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Lung ventilators and related equipment — Vocabulary and semantics

Ventilateurs pulmonaires et équipement associé — Vocabulaire et sémantique

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Foreword

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

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

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

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

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

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

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

Introduction

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

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

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

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

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

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

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

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

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

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

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

In this document, the following print types are used:

Definitions: roman type.

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

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

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

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

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

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

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

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

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

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

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

— Tables: D.1 to D.3, E.1 and E.2.

Lung ventilators and related equipment — Vocabulary and semantics

1 * Scope

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

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

— in health informatics standards,

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

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

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

— in electronic health records.

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

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

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

2 Normative references

There are no normative references in this document.

3 * Terms, definitions, symbols, and abbreviated terms

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

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

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

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

3.1 General artificial-ventilation terminology

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3.1.9
ventilation
cyclical movement of a respirable gas into and out of the *lungs*

Note 1 to entry: This might be by external or spontaneous means, or by a combination of both.

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

3.1.10
artificial ventilation
intermittent elevation of the pressure in the *patient's airway* relative to that in the *lungs* by external means with the intention of augmenting, or totally controlling, the *ventilation* of a *patient*

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

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

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

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

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

3.1.11
mechanical ventilation
artificial ventilation by means of a mechanical device

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

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

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

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

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

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

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

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

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

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

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

Note 2 to entry: See also Clause 1.

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

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

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

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

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

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

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

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

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

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

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

3.1.18
ventilator breathing system
VBS
anaesthesia breathing system
pathways through which gas flows to or from the *patient* at respiratory pressures, bounded by the *port* through which respirable gas enters, the *patient-connection port* and the gas *exhaust port*

Note 1 to entry: These pathways typically extend within and outside the body of the *ventilator*, with those outside being *operator*-detachable.

Note 2 to entry: The *port* of entry of a respirable gas into the *ventilator breathing system* can be inside the body of the *ventilator* and should not be confused with an external connection *port* into which respirable gas enters before being reduced to respirable pressures.

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

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

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

3.1.19
set
allocated a specific value

EXAMPLE 1 A *set* pressure *limit.*

EXAMPLE 2 The *set inspiratory pressure*.

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

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

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

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

3.1.20
measured
determined by a measuring device or system

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

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

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

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

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

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

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

— a tool,

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

— an individual *operator* password,

— voice recognition, or

— biometric means.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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 breaths* 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 *breaths* 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 breaths*, as are spontaneous *inspiration* and spontaneous *expiration*.

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 *breathe* 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) *inflations*.

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*.

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).

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 breaths* 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.

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.

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.

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 *ventilator*s 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 *breath*s 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 breath*s.

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.

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.

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).

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.

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.

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.

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).

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*.

Note 2 to entry: If additional *spontaneous breath*s 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.

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.

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).

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.

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.

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) *inflations* 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 cycles* 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 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, 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 breaths*, 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 *breaths* and spurious events.

Note 5 to entry: Many legacy *ventilators* 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 breaths* 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 breaths* with no assistance from an *inflation*, *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: See also *spontaneous breath* (3.2.3) and *unassisted breath* (3.2.12)

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*.

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.

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).

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.

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 *ventilators* 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.

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 *ventilators*.

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*.

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 effort*s and a component of flow due solely to the raised pressure of the *inflation*. However, currently, most *ventilator*s 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 effort*s 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.

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* expiratory *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 *expiratory 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 volume* (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.

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.

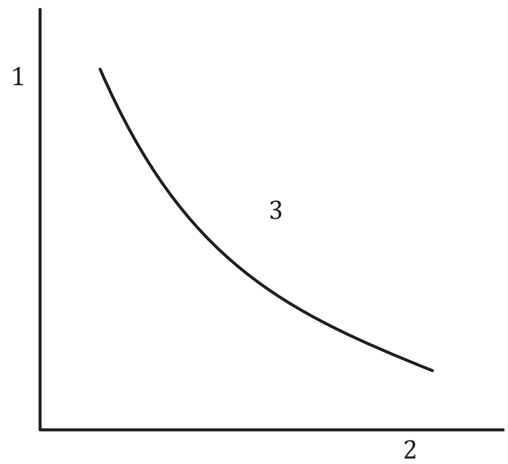
Note 2 to entry: A *decreasing flow pattern* is assumed to be nominally linear unless otherwise indicated. In most applications, the precise linearity of such a waveform is not critical and so this term is appropriate to describe a range of waveforms that includes those that might have minor nonlinearities,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

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 breath*s 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).

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 leakage* 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.

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 *ventilators* 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 breaths* 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).

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 pressure*s.

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 phase*s, 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 *inflation*s or *breath*s [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 cycle*s 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).

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 phase*s, 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 flow*s/volume, and the mean *inspiratory* and *expiratory pressure*s.

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*.

Note 1 to entry: In addition to its direct reference, this term or its symbol, V_{MAssd}, displayed in various character styles, is used, in context or by qualification, to designate this concept as a *set* quantity (3.1.19) for *ventilation-modes* with *volume-control* or *volume-targeted inflation-types*. It is a *measured* quantity (3.1.20) for *ventilation-modes* with *pressure-control inflation-types*.

Note 2 to entry: The *assured minute volume* is the *minute volume* resulting only from *inflations* assured to be delivered at intervals determined by the *set rate*.

Note 3 to entry: The volume of gas delivered at the *set rate* is only assured when *volume-control inflation-types* are selected for that delivery. The average volume of gas delivered can be assured by the selection of *volume-targeted pressure-control inflation-types.* With *pressure-control inflation-types*, only the rate of delivery is assured, and the volume of gas in each delivery can deviate from that initially *set*, which means that the actual *minute volume* resulting from the *assured inflations* can only be determined by *measurement.*

Note 4 to entry: Where leakage-compensated *measurements* of this quantity are available these may be used in the place of *expired minute volume measurements*.

Note 5 to entry: See also *ventilation* (3.1.9), *rate* (3.5.1.1), *ventilation-mode* (3.11.2), *volume targeted* (3.3.15), *inflation-type* (3.3.2), *assured inflation* (3.3.11) and *mandatory* (3.9.9).

3.8.12
additional minute volume
minute volume that is additional to the *assured minute volume*

EXAMPLE 1 The volume resulting from all *unassisted* and *supported breaths*.

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

Note 1 to entry: In addition to its direct reference, this term or its symbol, V_{MAddn}, 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 is the *minute volume* resulting from any *unassisted breaths* and from *inflations* delivered in addition to the *set rate*.

Note 3 to entry: In *assist/control* (A/C) *ventilation-modes*, the *additional minute volume* is determined as the *additional-breath-rate/total-respiratory-rate* proportion of the *expired minute volume* resulting from *inflations*.

Note 4 to entry: Where leakage-compensated *measurements* of this quantity are available these may be used in the place of *expired minute volume measurements*.

Note 5 to entry: See also *minute volume* (3.8.6), *assured minute volume* (3.8.11), *unassisted breath* (3.2.12), *supported breath* (3.2.13), *assist/control ventilation* (3.11.8), *rate* (3.5.1.1), *total respiratory rate* (3.5.1.2), *expired minute volume* (3.8.9) and *inflation* (3.3.1).

3.9 Initiation and termination terminology

3.9.1
initiate
cause a process or action to begin

Note 1 to entry: This word has been adopted in this document as the general term to designate the concept of causing a process or action to begin. This is to counter a tendency to use the word ‘trigger’ for this purpose; a trend that removes the ability of that term to differentiate its own special meaning from that of a simple timed switching action. In this document, an *inflation* can be *initiated* by, for example:

— a *patient-trigger event*;

— a timed signal;

— a manual input;

— a conditional *termination* of an *expiratory phase*;

— a signal from a remote device.

Note 2 to entry: In this document, an *inflation* that is *initiated* by a timed signal may be referred to as being *ventilator-initiated*.

Note 3 to entry: A conditional *termination* of an *expiratory phase* is typically achieved by establishing an *expiratory-flow* threshold at which the next *inflation* is *initiated*. An *initiation* of this type is sometimes used, for example, to optimize the *expiratory time* in an APRV (*airway pressure release ventilation*) *mode*. Such a threshold flow is typically expressed as either a *set expiratory flow* or a *set* percentage of the *peak expiratory-flow*.

Note 4 to entry: See also *trigger* (3.9.2), *ventilator-initiation* (3.9.12), *patient-trigger event* (3.9.6), *terminate* (3.9.14) and APRV (3.11.14).

3.9.2
trigger
DEPRECATED: time trigger
DEPRECATED: manual trigger
DEPRECATED: remote trigger
function that detects that the *measured* value(s) of a parameter(s) that can be attributed to the *patient* has reached the threshold value required to *initiate* another event

Note 1 to entry: This is the definition of the basic concept of a *trigger* function, as the term is used in this document. In practice, some such functions might monitor the value of more than one parameter and make use of dedicated detection algorithms in order that sensitive *settings* can be used with a minimum risk of *auto-triggering*.

Note 2 to entry: This term is used to differentiate that class of *inflation initiation* signals that depend upon the attainment of a threshold by the *measured* value of a *patient* parameter, and hence involve a sensitivity *setting*, from those generated directly by the operation of simple timed, manual or remote, binary-switch functions.

Note 3 to entry: See also *initiate* (3.9.1), *auto-trigger* (3.9.10), *inflation* (3.3.1) and *patient-trigger event* (3.9.6).

3.9.3
flow trigger
trigger that detects when changes of flow in the *ventilator breathing system* reach a *set* threshold level

Note 1 to entry: This is a classification for the means of detecting a *patient's inspiratory effort* in generating a *patient-trigger event*. As explained in Note 1 to 3.9.2, in practice, some such functions might monitor the value of more than one parameter and make use of dedicated detection algorithms in order that a sensitive *setting* can be used with minimal risk of *auto-triggering*. In a *flow-trigger* algorithm, flow will be the dominant parameter in determining attainment of the threshold level.

Note 2 to entry: The change of flow detected might be a change in a *bias flow* or a change in the flow through the *patient-connection port*.

Note 3 to entry: See also *trigger* (3.9.2), *ventilator breathing system* (3.1.18), *inspiratory effort* (3.2.7), *patient-trigger event* (3.9.6), *pressure trigger* (3.9.4), *auto-trigger* (3.9.10), *bias flow* (3.7.7) and *patient-connection port* (3.14.5).

3.9.4
pressure trigger
trigger that detects when pressure changes in the *ventilator breathing system* reach a *set* threshold level

Note 1 to entry: This is a classification for the means of detecting a *patient's inspiratory effort* in generating a *patient-trigger event*. As explained in Note 1 to 3.9.2, in practice some such functions might monitor the value of more than one parameter and make use of dedicated detection algorithms in order that a sensitive *setting* can be used with minimal risk of *auto-triggering*. In a *pressure-trigger* algorithm, pressure will be the dominant parameter in determining attainment of the threshold level.

Note 2 to entry: The change of pressure detected may be a change in a *measured* pressure or a change in a rate of a pressure change.

Note 3 to entry: See also *trigger* (3.9.2), *ventilator breathing system* (3.1.18), *inspiratory effort* (3.2.7), *patient-trigger event* (3.9.6), *flow trigger* (3.9.3) and *bias flow* (3.7.7).

3.9.5
trigger level
threshold value for a *trigger function*

Note 1 to entry: This term is used, in context or by qualification, only to designate this concept as a *set* value (3.1.20).

Note 2 to entry: The level might be labelled in units of pressure or flow, or with a simple sensitivity scale.

3.9.6
patient-trigger event
trigger-event
signal used to *initiate* an *inflation*, resulting from a *measured* value(s) of a parameter(s) that can be attributed to the *patient* reaching a threshold value

Note 1 to entry: Typical *patient* respiratory parameters that are monitored for this purpose are *airway pressure*, flow or volume, and electromyography signals (EMG). Far less commonly used parameters are chest-wall motion and transthoracic impedance. The detection algorithm may involve more than one of these parameters.

