BS EN ISO 19223:2021

BSI Standards Publication

Lung ventilators and related equipment — Vocabulary and semantics

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The UK participation in its preparation was entrusted to Technical Committee CH/121, Anaesthetic and respiratory equipment.

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

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Published by BSI Standards Limited 2021

ISBN 978 0 539 15017 9

ICS 01.040.11; 11.040.10

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This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 July 2019.

Amendments/corrigenda issued since publication

Date	Text affected
30 April 2021	This corrigendum renumbers BS ISO 19223:2019 as BS EN ISO 19223:2021

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 19223

April 2021

ICS 01.040.11; 11.040.10

English Version

Lung ventilators and related equipment - Vocabulary and semantics (ISO 19223:2019)

Ventilateurs pulmonaires et équipement associé - Vocabulaire et sémantique (ISO 19223:2019)

Beatmungsgeräte und zugehörige Geräte - Terminologie und Semantik (ISO 19223:2019)

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European foreword

The text of ISO 19223:2019 has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 19223:2021 by 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of an identical text or by endorsement, at the latest by October 2021, and conflicting national standards shall be withdrawn at the latest by April 2021.

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Endorsement notice

The text of ISO 19223:2019 has been approved by CEN as EN ISO 19223:2021 without any modification.

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Foreword

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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).

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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.

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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.

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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.

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INTERNATIONAL STANDARD **ISO 19223:2019**

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.

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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).

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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).

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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.

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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.

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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.

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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).

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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]

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3.2 Breath terminology

3.2.1
breath
increase in the volume of gas in the *lungs* resulting from an inward gas flow through the *airway*, paired with a corresponding decrease in volume resulting from its *expiration*

Note 1 to entry: The inward flow might be caused by a *positive-pressure inflation*, a *patient inspiratory effort*, or a combination of the two. Outward flow occurs whenever the pressure in the *lung* is higher than that at the *patient-connection port*.

Note 2 to entry: A *breath* is composed of two principle phases: an *inspiratory phase* (3.4.9) or an *inflation phase* (3.4.10), and an *expiratory phase* (3.4.2). Each of these can be subdivided into further phases. For example, the *inflation* or *inspiratory phase* can be considered to include a *termination* phase and the *expiratory phase* can be considered to include a *trigger* phase. An *inflation phase* can also be considered to include a *plateau inspiratory-pressure* phase.

Note 3 to entry: The volume of gas that enters and leaves the *lungs* during a *breath* might differ due to physical and/or compositional changes between inspired and expired gas, and leakages at the connection to the *patient's airway*. Temporarily, it might also differ, *breath*-to-*breath*, in the event of, for example, dynamic hyperinflation or specific *patient* actions.

Note 4 to entry: This definition accommodates the concept of *additional breath*s occurring within the period of an *assured-inflation cycle* where the paired *expiration* of the volume generated by the *assured inflation* can occur after one or more *expirations* of *additional breaths*.

Note 5 to entry: See also *lung* (3.1.16), *inspiratory volume* (3.8.3), *expired tidal volume* (3.8.4), *tidal volume* (3.8.1), *airway* (3.1.2), *inflation* (3.3.1), *inspiratory effort* (3.2.7), *plateau inspiratory pressure* (3.6.4), *patient-connection port* (3.14.5) and *additional breath* (3.2.8).

3.2.2
breathe
take gas into the *lungs* and then *expire* it

Note 1 to entry: *Breathing* is a spontaneous human activity that might be detected by a *ventilator* but, in this document, is never considered to be a *ventilator* function.

Note 2 to entry: This term is typically used to designate this action as a continuously repeated physiological process but it can be used to designate the taking of a single *breath* or even an *inspiration* or *expiration*.

Note 3 to entry: See also Reference [23] - Ventilators do not breathe.

3.2.3
spontaneous breath
breath initiated by the *patient*

Note 1 to entry: This definition is *patient*-centric and independent of a *ventilator* or *sleep-apnoea breathing-therapy equipment*.

Note 2 to entry: The detection of a *spontaneous breath* by a medical device depends on the *set* detection threshold of a relevant physiological parameter(s), which can include a parameter(s) that relates to the *patient's* intention to *breathe* and not the actual movement of gas.

Note 3 to entry: The qualifier 'spontaneous' makes it clear that such *breath*s occur as a result of the *patient's*, generally subconscious, physiological processes, and consequently have elements of unpredictability in initiation, size and duration.

Note 4 to entry: From an *artificial ventilation* perspective, a *spontaneous breath* is also one to which the *patient* has contributed at least a proportion of the work of *inspiration*. More specific terms, which provide an indication of relative magnitude, are subsets of the general term and range from '*breathing* effort' and '*breathing* activity' to '*natural breathing*'. These are all parts or types of *spontaneous breath*s, as are spontaneous *inspiration* and spontaneous *expiration*.

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Note 5 to entry: See also *breath* (3.2.1), *initiate* (3.9.1), *ventilator* (3.1.1), *sleep-apnoea breathing -therapy equipment* (3.1.29), *breathe* (3.2.2), *inspiration* (3.2.10), *expiration* (3.2.11) and *natural breathing* (3.2.4).

3.2.4
natural breathing
breathing with a workload within the range that a typical healthy person might expect to experience as normal when not connected to a *ventilator*

Note 1 to entry: See also *breathe* (3.2.2), *unassisted breath* (3.2.12) and *unrestricted breathing* (3.2.5).

3.2.5
unrestricted breathing
unassisted breathing with any workload imposed on the *patient* by the *ventilator* not exceeding that which could be experienced during *natural breathing*

Note 1 to entry: At present there is no standardized test specification to determine acceptable workloads imposed on the *patient* by *ventilators* and related equipment in *ventilation-modes* where the *patient* is intended to *breath*e without assistance, for example with CPAP or APRV. In the absence of such specifications, acceptability can only be assessed subjectively or comparatively, and this term has been adopted to denote this subjective criterion. It is expected that the introduction of this term will lead to the preparation of a corresponding test specification as has been introduced for the work of *breathing* imposed by non-medical breathing equipment. The term is used in this document as the criterion for assessing that the work imposed on a *patient* by such *ventilation-modes* is not subjectively different from that which would be experienced by a typical person not requiring *ventilatory* assistance, when *breathing* normally at rest in free air.

Note 2 to entry: See also *breathe* (3.2.2), *unassisted breath* (3.2.12), *natural breath*ing (3.2.4), *ventilation-mode* (3.11.2) and *ventilation* (3.1.9).

3.2.6
respiratory activity
activity of the *patient's respiratory system* related to the necessity to *breathe*

Note 1 to entry: This term typically serves as a reference to the minimum detectable form of the physiological indications of the *patient's* respiratory intentions, which might be used to improve the interaction between the *ventilator* and the *patient*. The term also serves as the reference to the level of effort to be supported during *effort-support* (ES) *inflation*s.

Note 2 to entry: This term may be used to express the activity during either of the phases of a *breath*, that is, a *patient inspiratory* activity or a *patient expiratory* activity.

Note 3 to entry: *Respiratory activity* can be detected as a *patient*-generated change in flow or pressure of gas in the *airway*, respiratory muscle activity, respiratory control-centre activity or other neural signals.

3.2.7
inspiratory effort
effort by the *patient's* respiratory muscles that contributes to the work of *inspiration* or that generates detectable changes sufficient to cause a *patient-trigger event*

Note 1 to entry: This definition is *patient*-centric and independent of the *ventilator* or *sleep-apnoea breathing-therapy equipment*.

Note 2 to entry: The detection of effort by the *patient's* respiratory muscles can be by measurements of parameters such as *airway pressure, airway* flow, *lung* elastance or neural signals, or by EMG.

Note 3 to entry: See also *breathe* (3.2.2), *effort-support* (3.3.7) and D.2.7.

3.2.8
additional breath
breath that is additional to those resulting from *assured inflations*

Note 1 to entry: This concept is mainly relevant to *ventilation-modes* classified as *Group 1 and 2* in this document in which *assured inflations* are always delivered at the set *rate*.

Note 2 to entry: The *additional breath rate* is the *total respiratory rate* minus the *set rate*.

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Note 3 to entry: With *assist/control* (A/C) *ventilation-modes,* when a proportion of the *inflations* are *patient*-triggered, it is usually not possible to identify any one *breath* as an *additional breath*; it is only possible to deduce the number of *additional breaths* per minute by comparing the *total respiratory rate* (RR_{tot}) with the *set rate,* using the relationship shown in Note 2 to entry.

Note 4 to entry: All *unassisted breaths* in *ventilation-mode Groups 1 and 2* are *additional breaths*.

Note 5 to entry: The concept of *additional breaths* facilitates the identification of an *additional-breath rate* (3.5.2.3) and an *additional minute volume* (3.8.12).

Note 6 to entry: See also *breath* (3.2.1), *assured inflation* (3.3.11), ventilation-mode groups (3.11), *set rate* (3.5.1.1), *total respiratory rate* (RR_{tot}) (3.5.1.2), *concurrent breath* (3.2.9), *unassisted breath* (3.2.12), *assisted breath* (3.2.14) and *supported breath* (3.2.13).

3.2.9
concurrent breath
additional breath, or phase of a *breath, initiated* during an *inflation phase*

EXAMPLE See Figures C.24, C.25 and C.35.

Note 1 to entry: The *inspiratory phase* of a *concurrent breath* can be unassisted or supported.

Note 2 to entry: This is a separate *breath*, or phase of a *breath*, following a change of *airway* flow direction or zero *airway* flow, while the *lung* is still *inflated*. Complete *unrestricted concurrent breaths* are only possible with the provision of ACAP or $ACAP_H$.

Note 3 to entry: It is only the detection of the *initiation* of the *inspiratory phase* of a *concurrent breath* that contributes to the *total respiratory rate* but the volume change that occurs during either concurrent phase is included in the respective *minute volume*. [See *spontaneous-breath rate* (3.5.1.3)].

Note 4 to entry: See also *additional breath* (3.2.8), *breath* (3.2.1), *initiate* (3.9.1), *inflation phase* (3.4.10), *inspiratory phase* (3.4.9), *airway* (3.1.2), *lung* (3.1.16), *inflation* (3.3.1), *unrestricted breathing* (3.2.5), *ACAP* (3.12.1), *total respiratory rate* (3.5.1.2) and *minute volume* (3.8.6).

3.2.10
inspiration
DEPRECATED: inhalation
DEPRECATED: inhale
process of gas entering the *lungs* through the *patient's airway*

Note 1 to entry: An *inspiration* can be caused by an *inspiratory effort*, by an *inflation* or by a combination of both.

Note 2 to entry: See also *inspiratory phase* (3.4.9), *inflation phase* (3.4.10), *airway* (3.1.2) and *expiration* (3.2.11).

3.2.11
expiration
exhalation
process of gas leaving the *lungs* through the *patient's airway* and which *terminates* when *inspiratory flow* next starts

Note 1 to entry: The admitted term, in its various grammatical forms, may be used instead of *expiration* in reference to a *patient* action, wherever the use of certain grammatical forms of *expiration* might seem inappropriate in the presence of *patients*. This admitted use is generally considered not to be necessary for impersonal purposes such as in medical databases and computer records.

Note 2 to entry: See also *airway* (3.1.2), *terminate* (3.9.14) and *inspiratory flow* (3.7.1).

3.2.12
unassisted breath
spontaneous breath by a *patient* connected to a *ventilator*, with no assistance from an *inflation*

Note 1 to entry: An increase of *airway pressure* applied during the *inspiratory phase* of an *unassisted breath*, with the declared *intended use* of compensating for any work of *breathing* imposed by an *airway device* or the functioning of the *ventilator*, is not classed as an *inflation* in this document. See also *tube compensation* (3.6.11).

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Note 2 to entry: The *patient's* work of *breathing* when taking a *spontaneous breath* can be reduced by the provision of ACAP or CPAP, but because no assistance is provided, such a *breath* is *unassisted*. See also *ACAP* (3.12.1).

