung ventilators and related equipment — Vocabulary and semantics*

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

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

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

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

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

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

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

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

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

201.3 Terms and definitions

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

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

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

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

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

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

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

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

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

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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 settings
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
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]

201.3.210
assured inflation-type rate
number of assured *inflation-type* initiations in a specified period of time, expressed as breaths per minute

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

201.3.211
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]

201.3.212
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]

201.3.213
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]

201.3.214
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.]

201.3.215
biocompatibility
ability to be in contact with a living system without producing an unacceptable adverse effect

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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 18562-1:2023, 3.6]

201.3.216
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]

201.3.217
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.]

201.3.218
breathing system filter
BSF
device intended to reduce transmission of particulates, including microorganisms, in *breathing systems*

[SOURCE: ISO 23328-2:2002, 3.2]

201.3.219
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'.]

201.3.220
communicator
COM
function of the *alarm system* that generates *alarm signals* to notify an *operator* (e.g. to the presence of an *alarm condition*)

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

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

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

201.3.221
connector
fitting to join two or more components

EXAMPLE *Connectors* for a *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

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

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.

[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

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

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

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

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

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

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

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

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

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

201.3.228
EMS ventilator
ventilator for emergency medical services environment
ventilator intended for use in the *EMS environment*

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

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

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

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

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performance (operational availability). The loss of *essential function* is commonly termed loss of protection, loss of control and loss of view respectively.

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

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

201.3.231
essential principles
essential principles of safety and performance
fundamental high-level requirements that when complied with ensure a medical device is safe and performs as intended

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

201.3.232
exhaust port
port of the medical equipment or device from which gas is discharged to the atmosphere during *normal use*, either directly or via an anaesthetic gas scavenging system

[SOURCE: ISO 19223:2019, 3.14.2]

201.3.233
expiratory pause
portion of the *expiratory phase* from the end of expiratory flow to the start of inspiratory flow

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

201.3.234
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.]

201.3.235
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]

201.3.236
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]

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201.3.237
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]

201.3.238
fresh gas
respirable gas delivered to a *ventilator breathing system*

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

201.3.239
gas intake port
port through which gas is drawn for use by the *patient*

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

[SOURCE: ISO 4135:2022, 3.1.4.21]

201.3.240
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]

201.3.241
gas pathway
interior surfaces, over which gases or liquids that can be inspired, in a medical device bounded by the ports through which gases or liquids enter and leave the medical device including the *patient* interface or the interior surfaces of *enclosures* that are in contact with gases or liquids that can be inspired

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

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

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

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

[SOURCE: ISO 18562-1:2023, 3.11

201.3.242
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]

201.3.243
healthcare professional
<adj> appropriately trained, knowledgeable, and skilled, providing systematic preventive, curative, promotional or rehabilitative healthcare services

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[SOURCE: ISO 80601-2-12:2023, 201.3.247]

201.3.244
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]

201.3.245
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]

201.3.246
home healthcare environment
dwelling place in which a *patient* lives or other places where *patients* are present, excluding *professional healthcare facility* environments where *operators* with medical training are continually available when *patients* are present

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

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

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

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

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

201.3.247
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]

201.3.248
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.]

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201.3.249
immunity
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]

201.3.250
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.]

201.3.251
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.]

201.3.252
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.]

201.3.253
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.]

201.3.254
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.]

201.3.255
inspiratory pause
interval from the end of inspiratory flow to the start of expiratory flow within a *respiratory cycle*

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

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201.3.256
inspiratory time
t_I
duration of an *inflation phase* or inspiratory phase

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

201.3.257
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.]

201.3.258
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.]

201.3.259
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]

201.3.260
latching alarm signal
alarm signal that continues to be generated after its triggering event no longer exists until stopped by deliberate *operator* action

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

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201.3.261
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]

201.3.262
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.]

201.3.263
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.]

201.3.264
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]

201.3.265
maximum limited pressure
$P_{\mathrm{LIM,max}}$
highest *airway pressure* that can occur during *normal use* or under *single fault condition*

[SOURCE: ISO 4135:2022, 3.1.4.41.3]

201.3.266
maximum working pressure
$P_{\mathrm{W\,max}}$
highest *airway pressure* that can be generated by the *ventilator* during *intended use* and *normal condition*

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

201.3.267
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

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[SOURCE: ISO 4135:2022, 3.2.1.1]

201.3.268
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*".]

