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Lung ventilators and related equipment — Vocabulary and semantics

Ventilateurs pulmonaires et équipement associé — Vocabulaire et sémantique

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Contents

Page

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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 ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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

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

This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 4, *Vocabulary and semantics*.

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

Introduction

The characteristics of *ventilation-modes* of current automatic *lung ventilator*s are often not well understood. The current terminology used for their description is based on that introduced in the early days of *mechanical ventilation,* but with the advances in *ventilator*s, and *ventilation-modes* that have evolved over recent years, the language used has been continuously adapted. In the absence of any effective international coordinating action, this has inevitably led to increasing inconsistencies in the way in which well-established terms and their derivatives are used.

To further compound the difficulties in understanding these complexities, some *ventilator manufacturers* have created new proprietary terms to describe these alternative ways of *ventilating patients*, and others have used existing terms with different meanings in different situations. This has led to *patient* safety hazards, an example being that *lung ventilator* clinical orders (*settings*) for one model of *ventilator* can be quite different from those required to get the same result from a different *ventilator*.

Recognizing these difficulties, ISO Technical Committee ISO/TC 121 requested its Subcommittee, SC 4, to completely review the terminology and semantics for *patient ventilation* with a view to compiling a standardized vocabulary that is applicable to current and, as far as possible, future practice. The primary objective was to use as much existing terminology as possible, while clarifying its meaning and limiting its potential for misuse by defining it more precisely. New terms were only introduced where there was no alternative, either in order to name new concepts or where the misuse of existing vocabulary has become so widespread that the term has become meaningless or unacceptably ambiguous. Importance was placed on a vocabulary that would communicate a clear mental model of how the selected *settings* would determine the interaction between the *patient* and the *ventilator*.

In order to achieve a vocabulary that is coherent, consistent and applicable to a range of fields such as *patient* care, research, data collection and incident reporting, this document has been developed with the participation, cooperation and assistance of members of other standards development organizations, and of major international *ventilator manufacturers*. The applications include *lung ventilators*, medical data systems facilitating clinical care and research, interoperability, incident reporting and equipment maintenance.

The early work by the subcommittee in establishing how a standardized vocabulary should be structured increasingly led to the conclusion that it would be necessary to revert to first principles. It was recognized that much of the current terminology has its origins in the early use of *automatic ventilation*, when the emphasis was inevitably on how best to save the lives of *patients* who could not *breathe* for themselves and, consequently, only made basic provisions for the *patient's* own *respiratory activity*. Since that time, *ventilators* have become increasingly interactive with the *patient*, such that it is now necessary to consider their use from a *ventilator-patient* system perspective because it is no longer possible, with any certainty, to predict ahead of time how that interaction will take place.

The terminology in this document is defined and used in a way that makes it capable of facilitating, unambiguously, both the *setting* of a *ventilator* and how to describe and record the resultant *ventilator-patient* interactions, continuously and at defined points within the course of *ventilation*. This includes the result of the complex interactions that occur when *additional breaths* are taken during an *assured-inflation cycle*, as can occur, for example, during APRV (*airway pressure release ventilation*).

This document seeks both to provide a consensus view and the basis for a coherent language for describing *ventilator* function. Now that the fundamental concepts of *artificial ventilation* practice within the scope of this document have matured, it has been possible to review the boundaries between the various concepts of established *ventilation-modes* and the methods of artificially inflating a *patient's lungs* and to formulate definitions that clarify the common elements and the distinctions. In particular, the scopes of several concepts that were appropriate to earlier technology and practice have become inadequate to encompass new developments and it was found necessary to subdivide them. Some of their designating terms have, therefore, had to be deprecated, replaced or constrained using more restrictive definitions, resulting in an inevitable reintroduction of some little-used legacy terms and the need to create a few new terms.

The overall objective is to encourage a more disciplined use of *ventilator* vocabulary so that *operators* trained in the application of this document will be able to move easily from one *ventilator* to another and operate each one, with confidence, after a minimum amount of training. Although it is recognized that change will not be immediate, it is expected that this discipline will feed through into scientific publications, textbooks and training so that, over time, a standardized basic language of *artificial ventilation* will become internationally established.