Note 2 to entry: An *inflation initiated* by a *patient-trigger event* may be referred to as being *patient triggered* or by the method of detection, for example, *pressure triggered*, *flow triggered*, etc.

Note 3 to entry: The interval from the instant the *patient initiates* an *inspiratory flow* until the point where the *inspiratory pressure* starts to increase in response to a *patient-trigger event* can be referred to as the 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. See also *expiratory phase* 3.4.2 and Figures C.3, C.6 and C.7.

Note 4 to entry: The *initiation* of an *inflation* by means of a manual input is not a manual trigger event; it is a manual *initiation*.

Note 5 to entry: It is important that users are made aware that a *patient-trigger event* might result from the detection of a spurious perturbation on a *measurement*, especially if the threshold value is *set* at too sensitive a level.

Note 6 to entry: See also *initiate* (3.9.1), *inflation* (3.3.1), *airway pressure* (3.6.1), *measured* (3.1.20), *trigger* (3.9.2), *pressure trigger* (3.9.4), *flow trigger* (3.9.3), *auto-trigger* (3.9.10) and *breath stacking* (3.9.11).

3.9.7
breath synchronization
timing adjustment of each *initiation* and/or *termination* of an *assured inflation* in order to match the pattern of any spontaneous *inspiratory* and/or *expiratory efforts*, while still maintaining the *set rate*

Note 1 to entry: Any such *initiation* timing adjustment will typically alter the *respiratory cycle time* of the *assured inflation*, *breath* to *breath*, but the average *initiation* rate will be maintained at the *set rate*.

Note 2 to entry: See also *initiate* (3.9.1), *terminate* (3.9.14), *assured inflation* (3.3.11), *inspiratory effort* (3.2.7) *set rate* (3.5.1.1) and D.2.6.

3.9.8
synchronization window
time interval following the scheduled *initiation* or *termination*, of an *assured inflation* during which actual *initiation* or *termination* can be synchronized with any *respiratory activity* of the *patient*

Note 1 to entry: See also *breath synchronization* (3.9.7), *initiate* (3.9.1), *terminate* (3.9.14), *assured inflation* (3.3.11), *respiratory activity* (3.2.6), Annex B and Figures B.1, C.19, C.29 and C.33.

3.9.9
mandatory
required to occur

Note 1 to entry: This term is defined as used in this document, with a specific meaning of the word mandatory, which in natural language has a spectrum of meanings. It has become firmly established in the vocabulary of *artificial ventilation* but, because of its ambiguity, it can denote either 'total control' or, as in this definition, 'required to occur'. In early *artificial ventilation* practice, it was usual for all aspects of the *patient's ventilation* to be taken over by the *ventilator* and so every *breath* could be described as mandatory in its broadest sense. Since then, with the introduction of *patient triggering* and the concept of support for *spontaneous breathing*, only a small percentage of *patients* currently have their *ventilation* totally controlled. However, there remains a mandatory component to all forms of *artificial ventilation* but a key aspect for an *operator* when *setting* a contemporary *ventilator* is being assured that, when a selected *inflation-type* is delivered within the selected *ventilation-pattern*, it will provide at least a minimum level of assistance and, in the case of apnoea, that the *ventilation* will be totally controlled.

These developments have led *manufacturers* to increasingly restrict the use of the term 'mandatory' to the context of *ventilation* that is assured to occur by the programmed delivery of a selected *inflation-type*, in predetermined patterns, at a rate that is independent of the *patient's respiratory activity*. This is the only sense in which the term mandatory is used in this document; which is mainly in the explanation of the classical mode names such as CMV (*continuous mandatory ventilation*), IMV (*intermittent mandatory ventilation*) and SIMV (*synchronized intermittent mandatory ventilation*). For other purposes, wherever possible, the term assured is used in its place.

Note 2 to entry: See also *artificial ventilation* (3.1.10), *ventilation* (3.1.9), *ventilator* (3.1.1), *inflation* (3.3.1), *assured inflation* (3.3.11), *inflation-type* (3.3.2), *respiratory activity* (3.2.6) and *assured minute volume* (3.8.11).

3.9.10
auto-trigger
DEPRECATED: auto-cycle
initiation of an *inflation* as a result of a false *patient-trigger event*

Note 1 to entry: A false *patient-trigger event* can be caused, for example, by external perturbations such as a movement of the breathing tube or a cardiac impulse creating pneumatic disturbances.

3.9.11
breath stacking
initiation of another *inflation* by either the *ventilator* or a *patient-trigger event*, before the previous *breath* has been fully *expired*

Note 1 to entry: This situation might be caused, for example, by *auto-triggering* or by the *expiratory time* being *set* too short; it causes an accumulation of gas in the *lungs* and associated *auto*-PEEP.

Note 2 to entry: *Breath stacking* is the generalized term for more than one *breath* in succession being *initiated* before completion of *expiration*. The specific case of *breath stacking* where only a second *breath* is *initiated* prematurely is commonly referred to as double-triggering.

3.9.12
ventilator-initiation
initiation of an *inflation* by means of a timed signal generated after a *set* interval

3.9.13
remote inflation-initiation
initiation of an *inflation* by means of a recognized signal caused by an event external to the *ventilator*

EXAMPLE 1 A signal from another medical device.

EXAMPLE 2 A synchronization signal from X-ray equipment.

3.9.14
terminate
DEPRECATED: cycle
bring to an end

Note 1 to entry: In this document this term is used in reference to the ending of *inflation phases*. The means of *termination* of an *inflation phase* constitutes the secondary classification of *inflation-types*. The *termination* of an *expiratory phase* is caused by the *initiation* of an *inspiration* or *inflation.*

Note 2 to entry: The term 'cycle' is currently commonly used in some countries with the meaning of 'terminate' but it is, in fact, an abbreviation of 'cycle-off''. These terms originated when *ventilator*s simply cycled between 'on' and 'off'. Typically, *ventilator*s are now equipped with a variety of different means to *terminate* and *initiate* an *inflation* and the term 'cycle' is considered to be misleading in this context; it also causes confusion with the common and scientific meaning of the term 'cycle' as used in this document.

Note 3 to entry: See also *inspiratory-termination flow* (3.7.3), *flow-termination* (3.9.15), *pressure-termination* (3.9.16), *time-termination* (3.9.17) and D.2.8.2.

3.9.15
flow-termination
DEPRECATED: flow cycling
termination of a *pressure-regulated inflation* when the *inspiratory flow* has satisfied the prevailing *inspiratory-termination flow* criterion

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 (3.1.20).

Note 2 to entry: This method of *termination* provides the means for the *patient's respiratory activity* to be used to influence the duration of an *inflation phase* in order to improve the match of the duration with the *patient's* own *breathing* pattern. See *pressure-support* for an example of an *inflation-type* that is typically *pressure-regulated* and *flow-terminated*.

Note 3 to entry: *Patient*-safety considerations dictate that a *time-termination* be provided as a backup where *flow-termination* is intended to be the primary means of *termination*. This *time-termination* can be *preset*, *operator*-adjustable or *set* by an algorithm.

Note 4 to entry: *Flow-terminated pressure-support inflation-types* have often been referred to as patient-terminated. The use of that term is deprecated in this document unless the *ventilator* is able to specifically indicate that the *termination* is due to the *patient's respiratory activity* and neither due to the inevitable decline in *inspiratory flow* as the passive *lungs* are inflated in the absence of any such activity, nor due to *time-termination*.

Note 5 to entry: See also *terminate* (3.9.14), *inflation* (3.3.1), *inspiratory flow* (3.7.1), *inspiratory-termination flow* (3.7.3), *respiratory activity* (3.2.6), *pressure-support* (3.3.6), *inflation-type* (3.3.2), *pressure-regulation* (3.3.9), *time-termination* (3.9.17), *preset* (3.1.21), *end-inspiratory flow* (3.7.4) and D.2.5.

3.9.16
pressure-termination
DEPRECATED: pressure cycling
termination of an *inflation phase* when the *inspiratory pressure* attains a *set* level

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 (3.1.20).

Note 2 to entry: The *set* level can be either the primary *termination* criterion for the *inflation-type* or a *set* safety *limit* for the protection of the *patient* during *normal condition* or under a *single fault condition*.

Note 3 to entry: See also *terminate* (3.9.14), *normal condition* (3.1.26), *single fault condition* (3.1.27), *limit* (3.1.23), *pressure limited* (3.13.2), *adjustable pressure limit* (3.13.9), *pressure-control* (3.3.4) and D.2.8.1.

3.9.17
time-termination
DEPRECATED: time cycling
termination of an *inflation phase* after a *set* elapsed time

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 (3.1.20).

Note 2 to entry: *Patient*-safety considerations dictate that all *inflation-types* have a directly or indirectly *set time-termination*. Typically, this can be the *operator*-selected primary means of *termination* or it can be a *preset* back-up to an alternative primary means of *termination.*

Note 3 to entry: See also *terminate* (3.9.14), *inflation phase* (3.4.10), *set* (3.1.19) *preset* (3.1.21) and *initiate* (3.9.1).

3.10 * Baseline and PEEP terminology

3.10.1
baseline airway pressure
baseline pressure
reference *airway-pressure* level that may be above the ambient pressure by a *set* amount and at which a *patient breathes* when unassisted and upon which *inflations* are superimposed

Note 1 to entry: The *setting* for the amount by which the *baseline airway pressure* is offset is designated by the acronym *BAP* (3.10.2).

Note 2 to entry: The *baseline airway-pressure* level for humans *breathing* without a *ventilator* is that of the ambient environment. Most *ventilators* have the capability for the *patient* to be *ventilate*d and be able to *breathe*, with a *baseline airway-pressure* level(s) that is artificially raised relative to the ambient pressure. In addition to the baseline at ambient pressure, this document utilizes baselines at the *set* BAP level (see Note 3 to entry), at the *set inspiratory-pressure* level of an *assured inflation* (see Note 5 to entry) and also, at the *set* level in CPAP *ventilation-modes* (see Note 7 to entry). With *ventilation-modes* designated as *bi-level* AV the baseline at the *inspiratory pressure* level may be designated as BAP_H.

Note 3 to entry: *Baseline airway pressures* at the *set* BAP level become the reference level for

— any *inflation* cycles *initiated* from that baseline,

— an ACAP *adjunct* if active at that level,

— the *expiratory-control algorithm* for any *inflation* cycles *initiated* from that baseline,

— the intended minimum alveolar pressure level throughout *expiratory phases* of *inflations initiated* from that baseline, and

— the intended PEEP (*positive end-expiratory pressure*) at the *patient-connection port*.

Note 4 to entry: The adoption of the concept of a *baseline airway pressure* at a *set* BAP level, to replace that of a PEEP *setting* that only determines a positive pressure at the end of each *expiratory phase*, is increasingly necessary because of the growing number of *ventilators* that incorporate an ACAP *adjunct*. These are able to generate required *airway-pressure* waveforms irrespective of both *inspiratory* and *expiratory flow* and during both *inspiratory* and *expiratory phases* of an *assured inflation*. With such an *adjunct* activated the *patient* is able to *inspire* and *expire* at any time at any BAP level. Such *inspirations* can be unassisted or supported and intended *expiratory-pressure* waveforms are maintained under the control of an *expiratory-control algorithm*. Unassisted *inspirations* are enabled by the provision of *demand flow* that is proportional to the *patient's* demands, with no dependency on a *patient-trigger event*. The functionality that such features enable requires a vocabulary that encompasses the concept of one or more continuous *baseline airway pressures* in addition to one that only specifies an intended *airway pressure* at the end of an *expiratory phase*.

Note 5 to entry: If an ACAP *adjunct* is provided during a *pressure-control* (PC) *assured-inflation,* the *set inspiratory pressure* level becomes the baseline for:

— any concurrent *support inflations initiated* from that baseline,

— the ACAP *adjunct* at that level, and

— the *expiratory-control algorithm* for any *inflation* cycles *initiated* from that baseline.