201.3.269
operator group
subset of *operators* who are differentiated from other *operators* by factors that are likely to influence their interactions with the *ME equipment*

Note 1 to entry: Attributes of *operator groups* can include age, culture, expertise.

[SOURCE: IEC 60601-1-6:2010+AMD1:2013+AMD2:2020, 3.3]

201.3.270
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]

201.3.271
operator's position
intended position of the *operator* with respect to the *alarm signal* generating part of the *alarm system*

Note 1 to entry: A *distributed alarm system* can have multiple *operator's positions*.

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

201.3.272
outlet
opening through which gas leaves a device or component

[SOURCE: ISO 4135:2022, 3.1.4.40]

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201.3.273
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.]

201.3.274
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.]

201.3.275
physiologic closed-loop control system
part of *ME equipment* or *ME system* used to adjust a physiologic variable (y) relative to a command variable (c) using a feedback variable (f)

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

201.3.276
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]

201.3.277
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.]

201.3.278
primary operating function
function that involves user interaction that is related to the safety of the medical device

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

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

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

201.3.279
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]

201.3.280
professional healthcare facility
facility that is continually staffed by suitably trained *healthcare professional operators*

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

[SOURCE: ISO 80601-2-12:2023, 201.3.285, modified — deleted note.]

201.3.281
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

[SOURCE: ISO 80601-2-12:2023, 201.3.286]

201.3.282
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.]

201.3.283
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]

201.3.284
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.]

201.3.285
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.

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[SOURCE: ISO 20417:2021, 3.26]

201.3.286
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.]

201.3.287
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.]

201.3.288
standard temperature and pressure, dry
STPD
pressure of 101,325 kPa at a temperature of 20 °C, dry

Note 1 to entry: See also rationale for 201.5.101.2.

[SOURCE: ISO 4135:2022, 3.1.1.8, modified — added note.]

201.3.289
sterile
free from viable microorganisms

[SOURCE: ISO 20417:2021, 3.28]

201.3.290
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]

201.3.291
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]

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201.3.292
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]

201.3.293
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]

201.3.294
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.]

201.3.295
tidal volume
$\boldsymbol{V_T}$
volume of gas that enters and leaves the *lung* during a breath

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

201.3.296
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.]

201.3.297
use environment
actual conditions and setting in which *operators* interact with the equipment

Note 1 to entry: The conditions of use or attributes of the *use environment* can include hygienic requirements, frequency of use, location, lighting, noise, temperature, mobility, and degree of internationalization. Social attributes such as team versus individual, chaotic versus calm, stress level and length of shift can also play a role.

[SOURCE: IEC 62366-1:2015+AMD1:2020, 3.20, modified — replaced "users" with "*operators*" and "medical device" with "equipment".]

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201.3.298
use scenario
specific sequence of tasks performed by a specific *operator* in a specific *use environment* and any resulting response of the equipment

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

201.3.299
validation
confirmation, through the provision of *objective evidence*, that specified requirements have been fulfilled

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

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

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

[SOURCE: ISO 9000:2015, 3.8.13]

201.3.300
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.]

201.3.301
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.]

201.3.302
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.]

201.3.303
ventilator-dependent
<*patient*> dependent upon *artificial ventilation* in order to prevent serious deterioration of health or death

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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]

201.3.304
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:

201.4.3 Essential performance

Addition:

201.4.3.101 Additional requirements for *essential performance*

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

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

Table 201.101 — Distributed *essential performance* requirements

Requirement	Subclause
Delivery of *ventilation* at the *patient-connection port* within the *alarm limits* set by the *operator* or generation of an *alarm condition*	
expired volume, if equipped	201.12.4.103
gas supply failure	201.13.102
high *airway pressure*	201.12.4.105
internal electrical power source depleted	212.8.2
inspiratory oxygen concentration, if equipped	201.12.4.101
system recovery	201.4.3.102
Subclauses 202.4.3.1 and 202.8.1.101 indicates methods of evaluating delivery of *ventilation* as acceptance criteria following specific tests required by this document.	