Examples of the application of this document are illustrated in the figures of Annexes C and F but these are not intended to indicate a requirement, nor to impose any restriction on the design of *artificial ventilation* devices.

Included with many of the terms are notes to entry that provide supplementary information, including explanations of the semantics of the term along with their classification schemes. This format is not only a requirement of ISO 704 but, unlike with such information in an annex, ensures that it remains associated with the term when viewed on the free-to-access ISO Online Browsing Platform.

Some of the terms in this document are principally intended for technical documents, informatics and related applications, and might have little applicability to *ventilator* labelling and instructions for use.

In this document, the following print types are used:

Definitions: roman type.

Material appearing outside of tables, such as notes, examples and references: smaller type.

Terms defined in Clause 3 of this document or as noted, apart from those in the form of acronyms or initialisms or when used in headings or tables: *italic* type.

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.

The verbal forms used in this document conform to the usage described in ISO/IEC Directives, Part 2, Annex H. For the purposes of this document, the auxiliary verb

— "shall" means that compliance with a requirement or a test is mandatory for compliance with this document,

— "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document, and

— "may" is used to describe a permissible way to achieve compliance with a requirement or test.

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

Colour coding is employed in most of the figures in Annexes B, C and F of this document to help distinguish between some of the specific characteristics being illustrated. The coding used for each figure, or set of figures, is provided either in its own specific key or in the introductory text of each annex, as applicable.

NOTE The following figures and tables have been reproduced from Reference [34] with permission:

— Figures: B.1, C.1 to C.35 and F.1 to F.7;

— Tables: D.1 to D.3, E.1 and E.2.

Lung ventilators and related equipment — Vocabulary and semantics

1 * Scope

This document establishes a vocabulary of terms and semantics for all fields of respiratory care involving *mechanical ventilation,* such as intensive-care *ventilation*, anaesthesia *ventilation*, emergency and transport *ventilation* and home-care *ventilation,* including *sleep-apnoea breathing-therapy equipment*. It is applicable

— in *lung ventilator* and *breathing*-therapy device standards,

— in health informatics standards,

— for labelling on *medical electrical equipment* and *medical electrical systems,*

— in *medical electrical equipment* and *medical electrical system* instructions for use and *accompanying documents,*

— for *medical electrical equipment* and *medical electrical systems* interoperability, and

— in electronic health records.

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

NOTE This document can also be used for other applications relating to *lung ventilation*, including non-electrical devices and equipment, research, description of critical events, forensic analysis and adverse event (vigilance) reporting systems.

This document does not specify terms specific to *breathing*-therapy equipment, or to physiologic closed-loop *ventilation*, high-frequency *ventilation* or *negative-pressure ventilation*; nor to respiratory support using liquid *ventilation* or extra-corporeal gas exchange, or oxygen, except where it has been considered necessary to establish boundaries between bordering concepts.

2 Normative references

There are no normative references in this document.

3 * Terms, definitions, symbols, and abbreviated terms

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

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

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

NOTE For convenience, an index and a list of sources of all defined terms used in this document are provided in Annex J.

3.1 General artificial-ventilation terminology

3.1.1
ventilator
lung ventilator
DEPRECATED: respirator
medical device or *medical electrical equipment* intended to provide *artificial ventilation*

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

Note 2 to entry: See also *ventilation* (3.1.9).

[SOURCE: ISO 80601-2-12:2011, 201.3.222, modified — Definition split into two terms (see 3.1.1 and 3.1.10).]

3.1.2
airway
connected, gas-containing cavities and passages within the *respiratory system*, that conduct gas between the alveoli and the oral and nasal orifices on the surface of the face, or the *patient-connection port* if an *airway device* is used

Note 1 to entry: This is a well-established term that is commonly used in isolation in references to the *airway* of a *patient*. Depending on the context, it is sometimes more helpful to use the qualified term, *patient's airway*.

Note 2 to entry: See also *airway device* (3.1.3).