Note 3 to entry: Unless *demand flow* is provided by the *ventilation-mode* selected, or by an ACAP *adjunct*, an unassisted *inspiration* might require an unsustainable *inspiratory effort*.

Note 4 to entry: See also *spontaneous breath* (3.2.3), *inflation* (3.3.1), *inspiratory phase* (3.4.9), *breathe* (3.2.2), *CPAP* (3.11.15), *unassisted breath* (3.2.12), *intended use* (3.1.25) and Figure C.2.

3.2.13
supported breath
spontaneous breath with assistance from a *pressure-support* or *effort-support inflation-type*

Note 1 to entry: See also *pressure-support* (3.3.6), *effort-support* (3.3.7), Annex B and Figures B.1, C.29, C.30 and F.6 a).

3.2.14
assisted breath
spontaneous breath with assistance from an *inflation* of the *assured inflation-type* but *initiated* by a *patient-trigger event*

Note 1 to entry: An *assisted breath* is assisted by an *inflation* of the *assured inflation-type* but only occurs if *initiated* before the next *assured inflation* is due to occur - which is at intervals determined by the *set rate*. Each *assisted breath*, therefore, occurs at a rate higher than that *set*; a rate which is solely determined by the *patient*.

Note 2 to entry: A *spontaneous breath* that is supported by a *pressure-support* (PS) or *effort-support* (ES) *inflation-type*, or by an *assured inflation* within a *synchronization window*, although also assisted, is separately identified by the specific characteristic that distinguishes it from an *assisted breath*, namely, *supported breath* or *synchronized breath*, respectively.

Note 3 to entry: See also *spontaneous breath* (3.2.3), *patient-trigger event* (3.6.9), *assured inflation* (3.3.11), *set rate* (3.5.1.1), *set* (3.1.19), *initiate* (3.9.1), *supported breath* (3.2.13), *synchronized breath* (3.2.15), Annex B and Figures B.1, and C.26 to C.28.

3.2.15
synchronized breath
spontaneous breath with assistance from an *assured inflation*, *initiated* by a *patient-trigger event* within a *synchronization window*

Note 1 to entry: *Synchronized breath*s are assured to occur at the *set rate*.

Note 2 to entry: See also *spontaneous breath* (3.2.3), *assured inflation* (3.3.11), *initiate* (3.9.1), *patient-trigger event* (3.9.6), *synchronization window* (3.9.8), *set rate* (3.5.1.1), *assisted breath* (3.2.14) and, Annex B and Figures C.14, C.19, C.29, C.32 and C.33.

3.2.16
controlled breath
breath resulting from a *ventilator-initiated assured inflation*

Note 1 to entry: A *controlled breath* is always *initiated* by the *ventilator* and subsequently, in the absence of any ensuing *spontaneous breathing* activity by the *patient*, generated entirely by the *inflation* waveform *set* or selected by the *operator*. *Controlled breath*s, therefore, are assured to occur at the *set rate*.

Note 2 to entry: See also *breath* (3.2.1), *ventilator-initiation* (3.9.12), *assured inflation* (3.3.11), *set* (3.1.19), *set rate* (3.5.1.1), Annex B and Figures B.1 and C.26 to C.28.

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3.3 Lung inflation terminology

3.3.1
inflation
positive-pressure inflation
ventilator inspiration
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

Note 1 to entry: The elevation of the *airway pressure*, above the PEEP of the previous phase, during an *inflation* and in the absence of total airway obstruction, generates an *inspiratory flow* that will either assist or totally control the *inflation* of the *patient's lungs*. This action relieves some of or all the *patient's* work of *breathing*.

Note 2 to entry: If the *inflation* is *pressure-regulated* and the *inspiratory phase* is *set* to extend beyond the *inspiratory-flow time*, then the *lungs* are held distended until the *inflation* is *terminated*. During this *inspiratory pause*, *concurrent breathing* can be possible, to the extent determined by the specific *ventilation-mode* selected and whether an ACAP *adjunct* is provided.

Note 3 to entry: Although, typically, there will be more than one *inflation-termination* criterion, for *patient*-safety reasons, these will always include *time-termination*, intended as either a primary or secondary means.

Note 4 to entry: If an *inflation* is intended to be *terminated* by means additional to time, this should be indicated, at least in the instructions for use, employing the *inflation-type* systematic naming and coding tables (see Annex D and Tables D.1, D.2 and D.3).

Note 5 to entry: The elevated pressure waveform is implemented by either a *flow-regulation* function or a *pressure-regulation* function.

Note 6 to entry: This is a context-sensitive term designating an intermittent elevated-pressure *ventilator* parameter, as distinct from a negative-pressure *ventilator inflation* or a *lung inflation* resulting solely from a *patient's inspiratory effort*. When used in its defined context, the preferred term is used by itself but in cases of possible ambiguity, the qualified form, '*positive-pressure inflation*', should be used.

Note 7 to entry: The admitted term *ventilator inspiration* is included to facilitate translation into languages that do not have a translation for the word, inflation, as it is used in this context.

Note 8 to entry: See also *ventilator* (3.1.1), *patient-connection port* (3.14.5), *terminate* (3.9.14), *PEEP* (3.10.4), *breathe* (3.2.2), *pressure-regulation* (3.3.9), *concurrent breath* (3.2.9), *ACAP* (3.12.1), *flow-regulation* (3.3.8), *positive-pressure ventilation* (3.1.13) and *negative-pressure regulation* (3.1.14).

3.3.2
inflation-type
inflation characterized by its temporal delivery pattern following *initiation*, and its *termination* criteria

Note 1 to entry: *Inflation-types* are designated in this document by their property-class common names, wherever possible. They are more precisely designated by the systematic coding scheme, which uses the abbreviations of the common names, where available, but which also often includes designators of additional properties and designates *inflation-types* with no common name yet attributed to them.

Note 2 to entry: A group of *inflation-types* that might be selected for a specific purpose is sometimes given a purpose-class name, but such a name is not an alternative name for that *inflation-type*. As an example, a *pressure-control inflation-type* might be selected to serve as the *assured inflation* within a *ventilation-mode,* but that only makes it the *assured* '*inflation-type*'; a name that identifies its function within a *ventilation-mode* as being assured to be delivered at least at the *set rate* but that does not change its *pressure-control* characteristics.

Note 3 to entry: For further information on *inflation-type* designations see Annex D and Tables D.1, D.2 and D.3.

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3.3.3
volume-control
VC
inflation-type that generates *inspiratory flow* to a selected flow-waveform, for a *set inspiratory-time*, or until the *set* volume has been delivered

Note 1 to entry: The selected *inspiratory-flow* waveform is typically that of a constant flow at a *set* value or of a *decreasing flow pattern*, sometimes after a *set rise time*. The constant flow is maintained for the duration of the *inflation phase* by means of a *flow-regulation* function.

Note 2 to entry: The *flow-regulation* function typically either maintains the *set inspiratory flow* or maintains an *inflation*-to-*inflation* adjusted *inspiratory flow* with the intention that the *set* volume is delivered in the *set* time, particularly when compensating for *ventilator breathing system* characteristics or an *airway leak.*

Note 3 to entry: See also *inspiratory flow* (3.7.1), *set* (3.1.19), *inspiratory time* (3.4.8), *inflation phase* (3.4.10), *flow-regulation* (3.3.8), *delivered volume* (3.8.2), *inspiratory volume* (3.8.3), *ventilator breathing system* (3.1.18), *airway leak* (3.7.11), Figures C.7, C.12, C.13, C.16, C.23 and C.27, Annex D and Tables D.1, D.2 and D.3.

3.3.4
pressure-control
PC
inflation-type that acts to generate a constant *inspiratory pressure* at a *set* level, after a *set rise time*

Note 1 to entry: After the *set rise time*, the *set inspiratory pressure* is typically maintained by means of a *pressure-regulation* function.

Note 2 to entry: If the *patient* makes an *inspiratory effort* during a *pressure-control inflation*, this will result in a corresponding increase in *inspiratory flow*, although not necessarily an increased *delivered volume*.

Note 3 to entry: If the *patient* makes an *expiratory* effort during a *pressure-control inflation*, the *inspiratory pressure* could rise above that *set*, which might cause immediate *termination* of the *inflation*. The addition of ACAP enables concurrent unrestricted *expiration* without *termination*.

Note 4 to entry: See *also inspiratory pressure* (3.6.2), *set* (3.1.19), *rise time* (3.3.10), *pressure-regulation* (3.3.9), *inspiratory effort* (3.2.7), *expiration* (3.2.11), *terminate* (3.9.14), *ACAP* (3.12.1), *concurrent breath* (3.2.9), *unrestricted breathing* (3.2.9), *high-pressure relief limit* (3.12.6), *high-pressure termination limit* (3.13.7), Figures C.3 to C.5, C.8, C.9, C.11and C.22 to C.33, Annex D and Tables D.1, D.2 and D.3.

3.3.5
dual-control
type of *inflation* in which the regulated variable changes from pressure to flow, or vice versa, during an *inflation phase* in accordance with the *inflation* algorithm

Note 1 to entry: A *dual-control* designation is incomplete without reference to the names of the *inflation-types* that most closely represent the initial and secondary functions within the *dual-control inflation*. For examples see Tables D.1 and D.2.

Note 2 to entry: *Pressure limitations*, as might be achieved by an *inspiratory-pressure relief* system or flow limitations and, consequently, where the *set delivered volume* might not be achieved, are not considered to be components of a *dual-control inflation-type*.

Note 3 to entry: See also *pressure limit* (3.13.1), D.2.8.3 and D.2.8.4.

3.3.6
pressure-support
PS
inflation-type that acts to generate a constant *airway pressure*, after a *set rise time*, and can be *terminated* by *patient respiratory activity*; only made available for selection with *ventilation-patterns* where it cannot be *initiated* other than in response to a *patient-trigger event*

Note 1 to entry: During and after the *set rise time*, the *set inspiratory pressure* is typically maintained by means of a *pressure-regulation* function.

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Note 2 to entry: *Pressure-support inflation-types* are so named because they are specified and configured to be used only to provide assistance to *spontaneous breathing*.

Note 3 to entry: *Pressure-support inflations* are typically *flow-terminated* but can be *terminated* by other means that allow *termination* by *patient respiratory activity*.

Note 4 to entry: It is possible for *flow-termination* to be caused by the passive characteristics of the *patient's respiratory system* alone, without any *respiratory activity*, in which case it is misleading to refer to the *inflation* as having been terminated by the *patient*. Because current *ventilators* cannot make this distinction, in this document, *flow-terminated inflation-types* are not referred to as being patient-terminated.

Note 5 to entry: As noted under *inflation*, *pressure-support* (PS) *inflations* are *time-terminated* if not *terminated* within the *set inspiratory time*; a *setting* that can be *preset* or *operator* adjustable.

Note 6 to entry: By convention, *inspiratory pressures* for *pressure-support* (PS) *inflations* are usually *set* relative to their related *baseline airway pressure* but, in this document, all such relative pressures are required to be identified as such by the use of the differential symbol, Δ (3.6.6).

Note 7 to entry: For *Group 2 ventilation-modes* with an ACAP *adjunct*, a single *pressure-support inflation setting* can be arranged to support *breaths* throughout the full *assured-inflation cycle* if its *set inspiratory-pressure* is higher than the *set inspiratory pressure* for the *assured inflation*. Alternatively, there can be a second level of *pressure-support*, relative to the *set inspiratory pressure* for the *assured inflation*, for the support of *concurrent breaths*.

Note 8 to entry: A *pressure-control* (PC) *inflation* that is *flow-terminated* is not classified as *pressure-support* (PS) if used in *ventilation-patterns* where it can be *ventilator-initiated*, it is then classified as a *pressure-control*, *flow-terminated* [PC(***q***)] *inflation*.