201.4.3.102 System recovery

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

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

NOTE 2 An *EMS ventilator* or a subassembly function can become disturbed by a malfunction that could jeopardize the *essential performance* of the *EMS ventilator*. Without *system recovery*, the *patient* would have to be disconnected and connected to an alternative means of *ventilation*. *Ventilation* would thus be interrupted until an alternative means of *ventilation* is connected. *System recovery*, as specified in this subclause, attempts

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to automatically re-establish *ventilation* in a shorter period. If necessary, the *EMS ventilator* can be replaced later when it is less consequential for the *patient's* therapy.

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

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

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

EXAMPLE The temporary blanking of the display.

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

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

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

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

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

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

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

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

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

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

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

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

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

201.4.4 Additional requirements for *expected service life*

Amendment (add as a second paragraph):

The *manufacturer* shall:

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

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b) 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):

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

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

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

Amendment (add at end of subclause):

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

Addition:

201.4.11.101 Additional requirements for pressurized gas input

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

201.4.11.101.1 Overpressure requirement

a) An *EMS ventilator* 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 an input pressure of 1 000 kPa.

b) An *EMS ventilator* with a maximum *rated* input pressure in excess of 600 kPa shall not cause an unacceptable *risk* under the *single fault condition* of twice the maximum *rated* input pressure.

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

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

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

201.4.11.101.2 Compatibility requirement for *medical gas pipeline systems*

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

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

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

b) under *normal condition*,

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

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

or:

3) the *accompanying documents* shall disclose:

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

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

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

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

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

201.4.11.101.3 Compatibility requirements for pressure regulators

If the *EMS ventilator* is intended to be connected to an oxygen gas cylinder via a pressure regulator then:

a) the *rated* range of input pressure shall cover the range specified in:

1) ISO 10524-1:2018; or

2) ISO 10524-3:2019; and

b) Under *normal condition*, the 10 s average input flow required by the *EMS ventilator* for oxygen shall not exceed 40 l/min at a pressure of 360 kPa, measured at the *gas intake port*.

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

EXAMPLE Highest driving gas consumption, highest *fresh gas* delivery and, if provided, the highest *rated* gas consumption at any gas power supply output.

201.5 General requirements for testing of *ME equipment*

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

Addition:

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

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

201.5.101.1 *EMS ventilator* test conditions

a) For testing, the *EMS ventilator:*

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

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

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

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

201.5.101.2 Gas flowrate and leakage specifications

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

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

a) are expressed at *STPD,*

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

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

201.5.101.3 *EMS ventilator* testing errors

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

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

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

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

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

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

EXAMPLE If the *manufacturer* wishes to claim a tolerance for delivered volume of ±(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 for each disclosed tolerance in the *technical description*.

Check conformity by inspection of the *technical description*.

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

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

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

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

Addition:

201.7.1.101 Information to be supplied by the manufacturer

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

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

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

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

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

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

Check conformity by application of ISO 20417:2021.

201.7.2.3 Consult accompanying documents

Replacement:

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

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

Addition:

201.7.2.4.101 Additional requirements for *accessories*

a) *Accessories* supplied separately shall:

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

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

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

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

201.7.2.18 External gas source

Amendment (add before the first dash):

aa) the gas name or chemical *symbol* in accordance with ISO 5359:2014+AMD1:2017,

bb) the *rated* range of gas pressure,

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

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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 supply hose or a gas cylinder intended to be attached to the *connector* of the *inlet*.

NOTE In some countries, other colour coding is used.

Addition:

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

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

a) The *EMS ventilator* shall be provided with a *clearly legible* permanently attached start-up *procedure* that is intended to be performed prior to use.

b) The start-up *procedure* may be provided electronically.

EXAMPLE A start-up *procedure* provided on the graphical *operator interface* or provided orally.

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

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

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

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

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

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

i) of the flow; or

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

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

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

EXAMPLE 1 WARNING: Gas Intake — Do not obstruct

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

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

i) for the *gas output port*; and

I) Symbol 0795 of ISO 7000 (Table 201.D.2.101, *symbol* 2) may be used for *gas output port*.

ii) for the *gas return port.*

I) *Symbol* 0794 of ISO 7000 (Table 201.D.2.101, *symbol* 1) may be used for *gas return port.*

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3) for a sampling gas *inlet*, either with the text "Gas sample" or the *Symbol* ISO 7000-0794, (Table 201.D.2.101, *symbol* 1).