3.1.3
airway device
device intended for use as an interface between the *patient-connection port* of a *ventilator* and the *patient's airway*, and which has no auxiliary features on which the *ventilator* is dependent for its normal operation

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

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

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

Note 3 to entry: See also *patient-connection port* (3.14.5), *airway* (3.1.2) and *ventilator breathing system* (3.1.18).

3.1.4
airway resistance
drop in pressure between the *patient-connection port* and the alveoli per unit rate of *airway* flow

Note 1 to entry: The *airway resistance* is normally expressed as a single coefficient, with the implicit assumptions that it is independent of the flow rate and of the direction of flow. In practice, these assumptions are typically only approximately valid.

Note 2 to entry: See also *airway* (3.1.2).

3.1.5
respiratory system compliance
respiratory compliance
DEPRECATED: lung compliance
elastic characteristic of the *lung* expressed as the change in *lung* volume per unit change of *airway pressure* in the absence of *respiratory activity*

Note 1 to entry: In addition to its direct reference, this term or its symbol, C_{rs}, is used, in context or by qualification, to designate this concept as a *measured* quantity (3.1.20).

Note 2 to entry: The *respiratory system compliance* is normally expressed as a single coefficient, with the implicit assumptions that it is independent of the volume of gas in the *lung* and of any hysteresis between increasing and decreasing volumes. In practice, these assumptions are typically only approximately valid.

Note 3 to entry: *Respiratory system compliance* is typically determined by a static measurement once the *airway pressure* has stabilized during an *inspiratory pause*. In *mechanically ventilated patients* it is typically determined as either a *static compliance* or a *dynamic compliance.* There might be differences between the values obtained by these different methods, not only due to the method itself but also due to viscoelastic effects, pressure balancing throughout the slower compartments of the *lungs* and possible recruitment effects.

Note 4 to entry: It is sometimes more applicable to express this characteristic as *lung* elastance, which is simply the inverse of *respiratory system compliance*.

Note 5 to entry: See also *lung* (3.1.16), *airway pressure* (3.6.1), *respiratory activity* (3.2.6), *respiratory system* (3.1.17), *inspiratory pause* (3.4.12), *pulmonary compliance* (3.1.6), *static compliance* (3.1.7) and *dynamic compliance* (3.1.8).

3.1.6
pulmonary compliance
elastic characteristic of the *lungs* expressed as the change in the *lung* volume per unit change of the difference between the alveolar pressure and the pressure in the pleural space

Note 1 to entry: In addition to its direct reference, this term or its symbol, C_L, is used, in context or by qualification, to designate this concept as a *measured* quantity (3.1.20). The specific symbol, C_L, has been adopted because of its established usage in the scientific community to represent the 'compliance of the *lungs*'.

Note 2 to entry: The *pulmonary compliance* is the compliance coefficient relating specifically to the *lungs*, as distinct from the *respiratory system compliance* coefficient, which relates to the whole of the *respiratory system* and, therefore, includes the compliance of the thoracic cage. For most *patients* it is not clinically necessary to differentiate between the compliance of the *lungs* alone, and the compliance of the *respiratory system*, so the more directly measurable *respiratory system compliance* provides sufficient information. If an impaired *respiratory system* is indicated, the difference might be significant and can justify the more invasive and skilled procedure required to obtain a measurement of pressure in the pleural space (the intrapleural pressure) and, thereby, that of the *pulmonary compliance*.

Note 3 to entry: The difference between the alveolar pressure and the pleural pressure is typically referred to as the transpulmonary pressure.

Note 4 to entry: The *pulmonary compliance* is normally expressed as a single coefficient, with the implicit assumptions that it is independent of the volume of gas in the *lungs*, of any hysteresis between increasing and decreasing volumes and of any variation of the pleural pressure within the pleural space. In practice, these assumptions are typically only approximately valid.

Note 5 to entry: See also *lung* (3.1.16), *airway pressure* (3.6.1), *respiratory system* (3.1.17) and *respiratory system compliance* (3.1.5).