Note 9 to entry: See also *terminate* (3.9.14), *initiate* (3.9.1), *time-termination* (3.9.17), *set* (3.1.19), *inspiratory time* (3.4.8), *respiratory activity* (3.2.6), *baseline airway pressure* (3.10.1), *assured ventilation* (3.11.6), *flow-termination* (3.9.15), *ACAP* (3.12.1), *concurrent breath* (3.2.9), *pressure-control* (3.3.4), *inflation* (3.3.1), D.2.5, D.2.8.4, Tables D.1 and D.3, and Figures C.6, C.10 and C.29 to C.34.

3.3.7
effort-support
ES
inflation-type that generates an *airway-pressure* waveform that is intended to be proportional to a *patient's inspiratory effort*

Note 1 to entry: The intention of this *inflation-type* is to unload a proportion of the work of *breathing* during an *inflation phase*.

Note 2 to entry: The required *airway-pressure* waveform is typically calculated moment-by-moment by a *ventilator* algorithm, using continuous measurements of parameters such as *airway pressure*, *inspiratory flow*, *lung* elastance, neural signals or EMG; it is generated by means of a *pressure-regulation* function tracking the calculated waveform.

Note 3 to entry: If the *effort-support* (ES) *inflation* is based on measurement of *inspiratory flow*, the support is most commonly determined as independent proportions of the resistive or elastance components of the *inspiratory effort*.

Note 4 to entry: The unloading of a proportion of the work of *breathing* during an *expiratory phase* can be provided by means of an *adjunct* under the control of an *expiratory-control algorithm*.

Note 5 to entry: The *inflation* is typically *terminated* when the *inspiratory flow* has declined to a *termination-flow* threshold but as noted under *inflation*, *effort-support* (ES) *inflations* are *time-terminated* if not *terminated* by other means within the *set inspiratory time*; a *setting* that can be *preset* or *operator*-adjustable.

Note 6 to entry: See also *inspiratory effort* (3.2.7), *respiratory system compliance* (3.1.5), *airway resistance* (3.1.4), *inflation* (3.3.1), *expiratory-control algorithm* (3.10.5), *terminate* (3.9.14), *preset* (3.1.21), D.2.7 and Tables D.1 and D.3.

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3.3.8
flow-regulation
function of the *ventilator* that varies the *airway pressure* as necessary with time to generate an intended *inspiratory-flow* waveform irrespective of changes to the *respiratory system* parameters or of *respiratory activity*

Note 1 to entry: See also *airway pressure* (3.6.1), *respiratory system* (3.1.17), *respiratory activity* (3.2.6), *inspiratory flow* (3.7.1) and *pressure-regulation* (3.3.9).

3.3.9
pressure-regulation
function of the *ventilator* that regulates the *airway pressure* as necessary with time to generate an intended *airway-pressure* waveform irrespective of changes to the *respiratory system* mechanics or of concurrent *unassisted inspirations*

Note 1 to entry: See also *concurrent breath* (3.2.9), *unassisted breath* (3.2.12), *pressure-control* (3.3.4), *pressure-support* (3.3.6) and *flow-regulation* (3.3.8).

3.3.10
rise time
indication of the time for the regulated parameter to rise to a *set* value following the *initiation* of an *inflation*

Note 1 to entry: The *rise time* is often expressed as the slope of a ramp or as the time-constant of the rise although neither of these terms depicts the actual typical trajectory of this pressure rise precisely.

Note 2 to entry: For *pressure-regulation*, this is the time to reach a *set inspiratory pressure*, for *flow-regulation* it is the time to reach a *set inspiratory flow*.

Note 3 to entry: See also *set* (3.1.19), *initiate* (3.9.1), *inflation* (3.3.1) and Figures C.1 and C.9 to C.13.

3.3.11
assured inflation
inflation, of a selected type, which is assured to be *initiated* at intervals as determined by the selected *ventilation-pattern* and the *set rate*

Note 1 to entry: The *inflation-type* selected for *assured inflations* is designated as an *assured inflation-type*.

Note 2 to entry: The *operator* has the assurance that, with *Group 1 and 2 ventilation-modes*, the selected *assured inflation-type* will be delivered at either on average the *set rate*, or at least the *set rate*, depending upon the selected *ventilation-pattern*. With *Group 3 ventilation-modes*, the selected *assured inflation-type* will be delivered at the *set rate* in the absence of *patient-trigger events* occurring at a rate faster than that *set*.

Note 3 to entry: The pre-coordinated term, 'assured', is used in this document as the preferred synonym to the legacy term, *mandatory*. It conveys the concept which *mandatory* is used to elicit in this document but avoids the ambiguities which that term engenders. For the reasons explained in the rationale to 3.9.9, *mandatory* is only used in this document when explaining the meaning of legacy *ventilation-patterns* that incorporate this term.

Note 4 to entry: The *breath* associated with an *assured inflation* is 'synchronized' or 'controlled'.

Note 5 to entry: See also *respiratory cycle* (3.4.16) for the derivation of the post-coordinated term, *assured-inflation cycle*.

Note 6 to entry: See also *inflation* (3.3.1), *initiate* (3.9.1), *ventilation-pattern* (3.11.3), *set* (3.1.19), *rate* (3.5.1.1), *assured inflation-type* (3.3.12), *assured-inflation cycle* (3.4.18), *ventilation-mode groups* (3.11.5), *assisted breath* (3.2.14), *synchronized breath* (3.2.15), *controlled breath* (3.2.16) and Figures B.1 and C.24 to C.33.

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3.3.12
assured inflation-type
inflation-type that has been selected for *assured inflations*

Note 1 to entry: In this document, *inflation-types* are classified either by their purpose, or by their properties in terms of their characteristic waveform. This term is a purpose-classification, as distinct from the name of an *inflation-type*, which is a property-classification.

Note 2 to entry: Although assured to be delivered at the *set rate*, the *assured inflation-type* can also be *initiated* by a *patient-trigger event* in *Group 1a ventilation-modes* such as *assist/control ventilation*. Any such *initiations* can lead to deliveries of the *assured inflation-type* at a rate greater than that assured by the *set rate*. It follows that although all *assured inflations* are of the *assured inflations-type*, not all deliveries of the selected *assured inflation-type* occur because they are assured.

Note 3 to entry: *Assured inflation-types* can be *initiated* either by the *ventilator* or by a *patient-trigger event*.

Note 4 to entry: See also *inflation* (3.3.1), *assured inflation* (3.3.11), *inflation-type* (3.3.2), *initiate* (3.9.1), *ventilation-mode groups* (3.11.5), *assist/control ventilation* (3.11.8), *SIMV* (3.11.10) and Figures C.14 to C.20 and C.24 to C.33.

3.3.13
support inflation
inflation, of a selected type, that is intended to be *terminated* in response to the *patient's respiratory activity* and for use in *ventilation-modes* where it can only be *initiated* in response to a *patient-trigger event*

Note 1 to entry: The *inflation-type* selected for *support inflations* is designated as a *support inflation-type*. *Pressure-support* and *effort-support inflation-types* are typically selected as *support inflation-types*.

Note 2 to entry: With *support inflations*, there is no assurance of delivery; they are so named because they are specified and configured to be used only to provide assistance to *spontaneous breaths*.

Note 3 to entry: *Support inflations* can be selected to support *spontaneous breaths* between *assured inflations*, concurrent with *assured inflations*, or throughout complete *assured-inflation cycles*.

Note 4 to entry: It is not generally possible to refer to *support inflations* as 'patient-terminated' because, in the absence of *respiratory activity*, they can, typically, also be *terminated* by the *patient's* passive *lung* without any definitive indication of the distinction.

Note 5 to entry: The *breath* associated with a *support inflation* is 'supported'. See *supported breath* (3.2.13).

Note 6 to entry: See also *inflation* (3.3.1), *terminate* (3.9.14), *respiratory activity* (3.2.6), *support inflation-type* (3.3.14), *spontaneous breath* (3.2.3), *assured inflation* (3.3.11), *assured-inflation cycle* (3.4.18), *lung* (3.1.16) and Figures C.21 and C.29 to C.34.

3.3.14
support inflation-type
inflation-type that has been selected for *support inflations*

Note 1 to entry: In this document, *inflation-types* are classified either by their purpose, or by their properties in terms of their characteristic waveform. This term is a purpose classification to designate the group of *inflation-types* that are solely used in *ventilation-modes* where they can only be *initiated* in response to a *patient's inspiratory effort* and that are intended to be *terminated* in response to the *patient's respiratory activity*.

Note 2 to entry: See also *inflation-type* (3.3.2), *support inflation* (3.3.13), *ventilation-mode* (3.11.2), *initiate* (3.9.1), *inspiratory effort* (3.2.7), *terminate* (3.9.14) and *respiratory activity* (3.2.6).

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3.3.15
volume targeted
automatic *inflation*-to-*inflation* adjustment of the *inflation settings*, with the target of achieving a *set inspiratory volume* for each *breath*

Note 1 to entry: The word 'target' is used because the inherent *inflation*-to-*inflation* delay, possible *respiratory activity* and other limitations in the adjustment, result in less precise control of each *inspiratory volume* than is achieved by direct feedback (for example, as is used for the *pressure-regulation* function) although the average *inspiratory volume* will typically converge towards the *set* value.

Note 2 to entry: This term is applicable to all *inflations* in which the delivery is *pressure-regulated* to a *set* value, including those classified as *pressure-support* (PS), but not to those that respond to *patient* parameters according to an alternative algorithm, for example, *effort-support* (ES). The concept is designated in the systematic coding scheme by the use of the letters, vt, as a prescript to an appropriate *inflation-type*, for example, vtPC or vtPS. Such a code becomes the generic classification for established proprietary terms such as, 'PRVC', 'Volume Support', 'Volume Guarantee', 'VC+' and 'Autoflow®[1)]'.

Note 3 to entry: See also *inflation* (3.3.1), *set* (3.1.19), *inspiratory volume* (3.8.3), *breath* (3.2.1), *pressure-regulation* (3.3.9) *pressure-support* (3.3.6), *effort-support* (3.3.7), D.2.2 and Tables D.1 and D.2.

3.4 * Time, phase and cycle terminology

3.4.1
expiratory time
duration of an *expiratory phase*

[SOURCE: ISO 4135: 2001, 3.4.6, modified — Admitted term was removed.]

Note 1 to entry: In addition to its direct reference, this term may be used, in context or by qualification, to designate this concept as a *set* quantity (3.1.19) or a *measured* quantity (3.1.20).

Note 2 to entry: The symbol, t_E,, displayed in various character styles, is typically used to designate the *expiratory time setting*, particularly where space is limited, such as on user interfaces.

Note 3 to entry: As a *set* quantity, the *expiratory time* is either the intended actual duration, the intended average duration or the assured maximum duration of the *expiratory phase* of the *assured inflation*, depending on the *ventilation-mode* selected.

Note 4 to entry: As a *measured* quantity, in *ventilation-modes* that facilitate simultaneous *respiratory cycles*, the *expiratory time* is that of the longest *respiratory cycle* unless otherwise specified.

Note 5 to entry: The *expiratory time* is commonly *set* indirectly, for example, by means of a *set rate* and a *set inspiratory time*.

Note 6 to entry: With *expiratory phase*s alternatively labelled as BAP *phase*s, *expiratory time* should be replaced with the term BAP *time*. In *ventilation-modes* labelled as *bi-level* AV, the *expiratory time* may be identified either by the term BAP *time* or *time-low*.

Note 7 to entry: For information on the use of symbols in the labelling of *ventilation* equipment see G.6 and H.2.

Note 8 to entry: See also *expiratory phase* (3.4.2), *assured inflation* (3.3.11), *respiratory cycle* (3.4.16), *BAP phase* (3.10.3), *BAP time* (3.12.6), *bi-level* AV (3.12.4) and Figures C.22 to C.29, C.34 and F.4.

1) AutoFlow® is the trademark of a product supplied by Draeger Medical AG & Co. KG. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of the product named. Equivalent products may be used if they can be shown to lead to the same results.