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

201.7.4.2 Control devices

Amendment (add between the first and second paragraph):

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

aa) An *EMS ventilator* with an oxygen concentration control with an error exceeding 20 % [see 201.12.1.101 b) 3) and 201.12.1.102 b) 3)] shall not be *marked* with quantitative numerical concentration values.

EXAMPLE "No air mix" or "High" for the setting for the maximum achievable oxygen concentration or "Air mix" or "Low" for the setting with a reduced oxygen concentration.

Check conformity by inspection.

201.7.4.3 Units of measurement

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

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

All gas volume, flowrate and leakage specifications:

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

bb) shall be expressed at *BTPS*.

Addition:

201.7.4.101 Labelling of units of measurement

Quantitative numeric indications of parameters and settings shall be labelled with the units of measurement, either:

a) continuously; or

b) on *operator* action.

201.7.9.2.1 General

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

— the intended position of the *operator*;

201.7.9.2.1.101 Additional general requirements

The *instructions for use* shall disclose the following:

a) the intended range of *inspiratory volume*.

Check conformity by inspection.

201.7.9.2.2.101 Additional requirements for warnings and safety notices

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

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a) The *instructions for use* shall include:

1) a warning statement to the effect of "Warning: This ventilator is intended to be continuously attended by an operator. Failure to be in close proximity to this ventilator can contribute to patient death or serious injury."

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

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

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

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

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

4) a warning statement to the effect of "WARNING: Do not add any attachments or accessories to the ventilator that are not listed as intended for use in combination with the ventilator in the instructions for use of the ventilator or accessory, as the ventilator might not function correctly leading to the risk of patient death or additional serious deterioration of health."

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

1) a warning statement to the effect of "WARNING: When using nebulisation or humidification, the breathing system filters can require more frequent replacement to prevent increased resistance and blockage.

2) a warning statement to the effect of "Warning: The ventilator shall not be used in a hyperbaric chamber. Such use might cause the ventilator to not function correctly causing patient death or additional serious deterioration of health."

3) a warning statement to the effect of "Warning: The ventilator accuracy can be affected by the gas added to the ventilator breathing system by use of a pneumatic nebuliser.

4) a warning statement to the effect of "Warning: Do not use the ventilator in explosive environments. Such use might cause an explosion."

Check conformity by inspection.

201.7.9.2.8.101 Additional requirements for start-up *procedure*

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

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

a) The *instructions for use* or the *operator interface* shall include a pre-use checklist.

b) The *instructions for use* shall disclose a method by which all of the *alarm signals* can be functionally tested by the clinical *operator* to determine if they are operating correctly.

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c) Portions of this test method may:

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

2) require *operator* action.

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

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

201.7.9.2.9.101 Additional requirements for operating instructions

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

The *instructions for use* shall disclose:

a) a listing of the following pressures:

1) the range of *maximum limited pressure* ($P_{\mathrm{LIM\ max}}$);

2) if provided, the *rated* range to which the *maximum working pressure* ($P_{W\ \mathrm{max}}$) can be set, if adjustable;

3) the means by which the *maximum working pressure* is accomplished.

EXAMPLE 1 Pressure cycling, pressure limiting, pressure generation.

b) the *rated* range of the following characteristics of the assembled *operator*-detachable parts of the *VBS*, over which the accuracies of set and monitored volumes and pressures are maintained:

1) inspiratory *gas pathway* resistance,

2) expiratory *gas pathway* resistance, and

3) *VBS* compliance.

i) These specifications may be presented in ranges.

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

NOTE 2 Compliance and resistance can be non-linear. These characteristics might need to be specified over a range (e.g. at 15 l/min, 30 l/min, 60 l/min and the maximum flowrate or the maximum pressure).

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

EXAMPLE 2 Interval of calibration of a flow sensor.

d) if end-tidal gas concentration measurement is provided, a summary of effects of respiratory rate on the end-tidal gas concentration measurement accuracy.

e) if a connection for a *distributed alarm system* is provided, a description of how to connect and test the connection of a *distributed alarm system*.

f) a cross reference between the *manufacturer*-specific naming of the *EMS ventilator's ventilation-modes* and the *ventilation-mode* systematic coding scheme in Annex E of ISO 19223:2019.