Note 6 to entry: *Ventilation-modes* in which ACAP is always active, at both the BAP and *inspiratory pressure* levels, may alternatively be labelled as *bi-level* AV.

Note 7 to entry: In a CPAP *ventilation-mode*, the baseline at the *set* CPAP level becomes the reference level for the ACAP *adjunct* that enables continuous *unrestricted breathing* at that constant level.

Note 8 to entry: Examples of *airway-pressure* baselines are shown as orange-coloured broken lines in the Figures in Annex C.

Note 9 to entry: See also *airway pressure* (3.6.1), *set* (3.1.19), *breathe* (3.2.2), *unassisted breath* (3.2.12), *inflation* (3.3.1), *BAP* (3.10.2), *bi-level* AV (3.12.4), BAP_H (3.12.7), *CPAP* (3.11.15), *initiate* (3.9.1), *expiratory-control algorithm* (3.10.5), *PEEP* (3.10.4), *ventilation* (3.1.9), *ventilation-mode* (3.11.2), *ACAP* (3.12.1), *adjunct* (3.11.4), *supported breath* (3.2.13), *unrestricted breathing* (3.2.5), Annexes C and F and Figures C.4, C.5, C.8 and C.9 to C.13.

3.10.2
BAP
pressure-low
PEEP
quantity by which the *baseline airway pressure* is *set* to be positively offset from the ambient pressure

Note 1 to entry: The acronym BAP is employed in this document for the designation this concept as a *set* quantity (3.1.19) and in reference to baselines at a *set airway-pressure* level. The full term (see 3.10.1) is used in reference to the concept and its function. For examples of this usage see the notes to subclauses relating to *baseline airway pressure* and the relevant subclauses in 3.10 and 3.12.

Note 2 to entry: In *ventilation-modes* with more than one *baseline airway pressure*, BAP is the *setting* for that at the lowest level.

Note 3 to entry: The admitted term, *pressure-low*, is included in this edition of this document based on its common current usage, in combination with *pressure-high,* in the labelling of *bi-level* AV *ventilation-modes* and the possible need for a longer transition time for the changeover to the use of the term BAP, should this prove necessary. It may be represented by an appropriate letter symbol, for example, p_L.

Note 4 to entry: Although, in the absence of a commonly accepted alternative term, the use of the term, 'PEEP' as an abbreviation of *positive end-expiration pressure*, has been implicitly extended to encompass that of the *setting* for the *baseline airway pressure* at the same pressure level, this has never been formalized. The term, itself, explicitly states that it is specifically related to the 'end'-*expiration pressure*, and since its introduction it has gradually acquired a range of meanings relating to that parameter alone. For these reasons, and because the increasing implementation of ACAP *adjuncts* has made the concept of a *baseline airway pressure* more important as a separate concept, the term BAP, the acronym for the more explicitly appropriate term, *baseline airway pressure*, has been adopted in this document as the preferred term for the designation of the *setting* for this concept.

However, in addition to its retention as the preferred term for the designation of the *positive end-expiratory pressure* as a *measurement*, as defined in 3.10.4, PEEP is retained in this edition of this document to also designate this separate concept of the *set* level for the *baseline airway pressure,* as an admitted term. This temporary retention is to provision for a longer transition time in the changeover to the use of the preferred term, BAP, should this prove necessary. It might also continue to be a more appropriate term for a *setting* on basic *ventilators* and resuscitators, where the concept of a *baseline airway pressure* is not relevant, and the *setting* of the *positive end-expiratory pressure* is the only necessity.

Note 5 to entry: See also *baseline airway pressure* (3.10.1), *set* (3.1.19), *ventilation-mode* (3.11.2), BAP_H (3.12.7), *PEEP* (3.10.4), *pressure-high* (3.12.7) and the Figures of Annex C.

3.10.3
BAP phase
pressure-low phase
alternative name for the phase between *assured inflations*, in particular on *ventilators* where unassisted or supported spontaneous *inspirations* are facilitated during that phase in at least one of the selectable *ventilation-modes* on that *ventilator*

Note 1 to entry: Although this is also the *expiratory phase* of the *assured-inflation cycle*, unless that association is made clear each time it is used, if there are additional *respiratory cycles* there is ambiguity as to which *expiratory phase* is being referred to. The use of the term, BAP *phase,* therefore adds concision. This is particularly relevant with SIMV and *bi-level* AV *ventilation-modes* that might use extended BAP *phases* of up to 30 seconds or more.

Note 2 to entry: This phase is designated as the BAP *phase* because, although the conceptual baseline at this *set* level is continuous, it is only required as a continuous reference following *termination* and up till the point of *initiation* of an *assured-inflation phase*. If *additional breaths* concurrent with an *assured inflation* are possible, these will be superimposed on a higher baseline, at the *inspiratory-pressure* level, which may be alternatively labelled as BAP_H.

Note 3 to entry: The reason for labelling all *expiratory phases* as BAP *phases* on *ventilators* with at least one *ventilation-mode,* where that is applicable, is to ensure consistent labelling on any one device. The term may also be applied to the *expiratory phases* of other classes of *inflation* if the resulting consistency is assessed as improving usability.

Note 4 to entry: The admitted term, *pressure-low phase*, is the typical alternative name for this phase when its *set* pressure level is designated by its alternative name, *pressure-low.*

Note 5 to entry: See also *expiratory phase* (3.4.2), *unassisted breath* (3.2.12), *supported breath* (3.2.13), *spontaneous breath* (3.2.3), *initiate* (3.9.1), *additional breath* (3.2.8), *assured-inflation cycle* (3.4.18), *respiratory cycle* (3.4.16), BAP_H (3.12.7), *pressure-low* (3.10.2), *bi-level AV* (3.12.4), *ventilation-mode* (3.11.2) and Figures C.23 to C.33 and F.1 to F.6.

3.10.4
PEEP
positive end-expiratory pressure
<actual and measured value> respiratory pressure at the end of an *expiratory phase*

Note 1 to entry: In addition to its direct reference, this term or its acronym, is used in this document to designate this concept as a *measured* quantity. Without qualification, the quantity is always that at the *patient-connection port* and relative to ambient pressure. When used as part of a post-coordinated term it may be attributed to other measurement sites or reference pressure levels. The term, in its acronym form only, is also an admitted term for the designation of the *set* value of the *baseline airway-pressure* level (which encompasses the *setting* for the end-*expiratory pressure*), thereby acting as a synonym for BAP. For further information on PEEP as an admitted term for this purpose see 3.10.2.

Note 2 to entry: As a *measured* quantity, the qualification 'positive' is not strictly necessary but its use is retained because it places emphasis on one of the main purposes for which PEEP is used, that is, retaining at least a minimum 'positive' pressure in the alveoli in order to guard against their collapse.

Note 3 to entry: Since its early use, this term has been used to designate this concept as both a *setting* and *measured* value with very little clarity as to which. As the term for a *measurement* it has been post-coordinated to form terms such as auto-PEEP, intrinsic PEEP, alveolar PEEP, total PEEP, dynamic intrinsic PEEP, static intrinsic PEEP, dynamic total PEEP and applied PEEP. The term extrinsic PEEP has also been used to designate the PEEP at the *patient-connection port* but it is usually not clear whether that is for the *set* or the *actual value*. Although, ideally both will have the same value the *actual value* is not dependent on the *set* value alone and might have a higher or lower value, depending on other factors such as the *expiratory time*, any *ventilator breathing system* or *airway device* leakage, or *patient respiratory activity.* An inspection of current *ventilator* labelling demonstrates that there is very little consistency in the way these various forms of the term are used and what they designate.

In practice, on modern electronically-controlled *ventilators*, there is still only the need for one term for the designation of the intended PEEP but a need for an increasing number of terms to designate the various *measured* outcomes that can be displayed. With the increased significance of the concept of a *baseline airway pressure* on such *ventilators* (for further information see 3.10.1), and because the intended PEEP is simply a specific point on that baseline, there is now a strong case for using the *set* BAP as the designator for both. This then leaves the acronym PEEP, along with its various post-coordinations, free to designate only *measured* quantities on those *ventilators* where there are one or more *measured* values to be displayed or recorded. However, on basic *ventilators* and resuscitators, where the concept of baselines is not relevant, and where no independent *measured* PEEP values are displayed or recorded, then it is logical to retain PEEP as the designator for the *set* value. These considerations are the basis for the notation adopted in this document.

Note 4 to entry: The *measured* value of this quantity informs the *operator* as to how closely the actual *airway pressure* at the end of *expiration* corresponded with the *set* BAP value.

Note 5 to entry: See *BAP* (3.10.2) for further information on the context in which PEEP is used in this document.

Note 6 to entry: See also *measured* (3.1.20), *set* (3.1.19), *patient-connection port* (3.14.5), *airway pressure* (3.6.1), *baseline airway pressure* (3.10.1), *expiratory pressure* (3.6.9), *actual value* (3.1.22), *total PEEP* (3.10.6), *auto-PEEP* (3.10.7), Post-coordinated terms G.1, Annex F and the Figures of Annex C.

3.10.5
expiratory-control algorithm
algorithm that determines the *expiratory-pressure* waveform of an *expiratory phase*

Note 1 to entry: The algorithm used for a specific *ventilation-mode* is specified by the *manufacturer*.

Note 2 to entry: The *expiratory-control algorithm* takes the relevant *baseline airway pressure* as its reference throughout the corresponding phases. See Note 1 to *baseline airway pressure* (3.10.1).

Note 3 to entry: The main purpose of this algorithm is that of managing the *expiratory-pressure* waveforms following *inflations* and *unassisted inspirations* in order to achieve a required objective(s) throughout each *expiratory phase*.

Note 4 to entry: A basic *expiratory-control algorithm* can be no more than that of switching the *expiratory* valve to its open state, leaving the *expiratory flow* waveform and the minimum *expiratory pressure* to be determined by an *expiratory pressure-relief* function (commonly known as a PEEP valve), which is *set* to the required BAP level. This relieves *expiratory pressure* by allowing *expiratory flow* to pass through to the *exhaust port* with minimal resistance when it is above the BAP level, but which inhibits *expiratory flow* below that level. However, with this arrangement, once the *expiratory flow* has ceased, any leakage from the *ventilator breathing system* or from an *airway device* can cause the pressure to continue to fall so that by the end of *expiration* the *measured airway pressure*, PEEP, could be below that *set*.

Note 5 to entry: Typically, *expiratory-control algorithms* are used to continuously control the *expiratory-pressure* waveform during expirations in order to achieve an optimum rate of pressure decay. This can involve, for example, achieving faster deflation of the *lungs* by temporarily reducing the *airway pressure* below the *baseline airway-pressure* level in early *expiration* but bringing it back up to *baseline airway pressure* early enough to ensure that the pressure in the *lungs* never decreases below the *baseline airway-pressure* level during that phase.

Note 6 to entry: With an *expiratory-control algorithm* acting in isolation during a BAP *phase*, an unassisted *inspiration* might result in additional work of *breathing*; also, 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 an ACAP *adjunct,* active at the BAP level.

Note 7 to entry: An increasing number of *ventilators* now use an *expiratory-control algorithm* to coordinate their *inspiratory* and *expiratory* control functions in a way that generates required *expiratory-pressure* waveforms irrespective of both *inspiratory* and *expiratory flow*. This can then be used in combination with the *pressure-regulation* function to assure the maintenance of a constant pressure throughout even extended *inspiratory* and *expiratory phases* of *pressure-regulated assured inflations*, thereby providing an ACAP (*assured constant airway pressure*) *adjunct*.