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3.4.2
expiratory phase
interval from the start of *expiratory flow* to the start of *inspiratory flow* within a *respiratory cycle*

[SOURCE: ISO 4135: 2001, 3.4.5, modified — Applicability clarified.]

Note 1 to entry: If *additional spontaneous breath*s are possible, all or part of their *expiratory phases* can occur within the *expiratory phase* of an *assured-inflation cycle*.

Note 2 to entry: In accordance with the conceptual framework of this document, the phase between *inflation*s in any *respiratory cycle* is the *expiratory phase* of that cycle. For *ventilator*s with which there can be simultaneous *respiratory cycle*s, it might not be clear as to which of the cycles is being referenced unless it is specifically associated with the *assured-inflation cycle* each time it is used. This is one of the reasons that the alternative name, BAP *phase*, has been introduced into this document; an introduction that is particularly relevant for use on *ventilator*s that facilitate *additional breath*s in the phase between *assured inflations*. For further information regarding these concepts, see 3.10, 3.11 and 3.12.

Note 3 to entry: If the *patient* generates flow that *initiates* an *inflation*, the *inspiratory flow* for the *initiated inflation cycle* is taken as starting at the *initiation* of the *inflation phase* and any measurable flow in advance of that *initiation* becomes the trigger flow. If necessary, depending upon the level of granularity required for a specific description of this trigger flow, its duration can be considered to constitute a trigger phase. Because the change from the trigger phase to the *inflation phase* is typically optimized at a level determined by *operator settings*, in this document it is treated as having occurred during the final moments of the *expiratory phase*, unless otherwise stated.

This concept is consistent with the pragmatic view that the *set inspiratory time* should be taken to start at the same point on the pressure *rise-time* waveform of an *inflation*, whether it is *initiated* by the *ventilator* or by a *patient-trigger event* (see Figures C.3 and C.4) - also, that the main significance of the actual duration of the *expiratory phase* is as a *setting* that determines a maximum interval between *inflations*; an aspect that becomes much less critical whenever the *patient* determines a shorter interval.

If the *patient* generates *inspiratory flow* that does not cause a *patient-trigger event*, then its detectable commencement is treated as the *initiation* of the *inspiratory phase* of the subsequent *unassisted spontaneous breath*.

Note 4 to entry: See also *expiratory flow* (3.7.5), *inspiratory flow* (3.7.1), *assured-inflation cycle* (3.4.18), *BAP phase* (3.10.3), *additional breath* (3.2.8), *spontaneous breath* (3.2.3), *respiratory cycle* (3.4.16), *assured-inflation cycle* (3.4.18), *assured inflation* (3.3.11), *ventilator-initiation* (3.9.12), *patient-trigger event* (3.9.6) and Figures C.2 to C.8, C.23 to C.34 and F.5.

3.4.3
expiratory-flow time
duration of the interval from the start of *expiratory flow* to its cessation

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

Note 2 to entry: In practice, it might be difficult to measure the actual flow time precisely because of the typically asymptotic decline of the *expiratory flow* at this point in the *expiratory phase* but this term is unlikely to be used in the description of situations where precision is critical.

Note 3 to entry: The *expiratory-flow time* and the *expiratory time* can be equal.

Note 4 to entry: See also *expiratory flow* (3.7.5) and *expiratory time* (3.4.1) and Figures C.1 and C.9 to C.13.

3.4.4
expiratory pause
portion of the *expiratory phase* from the end of *expiratory flow* to the start of *inspiratory flow*

[SOURCE: ISO 4135: 2001, 3.4.3, modified — Applicability clarified.]

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

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Note 2 to entry: See also *expiratory phase* (3.4.2), *expiratory flow* (3.7.5), *inspiratory flow* (3.7.1) and *expiratory hold* (3.4.6).

3.4.5
expiratory-pause time
duration of an *expiratory pause*

[SOURCE: ISO 4135: 2001, 3.4.4]

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

Note 2 to entry: See also *expiratory pause* (3.4.4).

3.4.6
expiratory hold
execution of a *ventilator* function intended to temporarily maintain a constant *lung* volume during a *set* extension of the *expiratory phase*

Note 1 to entry: The maintenance of a constant *lung* volume is typically used to either facilitate the measurement of *auto*-PEEP or to temporarily immobilize the torso (e.g., for diagnostic imaging).

Note 2 to entry: This function can be achieved by temporarily occluding the *airway*, by maintaining a pressure at the *patient-connection port* or by other means. For the measurement of *auto*-PEEP, it is necessary to use an *expiratory hold* achieved with an occluded *airway*.

Note 3 to entry: Both the *initiation* and the duration of the function are *settings*.

Note 4 to entry: See also *lung* (3.1.16), *expiratory phase* (3.4.2), *expiratory-hold time* (3.4.7), *expiratory pause* (3.4.4) and *initiate* (3.9.1).

3.4.7
expiratory-hold time
duration of an *expiratory hold*

Note 1 to entry: The hold time can be *set* by selecting a time or determined by the duration of a manual input.

3.4.8
inspiratory time
duration of an *inflation phase* or *inspiratory phase*

[SOURCE: ISO 4135: 2001, 3.4.13, modified — Rephrased.]

Note 1 to entry: In addition to its direct reference, this term or its symbol, t_I, may be used, in context or by qualification, to designate this concept as a *set* quantity (3.1.19) or a *measured* quantity (3.1.20).

Note 2 to entry: The symbol, t_I, displayed in various character styles, is typically used to designate the *inspiratory time setting*, particularly where space is limited, such as on user interfaces.

Note 3 to entry: For information on the use of letter symbols in the labelling of *ventilation* equipment see A.4 - 3 and G.6.

Note 4 to entry: See also Figures C.1, C.9 to C.13, C.22 to C.34.

3.4.9
inspiratory phase
interval from the start of *inspiratory flow* to the start of *expiratory flow* during an *unassisted breath*

[SOURCE: ISO 4135:2001, 3.4.12, modified — Rephrased.]

Note 1 to entry: This term is restricted to the designation of unassisted *inspirations* because, when used in relation to a *breath* in natural language, the verb inspire is closely associated with a *patient* action. In order to avoid any inference of '*ventilators breathing*', the intervals during which *inflations* are delivered are designated as *inflation phases*.

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Note 2 to entry: If additional *spontaneous breaths* are possible, their *inspiratory phase* can occur within the *inflation phase* of an *assured-inflation cycle*.

Note 3 to entry: See also *inflation phase* (3.4.10), *inspiratory flow* (3.7.1), *expiratory flow* (3.7.5), *unassisted breath* (3.2.12), *inspiration* (3.2.10), *breath* (3.2.1), *ventilator* (3.1.1), *breathe* (3.2.2), *inflation* (3.3.1), *spontaneous breath* (3.2.3), *assured-inflation cycle* (3.4.18) and Figures C.2, C.24, C.25, C.30 to C.32 and C.34.

3.4.10
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*

Note 1 to entry: With some *ventilation-modes*, a *concurrent breath* can result in a concurrent *inflation phase*, for example, it can *initiate* a *pressure-support* (PS) *inflation* that is concurrent with a *pressure-control* (PC) *assured inflation.*

Note 2 to entry: Depending upon the level of granularity required for a specific description, an *inflation phase* can be considered to include a *termination* phase.

Note 3 to entry: to entry See also *inspiratory phase* (3.4.9), *airway pressure* (3.6.1), *initiate* (3.9.1), *inflation* (3.3.1), *expiratory flow* (3.7.5), *terminate* (3.9.14), *breathe* (3.2.2), *concurrent breath* (3.2.9) and Figures C.3 to C.8 and C.23 to C.33.

3.4.11
inspiratory-flow time
duration of the interval from the start of *inspiratory flow* to its cessation

Note 1 to entry: In addition to its direct reference, this term may be used, in context or by qualification, to designate this concept as a *set* quantity (3.1.19) or a *measured* quantity (3.1.20).

Note 2 to entry: This term becomes relevant as a separate concept with *inflations* where there is an *inspiratory pause*. Where there is no *inspiratory pause*, it has the same value as the *inspiratory time*.

Note 3 to entry: See also Figures C.9 and C.12.

3.4.12
inspiratory pause
interval from the end of *inspiratory flow* to the start of *expiratory flow* within a *respiratory cycle*

[SOURCE: ISO 4135: 2001, 3.4.10, modified — Rephrased.]

Note 1 to entry: There is no *inspiratory pause* when the *inspiratory flow* ends with the transition to *expiratory flow*.

Note 2 to entry: See also *inspiratory hold* (3.4.14) and Figures C.9 and C.12.

3.4.13
inspiratory-pause time
duration of an inspiratory pause

[SOURCE: ISO 4135: 2001, 3.4.11]

Note 1 to entry: In addition to its direct reference, this term may be used, in context or by qualification, to designate this concept as a *set* quantity (3.1.19) or a *measured* quantity (3.1.20).

Note 2 to entry: See also *inspiratory pause* (3.4.12) and Figures C.9 and C.12.

3.4.14
inspiratory hold
ventilator function intended to enable the respiratory pressures to temporarily equalize throughout the *lungs* during a *set* extension of the end of an *inflation* or an *inspiratory phase*

Note 1 to entry: This function can be achieved by temporarily occluding the *airway*, by maintaining a pressure at the *patient-connection port* or by other means.

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Note 2 to entry: An *inspiratory hold* function is typically used to facilitate a separate clinical procedure, for example, the measurement of *lung* parameters or a diagnostic imaging examination.

Note 3 to entry: The *initiation* of the function might be determined by a direct *operator* action or in conjunction with the operation of other equipment.

Note 4 to entry: See also *inspiratory pause* (3.4.12), *ventilator breathing system* (3.1.18), *patient connection port* (3.14.5), *delivered volume* (3.8.2) and *expired minute volume* (3.8.9).

3.4.15
inspiratory-hold time
duration of an *inspiratory hold*

Note 1 to entry: The *inspiratory-hold time* might be determined by an elapsed time *setting* or by the duration of a manual input.

Note 2 to entry: See also *inspiratory hold* (3.4.14).

3.4.16
respiratory cycle
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

EXAMPLE 1 The sequence of respiratory events following the *initiation* of an *assured inflation*, through to the subsequent *initiation* of the following *assured inflation*.

EXAMPLE 2 A pressure-support (PS) inflation phase followed by its expiratory phase.

Note 1 to entry: The term *respiratory cycle* has become a generic term for a complete *breath* cycle, whether it is given some form of assistance, is unassisted or only results from an *assured inflation*. Its use addresses a problem that arises because in common usage the word, breath, is often used to refer to either a single phase alone or a complete *breath* cycle. It is also helpful in the consideration of the occurrence of *additional breath*s within an *assured-inflation cycle*. The term '*respiratory cycle*' is more concise than having to qualify the term *breath* in a way that removes all ambiguity.

Note 2 to entry: This generic term is not intended for use as a universal substitute for any more specifically applicable terms defined in this document. Its use should be restricted to the improvement of concision and readability in instances such as those cited in Note 1 to entry.

Note 3 to entry: For an *assured inflation*, the *respiratory cycle* starts with its *initiation* and ends with the *initiation* of the next *inflation* of the selected *assured inflation-type*. See also *assured-inflation cycle* (3.4.18).

Note 4 to entry: Additional, separate *respiratory cycle*s can be *initiated* within an *assured-inflation cycle* - see also *additional breath* (3.2.8).

Note 5 to entry: See also *lung* (3.1.16), *breath* (3.2.1), *unassisted breath* (3.2.12), *spontaneous breath* (3.2.3), *inspiratory phase* (3.4.9), *initiate* (3.9.1), *assured inflation* (3.3.11), *pressure-support* (3.3.6), *inflation phase* (3.4.10), *expiratory phase* (3.4.2), *assured-inflation cycle* (3.4.18) and Figure C.23.

3.4.17
respiratory cycle time
cycle time
duration of a respiratory cycle

Note 1 to entry: In addition to its direct reference, this term may be used, in context or by qualification, to designate this concept as a *set* quantity (3.1.19) or a *measured* quantity (3.1.20).