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g) whether or not the *EMS ventilator* is intended for use with closed suctioning.

Check conformity by inspection.

201.7.9.2.12 Cleaning, disinfection, and sterilization

Amendment: (add after normal use)

or in *single fault condition*

Amendment: (add after bulleted list)

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

Addition:

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

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

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

1) at least one set of *accessories*; and

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

b) If applicable, the *instructions for use* of the *EMS ventilator* shall disclose:

1) any restrictions on the positioning of components within the *ventilator breathing system*; and

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

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

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

201.7.9.3.1.101 Additional general requirements

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

a) The *technical description* shall disclose:

1) a summary description of the filtering or smoothing techniques for all measured or computed variables that are displayed or used for control necessary for the *operator* to form a mental model of the operation of the *EMS ventilator;*

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

3) a summary description of the means of initiating and terminating the *inflation phase* in each *ventilation-mode* of the *EMS ventilator*; and

4) the outside dimensions and mass of the *EMS ventilator.*

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

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

EXAMPLE Deadspace and resistance.

2) a description of the method used to calculate end-tidal gas readings.

Check conformity by inspection.

201.7.9.3.101 Additional requirements for the *technical description*

The *technical description* shall disclose:

a) a description of a *procedure* for checking the functioning of the *alarm system* for each of the *alarm conditions* specified in this document, if not performed automatically during start-up; and

b) which checks are performed automatically.

Check conformity by inspection of the *technical description*.

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

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

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

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

Addition:

201.9.4.3.101 Additional requirements for instability from unwanted lateral movement

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

a) An *EMS ventilator* shall include a means by which the *EMS ventilator* can be attached to prevent unwanted movement during transport while in use.

b) The means shall secure the *EMS ventilator* to withstand accelerations or decelerations of

1) 10 g longitudinal (forward, backward), 10 g transverse (left, right) and 10 g vertical (up, down) for at least 150 ms in each orientation for a road ambulance.

2) 20 g longitudinal (forward, backward), 20 g transverse (left, right), 20 g vertical (down) and 4 g vertical (up) for at least 3 s in each orientation for an air ambulance.

c) Terminal units and electrical sockets shall not be used as part of the fixation system.

d) If rail systems are used, they shall conform with ISO 19054:2005+AMD1:2016.

NOTE 2 Rail systems consist of e.g. rail supports, rails, rail clamps, equipment mount holders, equipment mounts, equipment pin holders and equipment pins.

e) The means to secure a *portable EMS ventilator* to withstand forces caused by accelerations or decelerations shall be operable without the use of a *tool*.

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f) The *technical description* shall disclose the technical details of this means for attachment.

Check conformity by inspection and functional testing.

EXAMPLE These tests can be performed by using static loading, acceleration sleds or centrifuges.

201.9.4.4 Grips and other handling devices

Replace list item b) with:

b) A *portable EMS ventilator* shall be designed such that it can be carried by no more than one hand.

1) It shall be possible for the *operator* to:

i) observe the display;

ii) recognize the *alarm signals;* and

iii) actuate the controls while holding the *EMS ventilator* with no more than one hand.

2) A carrying case or handle may be used to fulfill this requirement.

Amendment (add to the end of the compliance check):

Check conformity by functional testing while carrying with no more than one hand.

201.9.6.2.1.101 Additional requirements for audible acoustic energy

a) The A-weighted sound pressure level emitted by the *EMS ventilator* shall be:

1) measured in accordance with ISO 4871:1996 and ISO 3744:2010 using engineering method grade 2; and

2) disclosed in the *instructions for use*.

b) The A-weighted sound power level shall be:

1) calculated in accordance with 8.2.5 and 8.6 of ISO 3744:2010; and

2) disclosed in the *instructions for use*.

c) Check conformity with the following test:

1) Place the *EMS ventilator* on the sound-reflecting plane and attach the least favourable *VBS* from those indicated in the *instructions for use*.

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

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

3) Configure the test lung with the compliance and resistance components whose values are indicated in Table 201.102.

i) Acoustically isolate the test lung by a suitable means so that any noise caused by the test lung does not interfere with the sound measurement of the *EMS ventilator*.

ii) Connect the *patient-connection port* to the test lung.

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