Note 8 to entry: See also *baseline airway pressure* (3.10.1), *expiratory-pressure* (3.6.9), *expiratory phase* (3.4.2), *expiratory flow* (3.7.5), *unassisted breath* (3.2.12), *supported breath* (3.2.13), *expiratory pressure-relief* (3.6.10), *BAP* (3.10.2), *PEEP* (3.10.4), *ACAP* (3.12.1), A.4 – 3.12, Annex F and Figures F.3, F.6 and F.7.

3.10.6
total PEEP
tPEEP
DEPRECATED: intrinsic PEEP
stabilized *airway pressure* at the end of an *expiratory-hold* procedure that temporarily occludes the *airway*, in the absence of any *respiratory activity*.

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

Note 2 to entry: As the pressure at the *patient-connection port* falls during *expiration*, there is lag in the corresponding rate of fall of the alveolar pressure, mainly due to *airway resistance* and flow limitation factors. Usually, by the end of the *expiratory phase*, the alveolar pressure will equalize with the pressure at the *patient connection-port*. However, when there is a short *expiratory time* or with a diseased *lung*, the average alveolar pressure at the end of the *expiratory phase* can still be higher than the *measured expiratory pressure*, as the pressures might not have had sufficient time to equilibrate. The amount by which this average alveolar pressure exceeds the *measured* PEEP (*positive end-expiratory pressure*) cannot be *measured* directly, but its presence and order of magnitude is commonly ascertained by the use of an *expiratory-hold* procedure.

Note 3 to entry: The *airway-pressure measurement* at the end of an *expiratory-hold* procedure is the average of that of the pressurized gas in the alveoli that has been able to distribute uniformly throughout the *lung* during the *expiratory-hold time*, but it might not fully include the contribution of any trapped alveolar gas. An accurate *measurement* during this procedure is dependent upon the use of an *expiratory-hold time* that is sufficient to allow pressure stabilization and on the absence of any *respiratory activity* during the hold.

Note 4 to entry: In the absence of any *auto*-PEEP, a *measured total* PEEP has the same value as the *measured* PEEP for the same *expiration* and, therefore, has no relevance, other than to show that there is no *auto*-PEEP.

Note 5 to entry: Because of the diverse nature of a diseased *lung* there is currently no universally agreed definition of what constitutes *total* PEEP in an *artificially ventilated patient* although there appears to be a consensus that the value *measured* at the end of an *expiratory-hold* procedure during which there is no *respiratory activity* is the most reliable. This has, therefore, been adopted as the reference method for the determination of the value of this quantity in this document although a substantially equivalent value can be determined by other methods.

Note 6 to entry: See also *airway pressure* (3.6.1), *expiratory-hold* (3.4.6), *airway* (3.1.2), *patient-connection port* (3.14.5), *lung* (3.1.16), *expiratory pressure* (3.6.9), *auto-PEEP* (3.10.7), *PEEP* (3.10.4), *baseline airway pressure* (3.10.2), *artificial ventilation* (3.1.10), *respiratory activity* (3.2.6) and Annex F.

Note 7 to entry: Although sometimes used as a synonym for *total* PEEP, intrinsic PEEP is deprecated for use in this document because, although the adjective ‘intrinsic’ implies that term is denoting the totality of the PEEP within the *lungs*, there is a clear lack of consensus in medical publications and in *manufacturers*’ labelling as to whether it should be used to denote the *total* PEEP or only the *auto*-PEEP portion of *total* PEEP.

3.10.7
auto-PEEP
AP
DEPRECATED: intrinsic PEEP
portion of the stabilized *airway pressure* above that *set* for the end-*expiratory pressure*, at the end of an *expiratory-hold* procedure that temporarily occludes the *airway* and in the absence of any *respiratory activity*

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: As the pressure at the *patient-connection port* falls during *expiration*, in the absence of respiratory efforts there is an unavoidable lag in the corresponding rate of fall of the alveolar pressure, mainly due to *airway resistance* and other flow-limiting factors. Normally, the effects of this lag will have fully dissipated by the end of the *expiratory phase*, but with shorter *expiratory times* or with a diseased *lung*, the average alveolar pressure might still be above the *setting* for the end-*expiratory pressure* at the end of the *expiratory phase*. It is this additional pressure that was originally designated as *auto*-PEEP but as it is a quantity that cannot be measured directly it is defined in this document in terms of the measurements obtained from an *expiratory hold* procedure.

Note 3 to entry: If there is insufficient *expiratory time* for the *expiratory pressure* to reach its *baseline airway-pressure* level before the end of the *expiratory phase* then the *measured* PEEP will be greater than that intended by the BAP *setting*.

Note 4 to entry: This concept, although originally described using the name auto-PEEP, has since been referred to as intrinsic PEEP, occult PEEP, inadvertent PEEP, endogenous PEEP and internal PEEP. In the absence of standardization, and with inadequate transparency in the meaning of these alternative names, there has been little consensus as to whether they are synonyms of *auto*-PEEP or of *total* PEEP, whereas the 'auto' in *auto*-PEEP provides a clear disassociation from the '*set*' portion of *total* PEEP.

Because of its common use in the related scientific literature, the letter symbol for intrinsic PEEP, PEEPi, is also sometimes used to denote *auto*-PEEP, on the basis that the two terms are synonyms. This practice is not deprecated, providing it is a true synonym for *auto*-PEEP, although it is considered that the term *auto*-PEEP is sufficiently concise that the use of a letter symbol that might cause some confusion, is not justified.

The abbreviation AP is included as an admitted term in this document so that it can be used in descriptive text requiring repeated use of the term, but it is not advocated for user-interface labelling.

Note 5 to entry: As with *respiratory system compliance*, a value for *auto*-PEEP can also be obtained during normal uninterrupted *ventilation*. A typical means is the *measurement* of the change of *airway pressure* that is necessary to cause the transition from residual *expiratory flow* to the commencement of *inspiratory flow*. This *measured* value has become known as dynamic PEEP (PEEPi, dyn). However, although not deprecated, this method is not considered to be sufficiently established to justify a separate entry in this edition of this document.

Note 6 to entry: See also *total PEEP* (3.10.6), *PEEP* (3.10.4), *baseline airway pressure* (3.10.1) and Figures F.1 to F.4.

3.11 * Mode terminology

3.11.1
ventilator operational mode
operational mode
way in which a *ventilator* is *set* to operate

EXAMPLE Standby; calibration; *ventilator breathing system* check; start-up procedure.

Note 1 to entry: NIV also becomes an *operational mode* if it is selectable as an option.

Note 2 to entry: In the absence of the selection of a specific alternative *operational mode*(s), when *ventilation* is started, typically after a *ventilator* setup routine, a *ventilator* will commence *ventilation* using its intended *ventilation-mode* and as configured by the *operator's settings* and selections.

Note 3 to entry: See also *ventilator* (3.1.1), *set* (3.1.19), *ventilator breathing system* (3.1.18) and *NIV* (3.1.15).

3.11.2
ventilation-mode
specified manner in which a *ventilator* performs its *ventilatory* function when connected to a *patient*

Note 1 to entry: Although a large number of *ventilation-modes* have been described since *mechanical ventilation* was introduced, all can be seen to be comprised of two key features. These are, the method employed to make the necessary contribution to the *inflation* of the *patient's lungs* and the patterns with which these contributions occur, based on elapsed time or relative to any *respiratory activity* of the *patient*. Increasingly, these two features have been separately identified, classified and taught, and this practice has been formalized in this document, the development of which led to the adoption of the terms *inflation-type* and *ventilation-pattern* for their separate designation.

More recently, the introduction of microprocessor controls has led to the construction of adult *ventilator*s with a built-in facility for a *patient* to be able to make unrestricted *expirations*, as well as *inspirations*, at any time, including during an *inflation* at a constant pressure level - a feature previously confined to infant *ventilator*s. This feature is separately identified in this document as an ACAP *adjunct*.

Note 2 to entry: In this document, specific classification schemes have been introduced for *ventilation-modes*, *inflation-types*, *ventilation-patterns* and *ventilation-mode adjunct*s. These serve, not only to facilitate their identification and relationships, but as a basis for systematic naming and coding. For further information see Annexes D and E.

Note 3 to entry: Some *ventilation-modes*, or specific *setting* protocols for such *modes*, have a particular feature(s) that has been seen to justify an alternative name; a name that places emphasis on that feature. Names of such modes, which may be generic or proprietary, are classified as *alternative mode names* (3.11.20). Examples of such generic *ventilation-mode* names are *bi-level* AV and APRV (*airway pressure release ventilation*).

Note 4 to entry: Other *ventilation-modes* incorporate an additional supervisory function that is considered to distinguish it from the underlying pattern-based *ventilation-mode* to the extent that it too justifies a separate identity. Such a *ventilation-mode* is separately classified as a *superordinate mode*. Most of such *ventilation-modes* have proprietary names but an example of a generic *ventilation-mode* of this type is MMV.

Note 5 to entry: If a *ventilator* is *set* to automatically switch between alternative *ventilation-modes* when specified conditions are fulfilled, independent of whether an *alarm condition* is generated, in this document this arrangement may also be given a *superordinate mode* name. However, its systematic coding will require that both *ventilation-modes* are identified and that their systematic codes are linked by arrow symbols, as used to indicate *dual-control inflation-types*, for example, CSV-PS → CMV-VC. (See D.2.8.3, D.2.8.4 and Table D.3 for *dual-control inflation-types*).

Note 6 to entry: Although *alternative* and *superordinate mode* names, whether generic or proprietary, are adopted or permitted by this document as indicators of the additional or supervisory feature, they will not provide a complete description of the *ventilation-mode* without reference to the systematic code of the pattern-based *ventilation-mode* on which it is based, along with an explanation of the alternative or additional feature.

Note 7 to entry: See also *ventilator* (3.1.1), *ventilation* (3.1.9), *respiratory activity* (3.2.6), *ventilation-pattern* (3.11.3), *inflation-type* (3.3.2), *adjunct* (3.11.4), *ventilation-mode group* (3.11.5), *alternative mode name* (3.11.20), *superordinate mode* (3.11.21), *systematic ventilation-mode name* (3.11.19) and Tables E.1 and E.2.

3.11.3
ventilation-pattern
specified temporal pattern of sequenced interactions between a *ventilator* and the *patient*, including which, when and by what, selected *inflation-types* are *initiated*

Note 1 to entry: The *ventilation-pattern* also determines which *inflation-types* are appropriate for use with that pattern.

Note 2 to entry: *Ventilation-patterns* are invariably too complex to fully classify using a few simple words. It has therefore become customary to identify them by means of short descriptive names or by easily remembered associated abbreviations or acronyms although, because of a lack of standardization, the meanings attached to these identifiers have become very variable. However, in most cases the name has not been restricted to use with a specific *inflation-type* and it is therefore equally suitable to name just the *ventilation-pattern*. In this document, well established, non-proprietary *ventilation-mode* acronyms, or their names, have been adopted wherever possible as the generic names for the principle *ventilation-patterns* associated with them.

Note 3 to entry: When a named *ventilation-pattern* is selected, the features specified for that pattern in this document will be made available for *setting* and described in the instructions for use. However, it is necessary to recognize that, with some modern *ventilators*, particularly those with an ACAP *adjunct*, it is inevitable that some *ventilation-modes* can be *set* in such a way that they generate specific pressure or flow waveforms that could also be obtained with specific *settings* of a *ventilation-mode* with a different *ventilation-pattern* selected.

Note 4 to entry: The names or codes used to identify *ventilation-patterns* in this document are only used as systematic names or codes for *ventilation-modes* that conform to the definitions provided in this document. A *ventilation-pattern* that does not conform in this way should be described in terms of the most similar *ventilation-pattern*, with an explanation of the differences.