Note 2 to entry: The *set respiratory cycle time* of an *assured inflation* (in minutes) is typically determined indirectly as the reciprocal of the *set rate*. *Respiratory cycle times* are typically displayed in seconds, and rates as per minute; the *respiratory cycle time* then becomes 60/*set-rate.*

Note 3 to entry: See also Figures C.15 to C.33.

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3.4.18
assured-inflation cycle
respiratory cycle of an *assured inflation*

Note 1 to entry: In *ventilation-modes* such as SIMV, *supported* or *unassisted additional breaths* can be taken during the *expiratory phase* of the *assured-inflation cycle*; also, during the *inspiratory phase* if an ACAP *adjunct* is provided.

Note 2 to entry: In *ventilation-modes* alternatively labelled as *bi-level* AV, this cycle may be referred to as the bi-level cycle.

Note 3 to entry: See also *assured inflation* (3.3.11), *respiratory cycle* (3.4.16), *ventilation-mode* (3.11.2), *ACAP* (3.12.1), *adjunct* (3.11.4), *bi-level AV* (3.12.4) and Figures C.24 to C.33.

3.4.19
phase time ratio
I:E ratio
ratio of the *inspiratory time* to the *expiratory time* in a *respiratory cycle*

Note 1 to entry: In addition to its direct reference, this term or its symbol, I:E, may be used, in context or by qualification, to designate this concept as a *set* quantity (3.1.19) or a *measured* quantity (3.1.20).

Note 2 to entry: By mathematical convention, a colon or a slash is used to designate a ratio between two values so the addition of the word 'ratio' is not strictly necessary. However, its addition is widely practiced and is considered to add to the readability of descriptive texts and lists, but in this document, its use is optional.

3.4.20
inspiratory-time fraction
t_I:t_{TOT} ratio
ratio of the inspiratory time to the respiratory cycle time

Note 1 to entry: In addition to its direct reference, this term or its symbol, t_I:t_{TOT}, displayed in various character styles, may be used, in context or by qualification, to designate this concept as a *set* quantity (3.1.19) or a *measured* quantity (3.1.20).

Note 2 to entry: This value can be expressed as a ratio, fraction or percentage.

Note 3 to entry: See also *phase time ratio* (3.4.19), *inspiratory time* (3.4.8) and *respiratory cycle time* (3.4.17).

3.5 * Rate terminology

3.5.1 Preferred rate concepts[2)]

3.5.1.1
set rate
DEPRECATED: f
DEPRECATED: frequency
number of *assured inflations* that are *set* to occur in a specified period of time, expressed as *breaths* per minute

Note 1 to entry: In the absence of suitable standardization, manufacturers have devised their own abbreviations to denote the various terms relating to respiratory rate for use on user interfaces, where space is often limited, and in user manuals. In the case of *set rate*, it has become widely established custom and practice, when used in context and without further qualification, to adopt the abbreviation, "*Rate*", displayed in various character styles. With the introduction of the term *assured inflation* in this document the adoption of the abbreviation *AR* displayed in various character styles, to represent assured rate, would be appropriate as an alternative for this purpose.

Note 2 to entry: The *set rate* can be determined by the *operator* either by a direct *setting*, or indirectly by means of an algorithm (see Example 4).

2) The terms in this subclause are the designations for the preferred concepts relating to breath rate in this document. Examples of alternative designations for admitted concepts are listed in 3.5.2.

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Note 3 to entry: The *set rate* assures the *operator* that *inflations* of the selected *assured inflation-type* will be delivered at intervals (in minutes) not exceeding, on average, the reciprocal of the *set rate*, although the actual interval between any two successive *inflations* might not be constant.

Note 4 to entry: The deprecated symbol, *f*, and the term that it represents, frequency, are deprecated as synonyms for *set rate* in this document. Although having similar meanings, rate is the term more usually used in reference to the number of instances occurring in a certain period of time, with no inference that the interval between these instances is constant, whereas frequency has more of the connotation of occurring at constant intervals.

EXAMPLE 1 With an *assist/control* (A/C) *ventilation-mode*, the *set rate* is the assured minimum *ventilator-initiated inflation* rate; with any *patient-initiated* (assist) *inflation*s the *total respiratory rate* becomes higher. See Figure C.17.

EXAMPLE 2 With an IMV (*intermittent mandatory ventilation*) *mode*, the *set rate* is the rate at which the *assured inflations* are *initiated*. See Figure C.18.

EXAMPLE 3 With a SIMV (*synchronized intermittent mandatory ventilation*) *mode*, the *set rate* is the average rate at which the *assured inflations* are *initiated*. See Figure C.19.

EXAMPLE 4 With one means of achieving a MMV (*minimum minute volume*) *ventilation-mode,* the mode-control algorithm automatically adjusts the *set rate* downwards from its initial *setting*, as necessary to maintain the *set minute volume* as a minimum.

3.5.1.2
total respiratory rate
total rate
number of *respiratory cycle*s in a specified period of time, expressed as *breaths* per minute

Note 1 to entry: In addition to its direct reference, this term, and its abbreviation, RR_{tot}, displayed in various character styles, is only used, in context or by qualification, to designate this concept as a *measured* quantity (3.1.20).

Note 2 to entry: The *total respiratory rate* is the *spontaneous breath rate* plus the *ventilator-initiated inflation rate*.

Note 3 to entry: Separate *respiratory cycles initiated* within *assured-inflation cycles* are counted as part of the total.

Note 4 to entry: See also *additional breath* (3.2.8), *respiratory cycle* (3.4.16), *initiate* (3.9.1) and *assured-inflation cycle* (3.4.18).

3.5.1.3
spontaneous breath rate
spontaneous rate
ISO spontaneous-breath rate
total number of *spontaneous breath*s *initiated* in a specified period of time, expressed as *breath*s per minute

Note 1 to entry: In addition to its direct reference, this term, and its symbol, RR_{spont}, displayed in various character styles, is only used, in context or by qualification, to designate this concept as a *measured* quantity (3.1.20).

Note 2 to entry: The *spontaneous breath rate* is the difference between the *total respiratory rate* and the *ventilator-initiated inflation rate*.

Note 3 to entry: The detection of the beginning and end of a *breath* is dependent on the sensitivity of the *ventilator* sensors and the thresholds of the detection algorithms. For further information concerning the reliability of using the *patient*-triggered rate as a measure of the *spontaneous-breath rate*, see *patient-trigger event* (3.9.6).

Note 4 to entry: Because there is no dependent action required, as is the case with *assisted breath*s, the counting of an *unassisted spontaneous breath* can be delayed until its *inspiratory phase* has *terminated*, thereby allowing a higher level of discrimination between actual *breath*s and spurious events.

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Note 5 to entry: Many legacy *ventilator*s display and log the *spontaneous breath rate* as the *unassisted breath rate* plus the *supported breath* rate. While true for CSV *modes*, this practice does not include the *spontaneous breath*s that can *initiate assured inflations*, for example, in *assist/control* (A/C) *ventilation* and SIMV *modes*, making the *spontaneous breath rate* measurement dependent on the *ventilation-mode* that has been selected. This practice is considered to be misleading and is not supported in this document. The admitted term ISO *spontaneous-breath rate* has been included for use where it is necessary to highlight this distinction as, for example, was necessary in ISO/IEEE 11073-10101[22].

Note 6 to entry: See also *spontaneous breath* (3.2.3), *breath* (3.2.1), *initiate* (3.9.1), *unassisted breath* (3.2.12), *ventilator-initiation* (3.9.12) and *patient-trigger event* (3.9.6).

3.5.1.4
ventilator-initiated inflation rate
ventilator-initiated rate
number of *inflations initiated* by a timed signal within the *ventilator* in a specified period of time, expressed as *breaths* per minute

Note 1 to entry: In addition to its direct reference, this term, and its symbol, RR_{vent}, displayed in various character styles, is only used, in context or by qualification, to designate this concept as a *measured* quantity (3.1.20).

Note 2 to entry: *Ventilator-initiated inflations* generate *controlled breaths*.

Note 3 to entry: In this document an *inflation initiated* by a *patient-trigger event* is classed as a *patient*-triggered *inflation*; not as a *ventilator-initiated inflation*.

Note 4 to entry: See also *inflation* (3.3.1), *breath* (3.2.1), *initiate* (3.9.1), *ventilator-initiation* (3.9.12), *controlled breath* (3.2.16), *patient-trigger event* (3.9.6) and *assured inflation* (3.3.11).

3.5.1.5
total inflation rate
total number of *inflations initiated* in a specified period of time, expressed as *breaths* per minute

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

3.5.2 Secondary rate concepts — Rate terms for use if required for specific purposes[3)]

3.5.2.1
assured inflation-type rate
number of *assured inflation-type initiations* in a specified period of time, expressed as *breaths* per minute

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

Note 2 to entry: In *Group 1a) and Group 2 ventilation-modes* the *assured inflation-type rate* is assured to be equal to the *set rate*; in *Group 1b) ventilation-modes*, the *assured inflation-type rate* is assured to be at least equal to the *set rate* but will be higher if there are *additional breaths*.

3.5.2.2
unassisted breath rate
number of *spontaneous breath*s with no assistance from an *inflation*, *initiated* in a specified period of time, expressed as *breath*s per minute

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

Note 2 to entry: See also *spontaneous breath* (3.2.3) and *unassisted breath* (3.2.12)

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3) 3.5.1 lists the five principal rate concepts that are necessary for the majority of mode descriptions. Situations might arise where alternative rate concepts are required. Most of these may be formed as post-coordinated terms comprising combinations of simpler terms already defined in this document. The four such terms entered in this subclause are provided only as examples of possible post-coordinated terms.

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3.5.2.3
additional breath rate
number of *additional breaths initiated* in a specified period of time, expressed as *breaths* per minute

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

Note 2 to entry: The *additional-breath rate* is the difference between the *total respiratory rate* and the *set rate*.

Note 3 to entry: See also *additional breath* (3.2.8), *initiate* (3.9.1), *total respiratory rate* (3.5.1.2) and *set rate* (3.5.1.1).

3.5.2.4
concurrent unassisted-breath rate
number of *unassisted spontaneous breaths initiated* during *assured-inflation phases* in a specified period of time, expressed as *breaths* per minute

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

Note 2 to entry: See also *unassisted breath* (3.2.12), *spontaneous breath* (3.2.3) and *concurrent breath* (3.2.9).

3.6 Pressure terminology

3.6.1
airway pressure
pressure at the *patient-connection port*, relative to ambient pressure unless otherwise specified

Note 1 to entry: In addition to its direct reference, this term or its symbol p_{aw}, displayed in various character styles, is only used, in context or by qualification, to designate this concept as a *measured* quantity (3.1.20).

Note 2 to entry: The site(s) of actual measurement(s) may be anywhere in the *ventilator breathing system*, providing that the indicated value is referenced to that at the *patient-connection port*.

Note 3 to entry: This is the generic term for this fundamental concept. Post-coordinated terms, for example, *peak inspiratory pressure* and *baseline airway pressure*, are used in particular contexts.

Note 4 to entry: Although providing no explicit indication as to where along the *patient's airway* this pressure is *measured*, this term, along with its symbol, has become widely adopted as referencing the pressure at the point at which *artificial-ventilation* equipment is connected to the *patient's airway* or to an *airway device*. This is the final site where a common and replicable pressure can be continuously monitored, conveniently, before *breathing* gas enters the *patient*.

Note 5 to entry: A pressure measured in the *patient's airway* at a site other than at the *patient-connection port* is referred to in this document as a respiratory pressure.

Note 6 to entry: The following terms are deprecated for use as synonyms for *airway pressure*: patient pressure; proximal pressure; mouth pressure; pressure at the Y-piece; respiratory pressure; working pressure; inflation pressure; delivered pressure; applied pressure; ventilator pressure. Some of these terms might be valid synonyms but one of the objectives of a terminology standard is to select just one preferred term to represent a given concept.