3.1.7
static compliance
respiratory system compliance determined, under quasi-static conditions and while connected to a *ventilator*, as the measured change in *inspiratory volume* per unit change in the *measured plateau inspiratory pressure* relative to the *measured total* PEEP

Note 1 to entry: In addition to its direct reference, this term or its symbol, C_{stat}, is used, in context or by qualification, to designate this concept as a *measured* quantity (3.1.20).

Note 2 to entry: For the purposes of this measurement, quasi-static conditions are considered to occur during a respiratory phase of low *airway* flow and no significant *respiratory activity*.

Note 3 to entry: Expressed as an equation: *static compliance* = *inspiratory volume* / (*plateau pressure* – *total* PEEP). If the presence of *auto*-PEEP is not suspected or a value for *total* PEEP is not readily available, the *set* BAP may be used as a substitute for *total* PEEP in this equation.

Note 4 to entry: See also *respiratory system compliance* (3.1.5), *inspiratory volume* (3.8.3), *plateau inspiratory pressure* (3.6.4), *total PEEP* (3.10.6), *auto-PEEP* (3.10.7) and *BAP* (3.10.2).

3.1.8
dynamic compliance
respiratory system compliance determined during normal *mechanical ventilation*

Note 1 to entry: In addition to its direct reference, this term or its symbol, C_{dyn}, is used, in context or by qualification, to designate this concept as a *measured* quantity (3.1.20).

Note 2 to entry: *Dynamic compliance* is a dynamically calculated value obtained during normal *mechanical ventilation* by measuring the rate of change of *inspiratory volume* per unit change of *airway pressure.* A least squares or other curve-fitting algorithm can be used, typically in conjunction with the equation of motion for the *respiratory system,* to correct for any transient dynamic effects. When this term is used, the basis of the calculation employed should be made available to the user.

3.1.9
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.

Note 2 to entry: See also *spontaneous breath* (3.2.3), *artificial ventilation* (3.1.10), *automatic ventilation* (3.1.12), *mechanical ventilation* (3.1.11), *negative-pressure ventilation* (3.1.14), *positive-pressure ventilation* (3.1.13) and *inflation* (3.3.1).

3.1.10
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 80601-2-12:2011, 201.3.22, modified — Definition split into two terms (3.1.1 and 3.1.10).]

3.1.11
mechanical ventilation
artificial ventilation by means of a mechanical device

Note 1 to entry: This term has become the commonly used term for any form of *artificial ventilation* that involves specifically designed equipment comprising mechanical parts only or mechanical and electrical/electronic parts.

Note 2 to entry: A *mechanical ventilator* can provide *artificial ventilation* automatically or by manual operation and delivers either *positive-pressure ventilation* or *negative-pressure ventilation*.

3.1.12
automatic ventilation
continuous *artificial ventilation* by means of an automatic device

Note 1 to entry: *Automatic ventilators* deliver either *positive-pressure ventilation* or *negative-pressure ventilation*.

Note 2 to entry: This term can be used for the specific designation of the large class of *mechanical ventilators* that are not manually operated. The designation includes all *ventilators* that operate without continuous human intervention, extending from basic automatically-cycled resuscitators to *ventilators* providing physiological closed-loop control.

3.1.13
positive-pressure ventilation
PPV
DEPRECATED: IPPV
artificial ventilation achieved by the intermittent elevation of the *airway pressure* above any *set* BAP

Note 1 to entry: This is a general term for *artificial ventilation* achieved by the intermittent application of a raised pressure to some part of the *patient's airway* in order to assist or control an increase in the volume of gas in the *lung*. Each such intermittent elevation of the *airway pressure* constitutes an *inflation*.

Note 2 to entry: The original term for this means of applying *artificial ventilation* was intermittent positive-pressure ventilation (IPPV) but since the almost universal adoption of the practice of retaining some level of positive *airway pressure* at the end of *expiration* the 'positive pressure' is no longer intermittent because the *airway pressure* is continuously positive. Although it is only possible to achieve positive-pressure *artificial ventilation* by intermittently changing the *airway pressure*, whether it is by intermittent elevation or intermittent release of the pressure, depends on the objective and *settings*. With its now wide acceptance in the practice of *artificial ventilation*, the qualifying term 'positive-pressure' is, therefore, all that is required for its distinction.