Note 5 to entry: A specified *ventilation-pattern*, together with a specified *inflation-type*(s) and the type of any *ventilation-mode adjunct*, constitutes the core, systematic name of any *ventilation-mode* used for *positive-pressure ventilation*. In referring to groups of *ventilation-modes* that make use of the same *ventilation-pattern*, the acronym (or name) of that shared *ventilation-pattern* may be used for the designation of each of those *ventilation-mode* groups, as illustrated, for example, in Note 4 to entry of 3.11.5.2 (although acronyms or names of shared *inflation-types* may not be used in the same way).

Note 6 to entry: A *ventilation-pattern* is independent of the *inflation-type*(s) selected and of the *set* values for parameters such as the *set rate*, *inspiratory pressure* and *phase time ratio*.

Note 7 to entry: See also *inflation-type* (3.3.2), *ventilation-mode* (3.11.2), *adjunct* (3.11.4), Annexes E, H and I, and Tables E.1 and E.2.

3.11.4
adjunct
ventilation-mode adjunct
function of a *ventilator*, which provides ancillary actions to a *ventilation-mode*

EXAMPLE 1 ACAP.

EXAMPLE 2 *Tube compensation.*

EXAMPLE 3 Leak compensations.

EXAMPLE 4 *Ventilator breathing system* compliance compensation.

Note 1 to entry: NIV is also classified as an *adjunct* if it is permanently active.

Note 2 to entry: A *ventilation-mode adjunct* can be, for example, permanently active, *operator-initiated* or configured by the *responsible organization* or *manufacturer* to become active when a particular *ventilation-mode* is selected. Additional properties that are selectable by the *operator* in order to modify a specific *ventilation-pattern* or *inflation-type* are considered to be optional variations, not *ventilation-mode adjuncts.*

Note 3 to entry: The ancillary actions are adjunctive in that they only make changes that supplement the intended effect of the selected *ventilation-modes* and their *settings*.

Note 4 to entry: See also *ventilation-mode* (3.11.2), *adjunct* (3.11.4) and *NIV* (3.1.15).

3.11.5
*** ventilation-mode group**
group of *ventilation-modes* that share fundamental features with respect to the characteristics of their *ventilation-patterns*

Note 1 to entry: The systematic grouping described in this subclause has been introduced with the intent of helping with the discussion, understanding, memorization and teaching of how the various *ventilation-modes* relate to each other in terms of their functional characteristics.

Note 2 to entry: The characterization of *ventilation-modes* into groups in the labelling of *ventilators* is not a requirement for conformity with this document but where the groupings described in this document are employed, they are required to be in accord with those descriptions.

Note 3 to entry: See also Rationale A.4 - 3.11.5, *ventilation-mode* (3.11.2), *ventilation-pattern* (3.11.3) and Tables E.1 and E.2.

3.11.5.1
ventilation-mode Group 1
group of *ventilation-modes* sharing *ventilation-patterns* in which only one *inflation-type* can be selected at a time, this being assured to be *initiated* at least at the *set rate*

Note 1 to entry: The *inflation-type* selected is also referred to in this document by its generic, purpose-classification, that is, *assured inflation-type*.

Note 2 to entry: See also *inflation-type* (3.3.2), *assured inflation* (3.3.11), *initiate* (3.9.1), *set* (3.1.19), *set rate* (3.5.1.1) and *assured inflation-type* (3.3.12).

3.11.5.1.1
ventilation-mode Group 1a
subset of Group 1 *ventilation-modes* with no provision for the selected *inflation-type* to be *initiated* by a *patient-trigger event*

EXAMPLE CMV (*continuous mandatory ventilation*) *mode*.

Note 1 to entry: With *Group 1a modes*, there is no assurance that *spontaneous breaths* (3.2.3) will be facilitated except where *ACAP* (3.12.1) is provided as an *adjunct* (3.11.4).

Note 2 to entry: See also *patient-trigger event* (3.9.6) and *CMV* (3.11.7).

3.11.5.1.2
ventilation-mode Group 1b
subset of Group 1 *ventilation-modes* in which the selected *inflation-type* is assured to be *initiated* at successive intervals determined by the *set rate* if not *initiated* within such an interval by a *patient-trigger event*.

EXAMPLE *Assist/control* (A/C) *ventilation-mode*.

Note 1 to entry: In the absence of *patient-trigger events*, *assured inflations* are *initiated* at intervals of 1/*set-rate* minutes. *Patient-trigger events* can *initiate* the selected *assured inflation-type* at a rate greater than that assured by the *set rate*. It follows that although all assured deliveries are of the *assured inflations-type*, not all deliveries of the selected *assured inflation-type* occur because they are assured.

Note 2 to entry: See also *assist/control ventilation* (3.11.8), *assured inflation-type* (3.3.12) and *assured inflation-type rate* (3.5.2.1).

3.11.5.2
ventilation-mode Group 2
group of *ventilation-modes* sharing *ventilation-patterns* in which an *inflation-type* is selected to be *initiated* at the *set rate*; between these *assured inflations spontaneous breathing* is possible, which can be either *unassisted* or *supported* by a selected *support inflation-type*

Note 1 to entry: On *ventilators* with an ACAP *adjunct* any *inspiration* occurring concurrently with a *pressure-control assured inflation*, can be supported by either the selected *support inflation-type* if its *inspiratory pressure* is *set* to be greater than that of the *assured inflation*, or by a second selected *support inflation-type.*

Note 2 to entry: The *inflation-type* selected to be *initiated* at the *set rate* is also referred to in this document by its generic, purpose-classification, that is, *assured inflation-type* (3.3.12).

Note 3 to entry: The *inflation-type* selected to support any *spontaneous breaths* not assisted by an *assured inflation* is also referred to in this document by its generic, purpose-classification, that is, *support inflation-type* (3.3.14). This grouping does not preclude the possibility for the selected *support inflation-type* to be *set* to provide zero support in order to facilitate *unrestricted breathing* between *assured inflations*.

Note 4 to entry: *Group 2 ventilation-modes* include those based on the well-established *ventilation-patterns* used in IMV (*intermittent mandatory ventilation*) and SIMV (*synchronized intermittent mandatory ventilation*) *modes*. The scope of any *ventilation-mode* in this group is independent of whether *spontaneous breaths* are *set* to be supported or not between the *assured inflations* or whether these *inflations* are assured to be *initiated* at an unusual *set rate*, for example, at only once per minute, in order to recruit the *patient's lungs*.

Note 5 to entry: See also *rate* (3.5.1.1), *unassisted breath* (3.2.12) and *supported breath* (3.2.13), *support inflation* (3.3.13), *assured inflation* (3.3.11), *assured inflation cycle* (3.4.18), *ACAP* (3.12.1) and *adjunct* (3.11.4).

3.11.5.2.1
ventilation-mode Group 2a
subset of *Group 2 ventilation-modes* with no provision for the *assured inflations* to be *initiated* by a *patient-trigger event*

EXAMPLE IMV (intermittent mandatory ventilation) mode.

3.11.5.2.2
ventilation-mode Group 2b
subset of *Group 2 ventilation modes* with the *initiation* of each *assured inflation* being synchronized with any *spontaneous breathing* while maintaining the *set rate*

EXAMPLE SIMV (*synchronized intermittent mandatory ventilation*) *mode.*

3.11.5.3
ventilation-mode Group 3
group of *ventilation-modes* sharing *ventilation-patterns* in which every *patient-trigger event initiates* a selected *inflation-type*; if a *patient-trigger event* does not occur within a *set* time interval a second selected *inflation-type* is *initiated* by the *ventilator*

Note 1 to entry: The *ventilation-modes* in this Group are typically used in *ventilators* intended for *patients* that are not *ventilator*-dependent but need some support with each *breath* and might need *assured ventilation* during short periods of apnoea.

Note 2 to entry: *Group 3 ventilation-modes* include those based on the *ventilation-pattern* used in S/T (*spontaneous/timed*) *ventilation-modes*.

3.11.5.4
ventilation-mode Group 4
group of *ventilation-modes* sharing *ventilation-patterns* that enable continuous *unrestricted breathing* or continuous *supported breathing*, always with a constant *baseline airway pressure* at the *set* BAP level

Note 1 to entry: In this group of *ventilation-modes* no *inflation* is assured to be *initiated*. If *apnoea ventilation* is provided for instances of apnoea then this is classified in this document as an automatic change of *ventilation-mode*.

Note 2 to entry: *Group 4 ventilation-modes* include those based on the well-established *ventilation-patterns* used in CSV (*continuous spontaneous ventilation*) and CPAP (*continuous positive airway pressure*) *ventilation-modes*.

Note 3 to entry: See also *unrestricted breathing* (3.2.5), *supported breath* (3.2.13), *baseline airway pressure* (3.10.1), *pressure-support* (3.3.6), *effort-support* (3.3.7), *CSV* (3.11.12) and *CPAP* (3.11.15).

3.11.5.4.1
ventilation-mode Group 4a
subset of *Group 4 ventilation-modes* with provision to support each *inspiratory* activity that exceeds a threshold value

EXAMPLE CSV (*continuous spontaneous ventilation*) *mode.*

Note 1 to entry: The support provided in *Group 4a ventilation-modes* can be by means of *pressure-support* (PS) or *effort-support* (ES) *inflation-types*. With *pressure-support* the threshold value will be a *set* value, with *effort-support* the threshold will be the minimum value resolvable by the *ventilator*.

3.11.5.4.2
ventilation-mode Group 4b
subset of *Group 4 ventilation-modes* with no provision to support any *inspiratory* activity

EXAMPLE CPAP (*continuous positive airway pressure*) *ventilation-mode.*

3.11.6
*** assured ventilation**
mandatory ventilation
patient ventilation by assured inflations

Note 1 to entry: The duration of an *assured ventilation* episode can be that of a single *breath* or of a sequence of *breaths*, ending when a non-synchronising *patient-trigger event* occurs.

Note 2 to entry: The term *assured ventilation* is used in this document to better represent the core concept of the classical *ventilation-modes*, CMV (*continuous mandatory ventilation*), IMV (*intermittent mandatory ventilation*) and SIMV (*synchronized intermittent mandatory ventilation*). *Mandatory ventilation* is retained as an admitted term for this concept in order to provide a link between the use of the word mandatory in the *ventilation-mode* name and the more relevant interpretation of its meaning in this document, that is, the assurance provided by its being required to occur. [See also *mandatory* (3.9.9)]

Note 3 to entry: It is only *assured inflation-types* delivered at the *set rate* that contribute to *assured ventilation*. *Assured inflation-types* that are *patient*-triggered, and that increase the rate above that *set*, are not *assured inflations* and do not contribute to *assured ventilation*. (See also *assured inflation-type* (3.3.12).

Note 4 to entry: With some *Group 2 ventilation-modes*, for example, SIMV, the *assured inflations* are assured to be delivered at the *set rate* but are also required to be synchronized with any *spontaneous breaths*. This is achieved by the use of a *synchronization window* that is opened at equal intervals. The actual *initiation* of that *inflation* is then either *patient*-triggered within that window or *ventilator-initiated* when the window is *terminated*. This ensures that the *assured inflations* will be delivered at the *set rate* although there might be small variations in the *inflation*-to-*inflation* interval as a consequence of the synchronization.

Note 5 to entry: It is the intent to deprecate the admitted term *mandatory ventilation*, other than when used as part of a *ventilation-mode* name, in future editions of this document.

3.11.7
CMV
continuous mandatory ventilation
DEPRECATED: continuous mechanical ventilation
DEPRECATED: controlled mechanical ventilation
DEPRECATED: IPPV
DEPRECATED: CPPV
name of a *ventilation-pattern* in which a selected *inflation-type* is assured to be *initiated* at intervals determined by the *set rate*, with no facility for any *inflation* to be *initiated* by a *patient-trigger event*

Note 1 to entry: The selected *inflation-type* is classed as the *assured inflation-type* and every *inflation* may be referred to as an *assured inflation*.

Note 2 to entry: The interval determined by the *set rate* is 1/*set-rate* minutes.