Note 7 to entry: See also *patient-connection port* (3.14.5), *ventilator breathing system* (3.1.18), *airway* (3.1.2), *artificial ventilation* (3.1.10), *respiratory system* (3.1.17) and Annex C.

3.6.2
inspiratory pressure
support pressure
airway pressure during an *inspiratory* or *inflation phase*

Note 1 to entry: In addition to its direct reference, this term may be used, in context or by qualification, to designate this concept as a *set* quantity (3.1.19) or a *measured* quantity (3.1.20).

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Note 2 to entry: As a *setting*, the value of this quantity is the intended constant pressure level to be attained following a *set rise time*. *Inflation-types* that are *pressure-regulated* to a constant level include *pressure-control* and *pressure-support*.

Note 3 to entry: As a measurement, this is the general term for the pressure at any point in time during an *inspiratory* or *inflation phase*. It will typically be qualified to indicate the point in the phase to which the observation applies, examples being *peak inspiratory pressure*, *plateau pressure* and *end-inspiratory pressure*. It may also be displayed as a waveform. See also G.4.

Note 4 to entry: An *inspiratory pressure* (or *support pressure*) is always relative to ambient pressure, that is, independent of the *baseline airway pressure* unless indicated otherwise by the differential symbol, Δ, as a prefix. See 3.6.7.

Note 5 to entry: The term *support pressure* has been included as a special case of an *inspiratory pressure* that may be used to denote the *airway pressure* during *pressure-support inflations,* primarily because its *setting* is often used alongside a *setting* for a *pressure-control inflation* on a user interface and in this way can be easily separately identified.

Note 6 to entry: The symbols, p_{I} or p_{supp}, displayed in various character styles, are typically used to designate these pressure settings, particularly where space is limited, such as on user interfaces.

Note 7 to entry: The following terms are deprecated as synonyms for the term *inspiratory pressure*: delivered pressure; plateau pressure; pressure limit; respiratory pressure; working pressure; target pressure; end-inspiratory pressure; insufflation pressure.

Note 8 to entry: See also *airway pressure* (3.6.1), *inspiratory phase* (3.4.9), *inflation phase* (3.4.10), *set* (3.1.19), *rise time* (3.3.10), *pressure-regulation* (3.3.9), *baseline airway pressure* (3.10.1), *plateau inspiratory pressure* (3.6.4), *pressure limit* (3.13.1), *end-inspiratory pressure* (3.6.8), Δ *inspiratory pressure* (3.6.7) and Figures C.3 to C.13 and C.22 to C.34.

3.6.3
peak inspiratory pressure
peak pressure
highest *airway pressure* reached during a previous *respiratory cycle*

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

Note 2 to entry: *Peak inspiratory pressure* is always referenced to the ambient pressure.

Note 3 to entry: In this document, the use of *peak inspiratory pressure* or *peak pressure* to denote a *setting* is deprecated.

Note 4 to entry: See also *airway pressure* (3.6.1), *respiratory cycle* (3.4.16), *inspiratory pressure* (3.6.2) and Figures C.9 to C.13, C.23 and C.27.

3.6.4
plateau inspiratory pressure
plateau pressure
airway pressure during an *inspiratory pause* when the flow at the *patient-connection port* is zero

Note 1 to entry: In addition to its direct reference, this term is only used, in context or by qualification, to designate this concept as a *measured* quantity (3.1.20). The corresponding *set* value is that of the *inspiratory pressure*.

Note 2 to entry: Methods used to determine *plateau pressure* include assessment of the *inspiratory pressure* and *inspiratory flow* waveforms, the application of an *inspiratory hold* manoeuvre, whether manual or automated, or by applying a least squares curve-fitting analysis to the *inspiratory pressure* waveform.

Note 3 to entry: With a *pressure-control inflation*, unless the *airway pressure* reaches a constant level during the *inflation phase,* there will be no *plateau pressure* and, therefore, no valid measurement can be made.

Note 4 to entry: Concurrent *patient respiratory activity* or leaks can destabilize the pressure level.

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Note 5 to entry: When given sufficient time at its stabilized level and there is no *airway* flow due to *respiratory activity*, gas distributes throughout the *lungs* as far as is possible and the *plateau inspiratory pressure* typically will be an indication of the end-inspiratory average alveolar pressure.

Note 6 to entry: Although it will often have the same value, this term is not a synonym for *end-inspiratory pressure*.

Note 7 to entry: See also *inspiratory pressure* (3.6.2), *inspiratory hold* (3.4.14), *inspiratory pause* (3.4.12), *end-inspiratory pressure* (3.6.8), *concurrent breath* (3.2.9) and Figure C.12.

3.6.5
inspiratory-pressure relief
means of limiting the *maximum inspiratory pressure* to the *set* level by discharging excess *inspiratory flow* to the atmosphere

Note 1 to entry: The intended maximum *inspiratory pressure* level is determined by the *set pressure limit*.

Note 2 to entry: This form of *pressure limitation* will often result in the *delivered volume* falling below that *set* as the *set* relief-pressure is approached. Awareness of this characteristic is important for *operators* of the simple gas-powered *ventilator*s that typically use such pressure-limitation means and in which there is no independent measurement of the *inspiratory volume* or the *expired tidal volume*.

Note 3 to entry: See also *set* (3.1.19) and *pressure limit* (3.13.1).

3.6.6
Δ
delta
difference between two quantities

Note 1 to entry: This symbol is used in this document as a prefix to denote that the qualified parameter is referenced to another parameter. In particular, it is used in this document to qualify an *inspiratory* or *expiratory pressure* to denote when it is referenced to a *baseline airway-pressure* level instead of to the default, ambient pressure level.

Note 2 to entry: In verbal communication, Δ, as used in this document, is expressed as either 'delta' or 'differential'.

Note 3 to entry: See also *Δ inspiratory pressure* (3.6.7), *inspiratory pressure* (3.6.2), *expiratory pressure* (3.6.9), *baseline airway pressure* (3.10.1) and Figures C.1, C.9, C.10, C.29, C.30 and C.33.

3.6.7
Δ inspiratory pressure
Δ pressure
Δ support 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 (3.1.19) or a *measured* quantity (3.1.20).

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 Δ_H. 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.

Note 4 to entry: See also *Δ* (3.6.6) and Figures C.1, C.9, C.10, C.29, C.30 and C.33.

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3.6.8
end-inspiratory pressure
airway pressure at the point when *inflation termination* is *initiated*

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

Note 2 to entry: This pressure is displayed or recorded as the last *measured* value of the *inspiratory pressure* before the *initiation* of *inflation termination*.

Note 3 to entry: This pressure might be coincident with the *peak inspiratory pressure* or the end of an *inspiratory pressure plateau* and hence have the same value.

Note 4 to entry: The end-*inspiratory pressure* is always recorded and displayed as an *airway pressure*, that is, as relative to ambient pressure, unless indicated otherwise by the differential symbol, Δ, as a prefix.

Note 5 to entry: See also *airway pressure* (3.6.1), *inflation phase* (3.4.10), *initiate* (3.9.1), *terminate* (3.9.14), *peak inspiratory pressure* (3.6.3), *plateau inspiratory pressure* (3.6.4), *Δ inspiratory pressure* (3.6.7) and Figure C.9 to C.13.

3.6.9
expiratory pressure
respiratory pressure during an *expiratory phase*

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

Note 2 to entry: In this document, an *expiratory pressure* is taken to be an *airway pressure* unless used in a compound (post-coordinated) term, in which case the new name or its definition can indicate an alternative measurement reference site or reference pressure level.

Note 3 to entry: As a measurement, this is the general term for the pressure at any point in time during an *expiratory phase*. It will typically be qualified to indicate the point in the phase or the site to which the observation applies. It may also be displayed as a waveform.

Note 4 to entry: The *expiratory pressure* is always relative to ambient pressure, that is, independent of the *baseline airway pressure* unless indicated otherwise by the differential symbol, Δ, as a prefix.

Note 5 to entry: See also *airway pressure* (3.6.1), Figure C.9 to C.12, A.4 – 3, and G.4.

3.6.10
expiratory pressure-relief
means that relieves *expiratory pressure* at the *initiation* of and throughout the *expiratory phase* by allowing *expiratory flow* to pass through to the *exhaust port* with minimal resistance when above the BAP level, but which inhibits that flow below the BAP level

Note 1 to entry: Separate valves providing this function (often referred to as PEEP valves) are, typically, standard accessories with bag-valve-mask *ventilator*s.

Note 2 to entry: With this function acting alone during a BAP *phase*, an *unassisted inspiration* might incur additional work of *breathing*, and if there is a leak in the *ventilator breathing system* or at the connection to the *patient*, the *airway pressure* might fall towards the ambient pressure, which will result in a loss of the intended PEEP. Such consequences can be mitigated by the provision of a *bias flow* or prevented by the provision of *demand flow* or an ACAP *adjunct*, active at the BAP level.

3.6.11
tube compensation
TC
airway-pressure offset feature provided by a *ventilator* during the *inspiratory phase* of an *unassisted* or *supported spontaneous breath*, or during an *expiratory phase*, specifically for the intended purpose of compensating, at least in part, for any added *airway resistance* imposed by an *airway device*

Note 1 to entry: *Tube compensation* is not classified as an *inflation-type* because its intention is to provide compensation for an artificially imposed resistive load and not to unload some of the *patient*'s work of *breathing*.

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Note 2 to entry: The assistive offset is typically calculated by the *ventilator*, based on information entered by the *operator,* for example, the inside diameter of an endotracheal tube.

Note 3 to entry: The assistive offset is not intended to compensate for the effects of *lung* stiffness.

Note 4 to entry: To achieve compensation during the *expiratory phase* of a *breath* the *airway pressure* may be reduced below the *baseline airway pressure* for part of the *expiratory phase* but this document does not sanction the intentional application of sub-ambient pressures to the *patient-connection port*.

Note 5 to entry: See also *airway pressure* (3.6.1), *inspiratory phase* (3.4.9), *unassisted breath* (3.2.12), *supported breath* (3.2.13), *spontaneous breath* (3.2.3), *expiratory phase* (3.4.2), *baseline airway pressure* (3.10.1) and *patient-connection* port (3.14.5).

3.7 Flow terminology

3.7.1
inspiratory flow
DEPRECATED: peak flow
DEPRECATED: flow limit
flow of gas delivered to the *patient* through the *patient-connection port* during an *inspiratory* or *inflation phase*

Note 1 to entry: In addition to its direct reference, this term may be used, in context or by qualification, to designate this concept as a *set* quantity (3.1.19) or a *measured* quantity (3.1.20).

Note 2 to entry: In the absence of suitable standardization, the abbreviation, "*Flow*", displayed in various character styles, is typically used by manufacturers to designate the constant *inspiratory flow setting*, particularly on user interfaces where space is often limited, and in user manuals.

Note 3 to entry: Where an *inflation* serves to augment a *patient's spontaneous breath* then, conceptually, *inspiratory flow* can be seen as being comprised of a component of *demand flow* resulting from the *patient's inspiratory efforts* and a component of flow due solely to the raised pressure of the *inflation*. However, currently, most *ventilators* cannot separate these two components and so the unattributed inclusive term, *inspiratory flow*, has been adopted in this document for general use. The term *demand flow* is included in this document for use when there is a necessity to make reference to the flow resulting solely from the *patient's inspiratory efforts* as a separate concept.

Note 4 to entry: The *set inspiratory flow* will be a good representation of the actual flow that generates the *tidal volume* when it all enters the *patient's* respiratory tract. This is frequently not the case due to, for example, leakage at the *patient/airway device* interface [particularly in neonatal and NIV (*non-invasive ventilation)*] and from the *operator*-detachable part of the *ventilator breathing system*. With these conditions, a more reliable indication of the actual flow that will enter the respiratory tract will be provided if the *inspiratory flow* is leak-compensated relative to that *set*.