Note 3 to entry: See also *artificial ventilation* (3.1.10), *inflation* (3.3.1), *airway pressure* (3.6.1), *set* (3.1.19), BAP (3.10.2), *airway* (3.1.2), *lung* (3.1.16) and *expiration* (3.2.11).

3.1.14
negative-pressure ventilation
NPV
artificial ventilation achieved by intermittently changing a negative pressure applied to the exterior of the *patient's* thorax

Note 1 to entry: This document does not include terms specific to *negative-pressure ventilation*.

Note 2 to entry: See also Clause 1.

3.1.15
NIV
non-invasive ventilation
positive-pressure ventilation without the use of an invasive *airway device*

Note 1 to entry: The connection to the *patient* is typically by means of a specially designed face or nasal mask.

Note 2 to entry: The provision of NIV does not, in itself, require dedicated *ventilation-modes* although some might be more suited to its use, but it does typically require certain compensating measures, particularly those relating to the possibility of increased and variable leakage. These can include, added, extended or deactivated compensations, modified *alarms limits*, the deactivation of some alarms and the modification of *inflation initiation* and *termination* criteria.

Note 3 to entry: On *ventilators* intended for NIV only, these compensations are classified as a permanently active NIV *adjunct*. On *ventilators* where the compensations made to suit NIV are selectable as an option, although also adjunctive in their actions, these have been typically classified as an NIV *ventilator operational mode.*

Note 4 to entry: See also *positive-pressure ventilation* (3.1.13), *airway device* (3.1.3), *ventilator* (3.1.1), *ventilator operational mode* (3.11.1) and *adjunct* (3.11.4).

3.1.16
lung
each of the pair of compliant organs within the ribcage (thorax), bounded by the terminal bronchiole and the visceral pleura, which during *ventilation* provide gas/blood interfaces that enable oxygen from the gas to pass into the blood and carbon dioxide to be removed

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

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

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

Note 4 to entry: See also *ventilation* (3.1.9) and *breathe* (3.2.2).

3.1.17
respiratory system
anatomical system related to *breath*ing including the *airway*, *lungs*, chest wall, pleural space, brainstem respiratory control centre, phrenic nerves, neuromuscular junctions, diaphragm and accessory muscles of *ventilation*

3.1.18
ventilator breathing system
VBS
anaesthesia breathing system
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.

Note 3 to entry: See also *port* (3.14.1), *patient-connection port* (3.14.5), *exhaust port* (3.14.2) and *ventilator* (3.1.1).

Note 4 to entry: The admitted term is included in this document for use in reference to the specific class of *ventilators* that are configured to *ventilate patients* with an anaesthetic gas mixture. With this application, the definition may be made more specific with 'respirable gas' becoming 'anaesthetic gases and the '*port* through which respirable gas enters' becoming the 'fresh-gas inlet'.

[SOURCE: ISO 4135:2001, 3.1.6 and 4.1.1, and ISO 80601-2-12:2011, 201.3.221, modified — Rephrased.]

3.1.19
set
allocated a specific value

EXAMPLE 1 A *set* pressure *limit.*

EXAMPLE 2 The *set inspiratory pressure*.

Note 1 to entry: *Set* is used in this document as a prefix to distinguish an intended value for a controlled *ventilation* variable from a *measured* or *actual value* of the same quantity.

Note 2 to entry: The use of this term is not required if the distinction from a *measured* or *actual value* is evident from the context of use.

Note 3 to entry: A *set* value might be determined directly by the *operator* or indirectly by selection of an algorithm that determines the *setting* based on other *settings* or *measurements*.

Note 4 to entry: See also *actual value* (3.1.22) and the references to *settings* in Annexes A, C and D, and G.4.