Note 3 to entry: This is the characteristic *ventilation-pattern of Group 1a ventilation-modes*. See Figures C.15 and C.16 for schematic illustrations of this pattern.

Note 4 to entry: The abbreviation, CMV, related to this concept is retained because it is well established, although a number of different names have been associated with it. In this document, it is used only for a *ventilation-pattern* that does not respond to *patient-trigger events* of any magnitude (that is, its function is the same as *assist/control* (A/C) *ventilation* with its *trigger* function off).

Note 5 to entry: Although not now widely used on critical care *ventilators*, *ventilation-modes* with this pattern are still used on some simpler resuscitation and transport and emergency *ventilators*.

Note 6 to entry: On ventilators with an ACAP *adjunct* it is possible to *set* a *ventilation-mode* with this pattern so that it resembles one with an IMV (*intermittent mandatory ventilation*) pattern. In such a case, the manufacturer's description of the *ventilation-mode* determines its appropriate designation.

Note 7 to entry: See also *ventilation-pattern* (3.11.3), *inflation* (3.3.1), *inflation-type* (3.3.2), *assured inflation-type* (3.3.12) *trigger* (3.9.2), Figures C.15, C.16, and C.22 to C.25.

3.11.8
assist/control ventilation
A/C ventilation
A/C
name of a *ventilation-pattern* in which a selected *inflation-type* is assured to be *initiated* at intervals determined by the *set rate*, unless *initiated* by an earlier *patient-trigger event*

Note 1 to entry: With this *ventilation-pattern*, the selected *inflation-type* is classed as the *assured inflation-type* as the *operator* is assured that it will be *initiated* at least at the *set rate.* However, any *patient-trigger event* will result in a *total inflation rate* in excess of that *set* and give rise to *additional breaths* and *additional minute volume*. It is usually not then possible to identify any one of the resulting *breaths* as an *additional breath*; it is only possible to deduce the number of *additional breaths* per minute by comparing the *total inflation rate* with the *set rate*.

Note 2 to entry: The interval determined by the *ventilator set rate* is, 1/*set-rate* minutes.

Note 3 to entry: This *ventilation-pattern* name is descriptive of its function in that every *patient-trigger event* *initiates* the generation of an *assisted breath* whereas a *controlled breath* is generated if no *patient-trigger event* occurs within the interval determined by the *set rate*.

Note 4 to entry: The preferred terms are those advocated for use in a written format, with the forward slash being a key element by indicating that with this *ventilation-pattern* the *ventilator* will either assist a *spontaneous breath* or control the generation of a *breath* in the absence of a *patient-trigger event*. However, the term is typically spoken as 'assist control ventilation'.

Note 5 to entry: This is the characteristic *ventilation-pattern* of *Group 1b ventilation-modes*. See Figure C.17 for a schematic illustration of this pattern.

Note 6 to entry: See also *ventilation-pattern* (3.11.3), *ventilator* (3.1.1), *initiate* (3.9.1), *patient-trigger event* (3.9.6), *assured inflation-type* (3.3.12), *assured inflation* (3.3.11), *additional breath* (3.2.8), *additional minute volume* (3.8.12), *total inflation rate* (3.5.1.5), *assisted breath* (3.2.14), *controlled breath* (3.2.16), *spontaneous breath* (3.2.3) and Figures C.17 and C.26 to C.28.

3.11.9
IMV
intermittent mandatory ventilation
name of a *ventilation-pattern* in which a selected *inflation-type* is always *initiated* at a constant interval, as determined by the *ventilator set rate*; between these assured deliveries, *unrestricted breathing* is possible or *spontaneous inspirations* may be supported by a second selected *inflation-type*

Note 1 to entry: The *inflation-type* selected for delivery at the *set rate* is classed as the *assured inflation-type* and the second *inflation-type* selected is classed as a *support inflation-type*.

Note 2 to entry: On *ventilators* with an ACAP *adjunct* any *inspirations* occurring concurrently with a *pressure-control assured inflation-type*, may be assisted by either the selected *support inflation-type* or by an additional, third selected *inflation-type (*which can also be referred to as the second *support inflation-type*).

Note 3 to entry: This is the characteristic *ventilation-pattern* of *Group 2a ventilation-modes*. See Figure C.18 for a schematic illustration of this pattern.

Note 4 to entry: It is possible to *set ventilation-modes* conforming to this pattern so that they resemble *modes* with a CMV (*continuous mandatory ventilation*)*-pattern* on *ventilators* with an ACAP *adjunct*. In such cases the *manufacturer's* description of the *ventilation-mode* determines its appropriate designation.

Note 5 to entry: See also *ventilation-pattern* (3.11.3), *initiate* (3.9.1), *set* (3.1.19), *set rate* (3.5.1.1), *unrestricted breath* (3.2.5), *ventilation-mode group* (3.11.5), Annex B, and Figures C.18, C.31 and C.32.

3.11.10
SIMV
synchronized intermittent mandatory ventilation
name of a *ventilation-pattern* in which a selected *inflation-type* is *initiated* at the *set rate* but with each *initiation* being synchronized with any *spontaneous breathing*; between these *assured inflations unrestricted breathing* is possible or spontaneous *inspirations* may be supported by a second selected *inflation-type*

Note 1 to entry: Synchronization is achieved by the use of a *synchronization window*, which provides time for the *initiation* of the *assured inflation* to be in phase with any preceding *spontaneous breath* in order to minimize the possibility of *breath stacking*. It achieves this by allowing either direct *patient initiation* during the *synchronization window* or time for *expiration* of any *spontaneous breath* not completed.

Note 2 to entry: The *synchronization window* is configured so that the *initiation* of each *inflation* is synchronized with any *spontaneous breathing* while maintaining the assured average rate of delivery as determined by the *set rate*.

Note 3 to entry: The *inflation-type* selected for delivery at the *set rate* is classed as the *assured inflation-type* and the second *inflation-type* selected is classed as a *support inflation-type*.

Note 4 to entry: On *ventilators* with an ACAP *adjunct* any *inspirations* occurring concurrently with a *pressure-control assured inflation-type*, may be assisted by either the selected *support inflation-type* or by an additional, third selected *inflation-type* (which can also be referred to as the second *support inflation-type*).

Note 5 to entry: This is the characteristic *ventilation-pattern* of *Group 2b ventilation-modes*. See Figure C.19 for a schematic illustration of this pattern.

Note 6 to entry: See also *ventilation-pattern* (3.11.3), *unrestricted breathing* (3.2.5), *assured inflation* (3.3.11), *set rate* (3.5.1.1), *assured-inflation type* (3.3.12), *support inflation* (3.3.13), *synchronization window* (3.9.8), *ACAP* (3.12.1), *breath stacking* (3.9.11), *IMV* (3.11.9), Annex A, Annex B and Figures C.19, C.29, C.30 and C.33.

3.11.11
S/T ventilation
S/T
spontaneous/timed ventilation
name of a *ventilation-pattern* in which every *patient-trigger event initiates* an *inflation* of the selected *support inflation-type*; if a *patient-trigger event* does not occur within a *set* time interval *assured ventilation* is provided by a second selected *inflation-type* that is *initiated* by the *ventilator*

Note 1 to entry: The *inflation-type* selected for *patient initiation* is also referred to in this document by its generic, purpose-classification, that is, either a *support inflation-type* or an *effort-support inflation-type*.

Note 2 to entry: The *inflation-type* selected for providing *assured ventilation* can have the same *settings* as that selected for *patient initiation* but will typically be, for example, a PC, vtPC or PC(***q***) *inflation-type*.

Note 3 to entry: In the absence of *patient-trigger events*, *assured inflations* will be delivered at intervals of 1/*set-rate* minutes.

Note 4 to entry: *Patient-trigger events* cause an increase in the *total inflation rate* above that determined by the *set rate*.

Note 5 to entry: This is the characteristic *ventilation-pattern* of *Group 3 ventilation-modes*. See Figure C.20 for a schematic illustration of this pattern.

Note 6 to entry: *Ventilation-modes* with a *single inflation-type* other than a *support inflation-type*, that can be *initiated* by either a *patient-trigger event* or the *ventilator*, are classified as *assist/control* (A/C) *ventilation-modes*.

Note 7 to entry: See also *ventilation-pattern* (3.11.3), *patient-trigger event* (3.9.6), *initiate* (3.9.1), *support inflation-type* (3.3.14), *assured ventilation* (3.11.6), *assured inflation* (3.3.11), *set rate* (3.5.1.1), *total inflation rate* (3.5.1.5), *assured inflation-type* (3.3.12), *assist/control ventilation* (3.11.8) and Figure C.20.

3.11.12
CSV
continuous spontaneous ventilation
SPONT
name of a *ventilation-pattern* that enables continuous *supported breathing* with a continuously constant *baseline airway pressure*

Note 1 to entry: With CSV, although each *spontaneous breath* can be assisted by a *support inflation* no *assured ventilation* is provided.

Note 2 to entry: With *pressure-support set* to 'zero', or its minimum *setting*, *ventilation-modes* using this *ventilation-pattern* might appear to function in a similar manner to the CPAP *ventilation-pattern* but because *pressure-support* is still selected it cannot be designated as CPAP. In this document, a *ventilation-mode* classification is independent of the *setting* used.

Note 3 to entry: A CSV *ventilation-mode* may be reidentified as a CPAP mode on the user interface if the *pressure-support* is deselected, providing it acts to maintain the *airway pressure* at its constant level in a manner that is independent of any *trigger setting*. The *set* level may then either retain the label BAP on the user interface or become relabelled as CPAP.

Note 4 to entry: This is the characteristic *ventilation-pattern* of *Group 3a ventilation-modes*. See Figure C.21 for a schematic illustration of this *ventilation-pattern*.

Note 5 to entry: See also *supported breath* (3.2.13), *support inflation* (3.3.13), *assured ventilation* (3.11.6), *CPAP* (3.11.15) and Figures C.21, C.34 and F.7 b).

Note 6 to entry: *Ventilation-modes* using this *ventilation-pattern* are commonly labelled on user interfaces with abbreviations of 'spontaneous', such as 'SPONT', 'SPN' and 'SPON'.

3.11.13
MMV
minimum minute volume
DEPRECATED: mandatory minute volume
generic name of a *superordinate-mode* that provides assurance to the *operator* that the *patient* will receive at least the *set minute volume* in accordance with the selected *ventilation-mode* algorithm

EXAMPLE 1 *Ventilation-mode* using an SIMV *ventilation-pattern* where the *set rate* is adjusted by the MMV algorithm to maintain the *set minute volume* until the lower limit of the *setting* is reached.

EXAMPLE 2 *Ventilation-mode* using an SIMV *ventilation-pattern* where the *set rate* and the *set tidal volume* parameters are both continually automatically adjusted in relation to each other in accordance with an established minimum respiratory work of *breathing* equation and *lung* protective strategy algorithms, while maintaining the *operator-set minimum minute volume* whenever safely possible.

Note 1 to entry: It is possible for the *patient* to demand *minute volumes* in excess of the *set* value.

Note 2 to entry: This is not to be confused with ‘mandatory minute ventilation’, which was the first implementation of a *ventilation-mode* that was described by this abbreviation. That implementation was an adaptation of a *ventilator* intended for use during anaesthesia in the operating room and did not provide for spontaneous *ventilation* in excess of the *set minute volume*. It was not, therefore, suitable in that form for unattended or longer-term *ventilation*. Subsequent developments of the concept have eliminated that restriction and led to its replacement by various forms of ‘*minimum minute volume*’ *ventilation* (see Examples 1 and 2).

Note 3 to entry: This is a *superordinate mode* name because it does not describe a *ventilation-pattern*; it is simply a named *ventilatory* objective. This objective can be implemented with more than one pattern-based mode but in each case necessarily involving the *operator* transferring the responsibility for the adjustment of certain parameter *settings* to the *ventilation-mode* algorithm. Intrinsic to such algorithms, is the automatic adjustment of certain initial *settings* over time, according to the *respiratory activity* of the *patient*.