Note 5 to entry: For further information on the semantics of *measured* quantities and the term *inspiratory flow* in this document see A.4 -3, G.3, G.4 and Annex H.

Note 6 to entry: See also *inspiratory effort* (3.2.7), *demand flow* (3.7.10), *tidal volume* (3.8.1), *delivered volume* (3.8.2), *inspiratory volume* (3.8.3) and the Figures of Annex C.

3.7.2
peak inspiratory flow
highest flow of gas delivered to the *patient* through the *patient-connection port* during an *inspiratory* or *inflation phase*

Note 1 to entry: In addition to its direct reference, this term may be used, in context or by qualification, to designate this concept as a *measured* value but in this document, is not used to designate this concept as a *set* value (3.1.19).

Note 2 to entry: See also Figures C.1, C.2 and C.9 to C.11.

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3.7.3
inspiratory-termination flow
termination flow
inspiratory flow threshold at which the *termination* of a *flow-terminated inflation-type* is *initiated*

Note 1 to entry: In addition to its direct reference, this term is only used, in context or by qualification, to designate this concept as a *set* quantity (3.1.19).

Note 2 to entry: This threshold flow is typically expressed as either a *set inspiratory-termination flow* or a *set* percentage of the *peak inspiratory flow*.

Note 3 to entry: For labelling purposes a further abbreviation, such as, Term'n flow %, can be appropriate

Note 4 to entry: See also *inspiratory flow* (3.7.1), *flow-termination* (3.9.15), *termination* (3.9.14), *peak inspiratory flow* (3.7.2), *initiate* (3.9.1), and Figures C.6 and C.10.

3.7.4
end-inspiratory flow
inspiratory flow at the point when *inflation termination* is *initiated*

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

Note 2 to entry: This flow is that *measured* before the *inspiratory-flow* waveform trajectory transitions towards zero in response to a *termination* signal; the *inflation phase* itself does not *terminate* until the commencement of *expiratory flow*.

Note 3 to entry: The *measured* value can be expected to be closer to the *actual value* if the measurement is leak-compensated.

Note 4 to entry: See also *inspiratory-termination flow* (3.7.3), *terminate* (3.9.14), *inspiratory flow* (3.7.1), *initiate* (3.9.1), *inflation phase* (3.4.10) and Figure C.5.

3.7.5
expiratory flow
flow from the *patient* through the *patient-connection port* during an *expiratory phase*

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

Note 2 to entry: The integral of the *measured* ex*piratory flow* will be a good representation of the *expired tidal volume* when there is no gas loss. This is frequently not the case due, for example, to leakage at the *patient/airway device* interface [particularly in neonatal and NIV (*non-invasive ventilation*)]. With these conditions, a more reliable indication of the actual *expired tidal volume* will be provided if the ex*piratory flow* is leak-compensated.

Note 3 to entry: See also *patient-connection port* (3.14.5), *expiratory phase* (3.4.2), *expired tidal volume* (3.8.4), *leakage tidal volum*e (3.8.5), *airway device* (3.1.3), NIV (3.1.15) and the Figures of Annex C.

3.7.6
end-expiratory flow
expiratory flow at the point of *initiation* of an *inflation* or an *inspiration*

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

Note 2 to entry: This flow, if any, is that *measured* before the *expiratory-flow* waveform trajectory transitions towards zero in response to either an *inflation-initiation* signal or the *initiation* of an *unassisted breath*.

Note 3 to entry: As a *measured* value, *end-expiratory flow* is an indication of *auto*-PEEP that has not fully dissipated and, therefore, that the pressure in the *lungs* might be higher than the intended minimum.

Note 4 to entry: The *measured* value might be closer to the *actual value* if the measurement is leak-compensated.

Note 5 to entry: See also Figures C.8 and C.31.

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3.7.7
bias flow
flow that passes through the *ventilator breathing system* to the *exhaust port* but is not intended to contribute to the work of *lung ventilation*

Note 1 to entry: In addition to its direct reference, this term may be used to designate this concept, in context or by qualification, as a *set* value (3.1.20).

Note 2 to entry: The term *bias flow* is used to refer to an intended low-level flow that passes right through the *ventilator breathing system* with the purpose of improving the responsiveness and accuracy of the *ventilator*'s control and detection systems, and of minimising the rebreathing of expired gas. It is typically only maintained during an *expiratory phase* but can be maintained throughout a *respiratory cycle*.

3.7.8
continuous flow
gas flowing continuously through the *ventilator breathing system*, with a proportion intermittently passing to the *patient's lung* whenever the *airway pressure* is raised by the *ventilator* or an *operator* action, or flow is demanded by a *patient's inspiratory effort*

Note 1 to entry: In addition to its direct reference, this term may be used to designate this concept, in context or by qualification, as a *set* value (3.1.20).

Note 2 to entry: A constant, *continuous flow* in the *inspiratory* limb of the *ventilator breathing system* is commonly used in the *artificial ventilation* of neonatal and paediatric *patients*.

Note 3 to entry: The *airway pressure* can be intermittently raised to a *set pressure-limited inspiratory pressure*, for example, by the use of an adjustable pressure-relief valve operating in parallel with either the timed occlusions of an *expiratory* valve, or the manual occlusions of a normally-open *exhaust port*.

Note 4 to entry: See also *ventilator breathing system* (3.1.18), *lung* (3.1.16), *airway pressure* (3.6.1), *inspiratory effort* (3.2.7), *set* (3.1.19), *artificial ventilation* (3.1.10), *pressure-limited* (3.13.2) and *exhaust port* (3.14.2).

3.7.9
decreasing flow pattern
DEPRECATED: decelerating-flow pattern
airway-flow waveform with a continuously decreasing flow

Note 1 to entry: This term is applicable to the description of

— a selectable *inspiratory-flow* waveform pattern following an initial rise,

— the *inspiratory-flow* waveform pattern of a *pressure-regulated inflation* following an initial rise, and

— a typical *expiratory-flow* waveform.

Note 2 to entry: A *decreasing flow pattern* is assumed to be nominally linear unless otherwise indicated. In most applications, the precise linearity of such a waveform is not critical and so this term is appropriate to describe a range of waveforms that includes those that might have minor nonlinearities, providing these are essentially inconsequential.

Note 3 to entry: If the *decreasing flow pattern* is other than nominally linear this should be indicated – preferably by the addition of an appropriate descriptive term, thereby creating a new post-coordinated term.

Note 4 to entry: An example of a typical nonlinear pattern is illustrated in Figure 1, which is designated, for example, as a concave *decreasing flow pattern*. This a typical flow-waveform pattern resulting from a *pressure-regulated inflation* following an initial rise, or of a typical *expiration*. Although not a common feature, this term is alternatively applicable to the description of a selectable *inspiratory flow* waveform pattern of this form for a *volume-control* (VC) *inflation*; a selectable pattern intended to merge some of the benefits of a *pressure-control* (PC) *inflation* waveform with those of *volume-control*.

Note 5 to entry: A concave *decreasing flow pattern* is typical of the *airway* flow waveform observed in situations where the applied pressure difference across the *airway resistance* is changing due to the charging or discharging of the compliant *lung*. Such a pattern is sometimes referred to as an exponential waveform although there is generally too much nonlinearity in the system for that to be even approximately the case.

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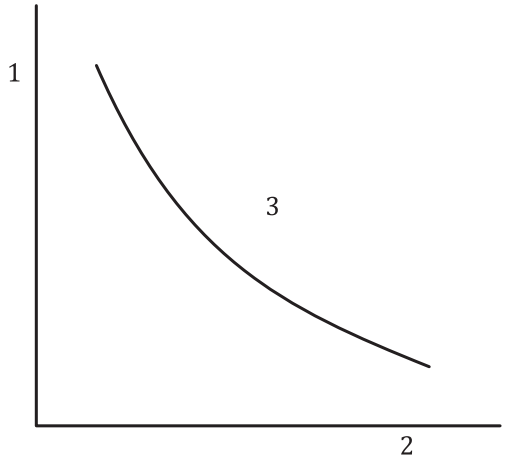
Note 6 to entry: Although a commonly used term, 'decelerating-flow pattern' is an incorrect designation for any form of decreasing flow pattern in that the rate of flow of a gas, which is essentially a measure of its velocity, cannot be 'decelerated'; it is only a volume of the gas that can be accelerated and decelerated - not the 'velocity' of that gas.



Key

1 inspiratory flow

2 time

3 concave decreasing flow pattern

Figure 1 — Example of a decreasing flow pattern

3.7.10
demand flow
flow generated by a *ventilator* solely to meet the flow demand of the *patient* while acting to maintain the *airway pressure* at its intended value

Note 1 to entry: In addition to its direct reference, this term may be used, in context or by qualification, to designate this concept as a *measured* quantity (3.1.20).

Note 2 to entry: This term denotes the specific subset of *inspiratory flow* that is solely due to the *patient's* spontaneous *inspiratory efforts* when connected to a *ventilator*. In certain contexts, a term for this distinction is helpful but where this is unimportant the concept can be assumed to be included within the scope of the generalized term, *inspiratory flow* (see Notes to 3.7.1).

Note 3 to entry: During *unassisted breathing*, the intention is that the *demand flow* will meet the *patient's* flow demands in a manner that allows *unrestricted breathing* at the applicable BAP level. This can involve the use of a function that temporarily elevates the *airway pressure* slightly, with the intention of compensating for the possible pressure drop across an *airway device* or for the inevitable pressure drop that is necessary for the *pressure-regulation* function to provide flow in proportion to the demand. Alternatively, it can be provided by the provision of ACAP, an *adjunct* that facilitates *unrestricted breathing* by the generation of *demand flow* in proportion to the *patient's* demand, with no dependency on a *patient-trigger event*.

Note 4 to entry: Where *spontaneous breaths* are given assistance by an *inflation*, the flow through the *patient-connection port* during the *inflation phase* will be the sum of that due to the raised pressure of the *inflation* and that due to the flow demand resulting from the *patient's inspiratory effort*. Because there is currently no reliable way to separate these two components, in this document the total of the flow generated is denoted by the inclusive, general term, *inspiratory flow*.

Note 5 to entry: Because a *demand flow* function is required to provide flow in proportion to the demand it is necessary for it to be independent of any *set trigger level*.

Note 6 to entry: See also *airway pressure* (3.6.1), *inspiratory flow* (3.7.1), *unrestricted breath* (3.2.5), *BAP* (3.10.2), *airway device* (3.1.3), *pressure-regulation* (3.3.9), *ACAP* (3.12.1), *patient-trigger event* (3.9.6), *spontaneous breath* (3.2.3), *inflation* (3.3.1), *inspiratory effort* (3.2.7), *set* (3.1.19) and *trigger level* (3.9.5).

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3.7.11
airway leak
loss of respiratory gas from its pathway between the *patient-connection port* interface and the *lungs*

Note 1 to entry: In addition to its direct reference, this term may be used, in context or by qualification, to designate this concept as a *measured* quantity (3.1.20).

Note 2 to entry: Loss of gas at the interface between a mask or endotracheal tube and the *patient* is considered to be an *airway leak,* as is also loss of gas at the *patient-connection port* interface.

Note 3 to entry: An *airway leak* can be expressed as a flow rate or a volume and during an *inspiratory, inflation* or *expiratory phase*, or during a period of time.

Note 4 to entry: See also *patient-connection port* (3.14.5), *airway* (3.1.2), *inspiratory phase* (3.4.9), *inflation phase* (3.4.10) and *expiratory phase* (3.4.2).

3.7.12
ventilator breathing system leak
VBS leak
loss of gas from the *ventilator breathing system*

Note 1 to entry: In addition to its direct reference, this term may be used, in context or by qualification, to designate this concept as a *measured* value (3.1.20).

Note 2 to entry: With this definition, this leak does not include any loss of gas at or beyond the interface at the *patient-connection port*.

Note 3 to entry: The term may be applied to the total *ventilator breathing system* leakage or, more specifically, to any leakage that influences the displayed values of *delivered volume* or *expired minute volume*. Any such implications should be disclosed by the *manufacturer*.