3.1.20
measured
determined by a measuring device or system

Note 1 to entry: This term is used in this document as a prefix to distinguish the value of a quantity as determined by a measuring device or system, from an *actual value* or *set* value of the same quantity.

Note 2 to entry: *Measured* values might be displayed or recorded as discrete values or as a continuous waveform.

Note 3 to entry: The use of this term is not required if the distinction from a *set* or *actual value* is evident from the context of use.

Note 4 to entry: See also *set* (3.1.19), *actual value* (3.1.22) and G.4.

3.1.21
preset
one of a set of stored configuration parameter(s), including selection of algorithms and initial values for use by algorithms, which affects or modifies the performance of the *ventilator*

Note 1 to entry: *Presets* are commonly configured by the *manufacturer* or a *responsible organization*.

Note 2 to entry: Access to a *preset* value is typically controlled by

— a tool,

— a *responsible-organization* password and a technical description, separate from the instructions for use,

— an individual *operator* password,

— voice recognition, or

— biometric means.

3.1.22
actual value
value of a quantity as it exists in fact

Note 1 to entry: This is the true value of a quantity, which might, or might not, be determinable by a measuring device.

Note 2 to entry: The definitions of terms denoting quantities, in this document, denote the *actual value* of that quantity. *Set* values are the means by which an operator informs the *ventilator* of the intended *actual value,* and *measured* values are displays or records of the *actual value*, to the accuracy and resolution of the *measuring* system.

3.1.23
limit
point or level beyond which the value of a parameter may not pass without an action by the *ventilator*

Note 1 to entry: The action might be a notification or the implementation of means to prevent or mitigate a *hazardous situation*.

Note 2 to entry: In this document, this term is restricted to the designation of safety constraints that provide *patient* protection that is completely independent of the controlled *ventilation* parameters.

Note 3 to entry: An alarm system uses an *alarm limit* in determining an *alarm condition*.

Note 4 to entry: See also *alarm system*, *alarm limit* and *alarm condition* (Annex J) and safety limits and alarm terminology (3.13).

3.1.24
normal use
operation, including routine inspection and adjustments by any *operator*, and stand-by, according to the instructions for use

Note 1 to entry: *Normal use* should not be confused with *intended use*. While both include the concept of use as intended by the *manufacturer*, *intended use* focuses on the medical purpose while *normal use* incorporates not only the medical purpose, but also matters such as maintenance, transport.

[SOURCE: IEC 60601-1:2005+AMD1:2012, 3.71]

3.1.25
intended use
intended purpose
use for which a product, process or service is intended according to the specifications, instructions and information provided by the *manufacturer*

[SOURCE: ISO/IEC Guide 63:2012, 2.5]

Note 1 to entry: *Intended use* should not be confused with *normal use*. While both include the concept of use as intended by the *manufacturer*, *intended use* focuses on the medical purpose while *normal use* incorporates not only the medical purpose, but also such matters as maintenance, service and transport.

3.1.26
normal condition
condition in which all means provided for protection against hazards are intact

[SOURCE: IEC 60601-1:2005+AMD1:2012, 3.70]

3.1.27
single fault condition
condition in which a single means for reducing a risk is defective or a single abnormal condition is present

[SOURCE: IEC 60601-1:2005+AMD1:2012, 3.116, modified — Restriction to electrical equipment only was removed.]

3.1.28
accompanying document
document accompanying medical *artificial ventilation* equipment, a medical *artificial ventilation* system, equipment or an accessory which contains information for the *responsible organization* or *operator*, particularly regarding basic safety and essential performance

[SOURCE: IEC 60601-1:2005+AMD1:2012, 3.4, modified — Restriction to electrical equipment only was removed.]

3.1.29
sleep-apnoea breathing-therapy equipment
medical equipment intended to alleviate the symptoms of a *patient* who suffers from sleep apnoea by delivering a therapeutic *breathing* pressure to the *patient*

Note 1 to entry: *Sleep-apnoea breathing-therapy equipment* is primarily used in the home healthcare environment by a lay *operator* without direct professional supervision.

[SOURCE: ISO 80601-2-70:2015, 201.3.212]