Note 4 to entry: See also *superordinate mode* (3.11.21), *respiratory activity* (3.2.6), *set* (3.1.19), *minute volume* (3.8.6), *ventilation-pattern* (3.11.3), *ventilation-mode* (3.11.2) and *set rate* (3.5.1.1).

3.11.14
*** APRV**
airway pressure release ventilation
alternatively named specific *setting* protocol of a *bi-level* AV *ventilation-mode* in which the *patient* is intended to take *unrestricted breaths* during an extended *assured-inflation phase* at the BAP$_{\mathrm{H}}$ level and in which the BAP *phase* is intended to be *set* to *terminate* as soon as the alveolar pressure has had time to descend to the BAP level

Note 1 to entry: APRV is an alternative name for a specific *setting* protocol for *ventilation-modes* such as IMV-PC <ACAP> or IMV-PC{S} <ACAP>; *settings* that give extreme inverse *phase time ratios* (t_{H}:t_{L}) such that the *patient* takes *unrestricted breaths* at a relatively high *baseline airway pressure* while being *artificially ventilated* by short intermittent airway pressure releases.

Note 2 to entry: *Ventilators* supporting this protocol can offer means of *setting* an appropriate duration for the alveolar pressure to have time to descend to the BAP level that include a time *setting* or based on the elapsed time for the *expiratory flow,* the *expiratory pressure* or an EMG signal to reduce by a *set* amount or to a *set* level. If the necessarily extreme inverse *phase time ratios* are made available, it is possible to achieve the intended function of APRV by making specific *settings* on any of a range of *bi-level* AV *modes*, of which IMV-PC <ACAP> is an example.

Note 3 to entry: The terminology used in this entry is that which is appropriate for the labelling of a *bi-level* AV *ventilation-mode* to be *set* to an APRV protocol.

Note 4 to entry: *Ventilation-modes* in which the *settings* and features have been configured with the specific intention of facilitating this *setting* protocol may be labelled as APRV as an *alternative mode name*, although, as with all *alternative mode names*, the full specification is incomplete without a disclosure of the underlying *systematic ventilation-mode name*.

Note 5 to entry: See also *bi-level AV* (3.12.4), *assured-inflation* (3.3.11), *inflation phase* (3.4.10), *BAP*$_{\mathrm{H}}$ (3.12.7), *BAP phase* (3.10.3), *terminate* (3.9.14), *unrestricted breathing* (3.2.5), *phase time ratio* (3.4.19), *baseline airway pressure* (3.10.1), *artificial ventilation* (3.1.10), *airway pressure* (3.6.1), Figures C.31 and C.32, and A.4 - 3.11.14.

3.11.15
CPAP
continuous positive airway pressure
ventilation-mode or *sleep-apnoea breathing-therapy mode* in which the *patient breathe*s continuously at a *set airway-pressure* level, above ambient pressure

Note 1 to entry: CPAP is intended to maintain the *airway pressure* at its *set* value apart from the inevitable minor deviations that are necessary for it to perform its function. Although there are currently no tests for acceptable levels for such deviations, they are expected to neither add to nor subtract from the *patient's* perceived work of *breathing* to a greater extent than could be experienced during *natural breathing*.

Note 2 to entry: This definition excludes the use of the term to describe *ventilation-modes* where spontaneous *inspirations* are supported by intermittently elevated pressures other than with the intention to compensate for any actual or perceived imposed work of *breathing*.

Note 3 to entry: Because, as used for this *ventilation-mode*, the concept of a CPAP level coincides with that of a *baseline airway pressure* the *setting* could be designated as for either concept but as the intention of the *operator* selecting this *ventilation-mode* will be to achieve a specific CPAP level, this becomes an acceptable admitted term to designate the *set* quantity.

Note 4 to entry: Although at the periphery of the spectrum of what constitutes a *ventilation-mode*, CPAP is included in this document because it is commonly made available on typical critical care *ventilators* for use as part of a continuum of a *patient's* treatment without the necessity to change to another device.

Note 5 to entry: It is possible for a *ventilation-mode* resembling CPAP to be realized on a *ventilator* by the use of CSV (*continuous spontaneous ventilation*) with the *pressure-support* (PS) *set* to 'zero' or 'none' but CSV *set* in this way is not equivalent to CPAP if its performance in response to a spontaneous *inspiration* is dependent on the *setting* of an appropriate *trigger level*.

Note 6 to entry: On *ventilator*s equipped with ACAP, this *adjunct* will enable *unrestricted breathing* whenever CPAP is selected.

Note 7 to entry: CPAP is a *Group 4b ventilation-mode*. Because no *inflation-type* is selected this *ventilation-mode* is identical to its *ventilation-pattern* and there is no necessity to distinguish between them. The *systematic ventilation-mode name* becomes, therefore, simply, CPAP. On *ventilators* where CPAP is enabled by means of an ACAP *adjunct* the systematic code is CPAP <ACAP>.

Note 8 to entry: When used for sleep-apnoea *breathing*-therapy, CPAP is not classed as a *ventilation-mode* - it becomes a sleep-apnoea *breathing-therapy mode*. Although the principle clinical intention of such a therapy mode is to maintain a positive pressure in the *patient's airway* during sleep in order prevent *airway* obstruction by the soft tissues in the throat it has become a common practice to reduce this pressure during *expiration*, principally to improve *patient* acceptability. *Ventilation-modes* with this feature are typically identified with names that allude to this use of two levels of positive *airway pressure*. The generic name adopted for the designation of such a *breathing-therapy mode* in this document is *bi-level* PAP.

Note 9 to entry: See also *natural breathing* (3.2.4), *unrestricted breath* (3.2.5), *baseline airway pressure* (3.10.1), *pressure-support* (3.3.6), *breathing-therapy mode* (3.11.22), *CSV* (3.11.12), *ventilation-mode Group 4b* (3.11.5.4.2), *ACAP* (3.12.1), *bi-level PAP* (3.12.5), A.4 - 3.12, and Figure C.2.

3.11.16
apnoea ventilation
apnea ventilation
safety provision by which the *ventilator* automatically switches to a predetermined *ventilation-mode* that generates *controlled breaths* whenever a hypoventilation *alarm condition* occurs or when a *breath* is not detected during a specified period of time

Note 1 to entry: A second preferred term for this concept is included in this document because each spelling of the key base word, apnoea, is universally used in specific spheres of influence; both within and outside of the scope of this document.

Note 2 to entry: See also *controlled breath* (3.2.16), *alarm condition* (Annex J), and *backup ventilation* (3.11.17).

3.11.17
backup ventilation
property of a *ventilation-mode* where the normal function is for the *ventilator* to automatically deliver an *inflation* of a predetermined *inflation-type* when a *breath* is not detected during a *set* period

Note 1 to entry: An *alarm condition* is not generated when a *backup ventilation inflation* is delivered.

3.11.18
fail-safe ventilation
DEPRECATED: apnea *ventilation*
DEPRECATED: apnoea *ventilation*
DEPRECATED: backup ventilation
safety provision by which the *ventilator* automatically switches to a predetermined alternative *ventilation-mode* intended to maintain *patient* safety in the event of a component, sensor or function becoming inoperable

Note 1 to entry: Such provisions could be necessitated by a *ventilator* component failure such as pressure sensor failure or a microprocessor failure.

Note 2 to entry: The automatic *initiation* of *fail-safe ventilation* usually generates a technical *alarm condition.*

Note 3 to entry: See also *apnoea ventilation* (3.11.16).

3.11.19
systematic ventilation-mode name
systematic mode name
methodically derived designation for any specific *ventilation-mode* based on its *ventilation-pattern*, the *inflation-type*(s) used and any active *adjuncts*

Note 1 to entry: The concept of a *systematic ventilation-mode name* has been introduced into this document to provide the basis for a unique coding system with the capability of identifying any *ventilation-mode* that is within the scope of this document to the high level of granularity facilitated by the relevant definitions and tables in this document. In the case of a *superordinate mode* or the use of an *alternative mode name*, it is used to identify the *ventilation-pattern* based *ventilation-mode* that underlies its operation.

Note 2 to entry: The *systematic ventilation-mode name* may be represented either by its full name or in its coded form but the conciseness of the coded form makes it more suitable for general use.

Note 3 to entry: See Tables E.1 and E.2 for illustrations of the structure of the *systematic ventilation-mode name* and typical examples of both the systematic name and its associated code.

Note 4 to entry: The inclusion of any active *ventilation-mode adjuncts* can be indicated by either a global checkbox covering all, or just specifically specified, *ventilation-modes* available on that *ventilator* or as an addition to any individual code, enclosed between angled brackets (for example, <ACAP>).

Note 5 to entry: Wherever possible and appropriate, it is the abbreviations provided for any terms in this document that should be employed in the formation of the systematic code for any specific *ventilation-mode*. Examples of *systematic ventilation-mode names* in a coded form are A/C-VC, SIMV-VC\PS, IMV-PC\PS <ACAP> and CSV-PS.

Note 6 to entry: See also *ventilation-pattern* (3.11.3), *inflation-type* (3.3.2), *adjunct* (3.11.4), *ACAP* (*assured constant airway pressure*) (3.12.1), Annexes D and E, Tables D.1, D.2 and D.3, Tables E.1 and E.2, and Tables I.1 and I.3.

3.11.20
alternative mode name
alternative ventilation-mode name
name used to identify a *ventilation-mode*, or a specific *setting* protocol for a *ventilation-mode*, which is an alternative to the *systematic ventilation-mode name*, with the intention of placing emphasis on a particular characteristic feature of that *ventilation-mode* or the manner in which it might be used

EXAMPLE 1 *Bi-level* AV (*bi-level artificial ventilation*).

EXAMPLE 2 APRV (*airway pressure release ventilation*).

Note 1 to entry: The alternative name can be used to identify a single *ventilation-mode*, or several *ventilation-modes* with the same characteristic feature or features.

Note 2 to entry: The alternative name can be either a standardized generic name or a proprietary name.

Note 3 to entry: The specification of an alternatively named *ventilation-mode* is incomplete without reference to its *systematic ventilation-mode name*.

Note 4 to entry: The selection of a *ventilation-pattern* and *inflation-types* is fundamental to all *ventilation-modes* but some such *modes* have overriding, clinically significant, combinations of features that have been considered to justify their own generic or proprietary name. Such *ventilation-modes* sometimes use higher-order or interventional control algorithms in order to achieve additional objectives, for example, a *ventilation* strategy or procedure, and which have therefore been identified solely by a name relating only to that objective. In other instances, specific combinations of *ventilation-pattern*, *inflation-type(s)* and range of *settings* have been characterized by a name that puts emphasis on a particular *ventilation* concept. Although this practice can be useful as a shorthand reference such *ventilation-mode* names do not currently provide a complete description. A *ventilation-mode* selected on a *ventilator* using vocabulary conforming to that of this document will enable identification of the standardized selected *ventilation-pattern* and selected *inflation-type*(s).

3.11.21
superordinate mode
one of a group of *ventilation-modes* that has a significant feature in addition to those of the underlying *ventilation pattern*-based *mode*, and by which it is separately identified

Note 1 to entry: The additional feature is typically a supervisory function that is *set* to adjust the *settings* of the controls of the *ventilator* automatically, with the intention of achieving a progressive care plan with the *patient*.

Note 2 to entry: The specification of a *superordinate mode* is incomplete without reference to the *systematic ventilation-mode name* of the underlying *ventilation-mode* on which its operation depends.

Note 3 to entry: Examples of proprietary *superordinate-mode* names are SmartCare®[4], Automode®[5] and ASV®[6].

Note 4 to entry: See also *alternative mode name* (3.11.20) and *systematic ventilation-mode name* (3.11.19).