Note 4 to entry: Relevant international standards generally require that *ventilator breathing system leakag*e should not exceed a specified rate of flow, expressed at BTPS (body temperature and pressure, saturated).

Note 5 to entry: See also *ventilator breathing system* (3.1.18), *patient-connection port* (3.14.5), *delivered volume* (3.8.2) and *expired minute volume* (3.8.9).

3.8 Volume terminology

3.8.1
tidal volume
volume of gas that enters and leaves the *lung* during a *breath*

Note 1 to entry: In addition to its direct reference, this term or its symbol, V_T, displayed in various character styles, may be used, in context or by qualification, to designate this concept as a *set* quantity (3.1.19). As a *measured* quantity, it is only used to designate this concept when expressed as a compensated value.

Note 2 to entry: In practice, the volumes that enter and leave the *lung* are typically *measured* as *delivered* (or *inspiratory*) *volumes* and *expired tidal volumes* because, even without leakage, these two quantities will only be nominally equal due to physical and/or compositional changes of the gas and normal physiological variation in end-*expiratory lung* volume. Leakages between the point at which the flow towards the *patient* is *measured* and the *lung*, such as occur at the connection to the *patient's airway*, will increase these discrepancies.

Note 3 to entry: Without leakage compensation the *measured expired tidal volume* will be a better representation of the actual *tidal volume* because leakage is less during *expiration* than during delivery due to the lower mean *airway pressure*. Where leakage compensation is in operation, the actual *delivered* and *inspiratory volumes* are typically greater than the *set tidal volume*, but the compensated *tidal volume* provides a better representation of the actual *tidal volume*.

Note 4 to entry: With *ventilation* equipment where no *inspiratory* or *expired* volume *measurements* are available the actual *tidal volume* might deviate from the *set* value as a result of the factors referred to in Note 2 to this entry.

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3.8.2
delivered volume
net volume of gas delivered to the *gas output port* during an *inspiratory* or *inflation phase*

Note 1 to entry: In addition to its direct reference, this term or its symbol, V_{Del}, displayed in various character styles, may only be used, in context or by qualification, to designate this concept as a *measured* quantity (3.1.20).

Note 2 to entry: The *delivered volume* is a good representation of the actual *tidal volume* when all of the *delivered volume* enters the *patient's* respiratory tract. This is frequently not the case due to, for example, leakage around the endotracheal tube or face mask [particularly in neonatal and NIV (*non-invasive ventilation*)]. However, where the actual *delivered volume* is leak-compensated relative to that *set* the *setting* is considered to be a sufficiently reliable indication of the *tidal volume* for it to be so labelled.

Note 3 to entry: The *delivered volume* is defined as a net volume because it is the actual volume delivered minus any volume that passes through the *expiratory* valve as a consequence of a *bias flow*.

Note 4 to entry: See also *gas output port* (3.14.3), *inflation* (3.3.1), *inspiratory phase* (3.4.9), *tidal volume* (3.8.1), *set* (3.1.19), *expiration* (3.2.11) and *bias flow* (3.7.7).

3.8.3
inspiratory volume
volume of gas delivered through the *patient-connection port* during an *inspiratory* or *inflation phase*

Note 1 to entry: In addition to its direct reference, this term or its symbol, V_{I}, displayed in various character styles, may only be used, in context or by qualification, to designate this concept as a *measured* quantity (3.1.20).

Note 2 to entry: This is the concept designated by 'delivered volume', in ISO 4135:2001,3.4.2; a term that has not been widely adopted to date. It is a concept relevant to where *measurements* of volume made close to the *patient-connection port,* such as is typically the case with self-contained, multi-parameter *patient* monitors, as distinct from the redefined *delivered volume*, which is applicable to *ventilator*s where the *inspiratory flow* is determined or *measured* within the body of the *ventilator*. The closer site of *measurement* means that this quantity only differs from the actual volume entering the *lung* by the amount of any volume loss occurring at the connection to the *patient's airway*.

Note 3 to entry: See also *patient-connection port* (3.14.5), *inspiratory phase* (3.4.9), *inflation phase* (3.4.10), *delivered volume* (3.8.2), *inspiratory flow* (3.7.1) and *tidal volume* (3.8.1).

3.8.4
expired tidal volume
volume of gas leaving the *lung* through the *patient-connection port* during an *expiratory phase*

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

Note 2 to entry: Where there is *concurrent breathing*, although the *ventilator* can determine the *inspiratory volumes* of the *additional breath*s their *expirations* will most often be inevitably combined with that from the *assured inflation*, which is typically displayed with no separate attributions.

Note 3 to entry: This term would be appropriate to designate this concept, in context or by qualification, as a *set* target value for this quantity but this is typically not currently practiced because of other factors that would have to be taken into account.

Note 4 to entry: See also *lung* (3.1.16), *patient-connection port* (3.14.5), *expiratory phase* (3.4.2), *concurrent breath* (3.2.9), *inspiratory volume* (3.8.3), *additional breath* (3.2.8), *assured inflation* (3.3.11) and *set* (3.1.19).

3.8.5
leakage tidal volume
volume of gas lost between the *measurement* of the volume passing to the *patient* and the *measurement* of the corresponding *expired tidal volume*, due to leakage during a *respiratory cycle*

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

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Note 2 to entry: This leakage is typically estimated based on a comparison of the *measured* volume passing to the *patient* with the *measured expired tidal volume*, and the mean *inspiratory* and *expiratory pressures*.

Note 3 to entry: See also *respiratory cycle* (3.4.16), *airway leak* (3.7.11), *expired tidal volume* (3.8.4), *inspiratory pressure* (3.6.2) and *expiratory pressure* (3.6.9).

3.8.6
minute volume
DEPRECATED: $\dot{V}$
volume of gas either passing to or leaving the *lung* during *inspiratory* or *inflation phases*, or *expiratory phases*, respectively, expressed as a volume per minute

Note 1 to entry: In addition to its direct reference, this term or its symbol, V_M, displayed in various character styles, may be used, in context or by qualification, to designate this concept as a *set* quantity (3.1.19). As a *measured* quantity, it is only used to designate this concept when expressed as a compensated value.

Note 2 to entry: Unless otherwise qualified, this term designates the volume either passing to or leaving the *lung* during all of the respective *inspiratory* or *inflation phases*, or *expiratory phases* that have occurred during the period of *measurement*. This term is appropriately qualified when used to denote the *minute volumes* resulting from specific types of *inflations* or *breaths* [for an example, see *assured minute volume* (3.8.11)].

Note 3 to entry: While a *minute volume* is expressed as a volume per minute, the actual measurement period will typically be that of a specified number of complete *respiratory cycles* or of a time other than one minute, in order to provide a more consistent average value. The term by itself suggests that its value is that of a volume but experience has indicated that users prefer the assurance of it being expressed as an average flow rate, that is, as a volume/min.

Note 4 to entry: In practice, the volumes that enter and leave the *lung* per minute are typically *measured* as *delivered* or *inspiratory minute volumes* and *expired minute volumes* because, even without leakage, these two quantities will only be nominally equal due to physical and/or compositional changes of the gas and normal physiological variations in end-*expiratory lung* volume. Leakages between the point at which the flow towards the *patient* is *measured* and the *lung*, such as occur at the connection to the *patient's airway*, will increase these discrepancies.

Note 5 to entry: Without leakage compensation, the *measured expired minute volume* is expected to be a better representation of the actual *minute volume* because leakage is less during *expiration* than during delivery due to the lower mean *airway pressure*. Where leakage compensation is in operation the actual *delivered* and *inspiratory minute volumes* are typically greater than the *set minute volume* but the compensated *minute volume* provides a better representation of the actual *minute volume*.

Note 6 to entry: With *ventilation* equipment where no *inspiratory* or *expired minute volume* measurements are available the actual *minute volume* might deviate from the *set* value as a result of the factors referred to in Note 2 to this entry.

Note 7 to entry: See also *lung* (3.1.16), *respiratory cycle* (3.4.16), *delivered minute volume* (3.8.7), *inspiratory minute volume* (3.8.8), *expired minute volume* (3.8.9), *inspiratory volume* (3.8.3) and *expiration* (3.2.11).

Note 8 to entry: The symbol, $\dot{V}$, is sometimes used as a designation for *minute volume*. This is incorrect because $\dot{V}$ is a symbol for the differential of volume with time, that is, dV/dt, which is an instantaneous flow rate. *Minute volume* is the integral of a varying flow rate and so reflects the average rate of flow. For correct representation this would require the addition of '¯' above the $\dot{V}$, which presents typological difficulties.

3.8.7
delivered minute volume
net volume of gas delivered to the *gas output port* during all *inflation* and *inspiratory phases*, expressed as a volume per minute

Note 1 to entry: In addition to its direct reference, this term or its symbol, V_{MDel}, displayed in various character styles, may only be used, in context or by qualification, to designate this concept as a *measured* quantity (3.1.20).

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Note 2 to entry: *Delivered minute volume* is also referred to as *minute volume* when all of the *delivered volume* enters the *patient's* respiratory tract. This is frequently not the case due to, for example, leakage at the *patient/ventilator* interface [particularly in neonatal and NIV (non-invasive ventilation)]. However, where the displayed *minute volume* of gas delivered is leak-compensated the observation is considered to be a sufficiently reliable indication of the *minute volume* for it to be so labelled.

Note 3 to entry: See also *ventilator breathing system* (3.1.18), *inflation phase* (3.4.10), *inspiratory phase* (3.4.9), *minute volume* (3.8.6), *delivered volume* (3.8.2) and NIV (3.1.15).

3.8.8
inspiratory minute volume
volume of gas delivered through the *patient-connection port* during all *inflation* and *inspiratory phases*, expressed as a volume per minute

Note 1 to entry: In addition to its direct reference, this term or its symbol, V_{MI}, displayed in various character styles, may only be used, in context or by qualification, to designate this concept as a *measured* quantity (3.1.20).

Note 2 to entry: This is the concept designated by delivered ventilation, in ISO 4135:2011,3.4.1; a term that has not been widely adopted to date. It is a concept relevant to *measurements* of volume made close to the *patient-connection port*, such as is typically the case with self-contained, multi-parameter *patient* monitors, as distinct from the redefined *delivered minute volume* (3.8.7), which is applicable to *ventilators* where the *inspiratory flow* is determined or *measured* within the body of the *ventilator*. Having the site of *measurement* closer to the *patient* means that this quantity only differs from the actual volume entering the *lung* per minute by the amount of any *leakage minute volume* occurring at the connection to the *patient's airway*.

Note 3 to entry: See also *minute volume* (3.8.6), *patient-connection port* (3.14.5), *delivered minute volume* (3.8.7), *inspiratory flow* (3.7.1), *lung* (3.1.16), *leakage minute volume* (3.8.10), *airway* (3.1.2) and *expired minute volume* (3.8.9).

3.8.9
expired minute volume
DEPRECATED: expired ventilation
volume of gas leaving the *lung* through the *patient-connection port* during all *expiratory phases*, expressed as a volume per minute

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

Note 2 to entry: See also *expired tidal volume* (3.8.4), *minute volume* (3.8.6) and *inspiratory minute volume* (3.8.8).

3.8.10
leakage minute volume
volume of gas lost between the *measurement* of the volumes passing to the *patient* and the *measurement* of the corresponding *expired minute volumes*, due to leakage during a specified time or number of *respiratory cycles*, expressed as a volume per minute

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

Note 2 to entry: This leakage is typically estimated based on a comparison of the known delivered flows/volume with the *measured expiratory flows*/volume, and the mean *inspiratory* and *expiratory pressures*.

3.8.11
assured minute volume
minute volume due to the *ventilation set rate*

EXAMPLE 1 The *minute volume* resulting from all the *assured inflations* in an SIMV *mode*.

EXAMPLE 2 The *minute volume* resulting from the *set* number of *assured inflations* in an *assist/control* (A/C) *ventilation-mode*.

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