3.11.22
breathing-therapy mode
respiratory mode of a device that delivers a respirable gas at therapeutic *breathing* pressures to the *patient's airway* with a primary intention other than to support a proportion of the *patient's* work of *breathing*

EXAMPLE 1 Sleep-apnoea therapy.

EXAMPLE 2 CPAP.

EXAMPLE 3 High flow oxygen therapy.

EXAMPLE 4 Bi-level PAP.

Note 1 to entry: See also CPAP - Note 8 to entry (3.11.15), *bi-level PAP* (3.12.5), *ventilation-mode* (3.11.2), *breath* (3.2.1) and *airway* (3.1.2).

4) SmartCare® is the trademark of a product supplied by Dräger 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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3.12 * Bi-level terminology

3.12.1
ACAP
assured constant airway pressure
built-in *adjunct* that enables *unrestricted breathing* by acting to maintain the *airway pressure* at its *set* value, irrespective of *inspiratory* or *expiratory flows*, or specified permitted leakage, whenever it is intended to be at a constant level

Note 1 to entry: This *adjunct* is intended to maintain the *airway pressure* at its *set* value apart from the inevitable minor deviations that are necessary for it to perform its function. Although there are currently no standardized tests for acceptable levels for such deviations, they are expected to neither add to nor subtract from the *patient's* perceived work of *breathing* to a greater extent than might be experienced during *natural breathing*.

Note 2 to entry: If the *ventilator* is connected to the *patient* with an *airway device* with sufficient resistance to hinder *unrestricted breathing* its effect can be offset if the *operator* selects a *tube compensation* (TC) function.

Note 3 to entry: The concept of an ACAP *adjunct* is that of a function that is built into the design of a *ventilator*. A typical implementation of ACAP on a gas-powered *ventilator* might involve the use of a proportional *expiratory* valve under the continuous control of an *expiratory-control algorithm*. When this is controlled in unison with the control of a proportional *inspiratory* valve it becomes possible to generate the required pressure waveform, irrespective of the possibly rapidly changing *inspiratory* and *expiratory flow*s of *natural breathing*, during both the *inflation* and *expiratory phase*s of an *assured-inflation cycle*. This enables the *patient* to *inspire* and *expire* at any time, at any BAP level, unassisted or supported. Unassisted *inspirations* are enabled by the provision of *demand flow* that is proportional to the *patient's* demands, with no dependency on a *patient-trigger event*.

The additional functionality provided by ACAP is denoted with the term 'open system' by one *manufacturer*. This is helpful in communicating a sense of its basic function in allowing free *breathing* to atmosphere but an ACAP *adjunct* additionally facilitates the same free *breathing* with *airway pressures* maintained at constant levels above that of the atmosphere. In most cases this is achieved without the use of a truly open system.

This *adjunct* can also be provided by a *ventilator* that uses alternative proportional gas control or pressure generation elements.

Note 4 to entry: ACAP is typically configured to be active whenever appropriate for the selected *ventilation-mode*.

Note 5 to entry: Examples of instances of where ACAP is active, if provided, are

— during the intended constant-pressure portion of the waveform of a *pressure-control* (PC) *assured inflation*,

— after the expiratory pressure has stabilized at its BAP level during the *expiratory phases* of *assured-inflation* cycles and between any *support inflations*,

— between any *support inflations* during CSV and continuously when *pressure-support* (PS) is *set* to 'zero' or 'off', and

— during CPAP *ventilation-modes*.

Note 6 to entry: The constant pressure levels at which ACAP is active become the *baseline airway pressures* for that activity.

Note 7 to entry: For *unassisted breaths*, an ACAP *adjunct* facilitates *unrestricted breathing* by the generation of *demand flow* in proportion to the *patient's* demands, without any *trigger* threshold, during *inspiration* and by the provision of minimal resistance during *expiration*.

Note 8 to entry: Although this *adjunct* might not be required to maintain the *baseline airway pressures* if *pressure-support* is provided during an *expiratory phase*, it will serve to prevent the pressure dropping below the *set* BAP level towards the end of *expiration* due, for example, to any *ventilator breathing system* or *airway leaks*. It also allows *unrestricted breathing* below the *set trigger level*, or when any *pressure-support* (PS) is switched off.

Note 9 to entry: Some of the functions of ACAP might also be achievable by using specific *settings* with certain *ventilation-modes* but, although such *settings* can be described as providing an equivalent function to ACAP, because its function is dependent on *set* values such an arrangement does not constitute an ACAP *adjunct*. If equivalence is claimed, the means used to facilitate *unrestricted breathing* should be described in the *accompanying documents*.

Note 10 to entry: *Group 2 ventilation-modes* with a *pressure-control inflation-type* selected and an ACAP *adjunct*, facilitate unrestricted *inspirations* and *expirations* at both pressure levels of the *assured-inflation cycle* and may, therefore, be designated by the *alternative mode name, bi-level* AV.

Note 11 to entry: See also *adjunct* (3.11.4), *ACAP*$_L$ (3.12.2), *ACAP*$_H$ (3.12.3), *unrestricted breathing* (3.2.5), *natural-breathing* (3.2.4), *tube compensation* (3.6.11), *assured-inflation* (3.3.11), *support inflation* (3.3.13), *trigger level* (3.9.5), *baseline airway pressure* (3.10.1), *BAP* (3.10.2), *bi-level AV* (3.12.4), *demand flow* (3.7.10), D.2.8.5, Annex A.4 - 3.12, Annexes D, E and F, Tables D.1, E.1 and E.2, and Figures C.24, C.25, C.28, C.29 to C.33 and F.7.

3.12.2
ACAP$_L$
ACAP-low
adjunct that enables *unrestricted breathing* by acting to maintain the *expiratory pressure* at the *set* BAP level, irrespective of *inspiratory* or *expiratory flows*, or specified permitted leakage, after the *expiratory pressure* has decreased to the BAP level during the *expiratory phases* of *assured-inflation cycles* and between any *support inflations*

Note 1 to entry: As an *adjunct* that is only active during the *expiratory phases* of *assured-inflation cycles*, ACAP$_L$ can be the most appropriate for use, for example, with a *ventilation-mode* using a *flow-regulated inflation-type* as the *assured inflation*.

Note 2 to entry: This *adjunct* is intended to maintain the *airway pressure* at its *set* value apart from the inevitable minor deviations that are necessary for ACAP$_L$ to perform its function. Although there are currently no standardized tests for acceptable levels, with ACAP$_L$, such deviations are expected to neither add to nor subtract from the *patient's* perceived work of *breathing* to a greater extent than could be experienced during *natural breathing*.

Note 3 to entry: Where provided, ACAP$_L$ is typically preselected to be active wherever appropriate - depending on the *ventilation-mode* that has been selected.

Note 4 to entry: For *unassisted breaths*, an ACAP$_L$ *adjunct* typically facilitates *unrestricted breathing* at the BAP level, by the generation of *demand flow* in proportion to the *patient's* demands, without any *trigger* threshold, during *inspiration* and by the provision of minimal resistance during *expiration*.

Note 5 to entry: Although this *adjunct* might not be required to maintain the *baseline airway pressure* if *pressure-support* (PS) is provided during an *expiratory phase*, it will serve to prevent the pressure dropping below the *set baseline airway pressure* towards the end of *expiration* due, for example, to any *ventilator breathing system* or *airway leaks*. It also allows *natural breathing* below the *set trigger level*, or when any *pressure-support* (PS) is switched off.

Note 6 to entry: Some of the functions of ACAP$_L$ might also be achievable with the use of specific *settings* with certain *ventilation-modes* but, although such *settings* might resemble an equivalent function to ACAP$_L$, because its function is dependent on *set* values such an arrangement does not constitute an ACAP$_L$ *adjunct*. If equivalence is claimed, the means used to facilitate *unrestricted breathing* should be described in the *accompanying documents*.

Note 7 to entry: See also: *adjunct* (3.11.4), *unrestricted breathing* (3.2.5), *set* (3.1.19), *BAP* (3.10.2), *baseline airway pressure* (3.10.1), *demand flow* (3.7.10), *flow regulation* (3.3.8), *assured inflation* (3.3.11), assured-*inflation cycle* (3.4.18) and Figures C.23 and F.6.

3.12.3
ACAP$_H$
ACAP-high
mode adjunct that maintains the *airway pressure* at its *set assured-inflation inspiratory-pressure* level, irrespective of *inspiratory* or *expiratory flows*, whenever it is intended to be constant at that level

Note 1 to entry: Note to 1 entry: This *adjunct* is provided for use only during the *inflation phases* of pressure-regulated *assured-inflation cycles*. ACAP$_H$ is not applicable during *inflations* with *flow-regulated inflation-types*, for example, *volume-control*, because the *inspiratory pressure* is not intended to be at a constant level during such *inflations*. If additional *inspiratory flow* is provided on demand with a *volume-control inflation-type*, this is classed as a *dual-control inflation* not *volume-control* with ACAP.

Note 2 to entry: This *adjunct* is intended to maintain the *airway pressure* at its *set* value with the exception of the inevitable minor deviations that are necessary for $ACAP_H$ to perform its function. Although there are currently no standardized tests for acceptable levels, with $ACAP_H$, such deviations are expected to neither add to nor subtract from the *patient's* perceived work of *breathing* to a greater extent than could be experienced during *natural breathing*.

Note 3 to entry: Where provided, $ACAP_H$ is typically preselected to be active wherever appropriate, depending on the *ventilation-mode* that has been selected.

Note 4 to entry: For *unassisted breaths*, an $ACAP_H$ *adjunct* facilitates *unrestricted breathing* by the generation of *demand flow* in proportion to the *patient's* demands, without any *trigger* threshold, during *inspiration* and by the provision of minimal resistance during *expiration*.

Note 5 to entry: Some of the functions of $ACAP_H$ might also be achievable by using specific *settings* with certain *ventilation-modes* but, although such *settings* might resemble an equivalent function to $ACAP_H$, because its function is dependent on *set* values such an arrangement does not constitute an $ACAP_H$ *adjunct*. If equivalence is claimed, the means used to facilitate *unrestricted breathing* should be described in the *accompanying documents*.

Note 6 to entry: See also *adjunct* (3.11.4), *baseline airway pressure* (3.10.1), *dual-control* (3.3.5), *assured inflation* (3.3.11) and D.2.8.5.

3.12.4
bi-level AV
bi-level artificial ventilation
bi-level
alternative name for *Group 2 ventilation-modes* with a *pressure-control assured inflation-type* and ACAP as an *adjunct*, where the intention is to place emphasis on the facility for *unrestricted breathing* at both *baseline airway-pressure* levels of the *assured-inflation cycle*

Note 1 to entry: With the provision of ACAP, *unrestricted breathing* is possible at two alternating pressure levels, thereby adding to the *ventilation* provided by the assured *pressure-control* (PC) *inflations*.

Note 2 to entry: It is common practice to also adopt an alternative naming scheme for the *set* and *measured* quantities that are affected by this intended change of emphasis. Figures in Annex C that illustrate *ventilation-modes* that can be alternatively designated as *bi-level* AV also show how the alternative terms, standardized for that purpose, are used. Preferred and admitted terms for these quantities are listed in following entries in 3.12.

Note 3 to entry: This is the generic name for a class of *ventilation-modes* based on one originally introduced with the proprietary name BIPAP®[7)] (which is not to be confused with the proprietary name BiPAP®[8)], a *breathing-therapy mode*).

Note 4 to entry: See also *Group 2 ventilation-modes* (3.11.5.2), *ACAP* (3.12.1), *bi-level PAP* (3.12.5), *APRV* (3.11.14), and Figures C.30 to C33.

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8) BiPAP® is the trademark of a product supplied by Respironics Inc. 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.

3.12.5
bi-level PAP
bi-level positive airway pressure
BPAP
sleep-apnoea *breathing-therapy mode* in which there are two therapeutic positive pressure levels at the *patient-connection port* during the *respiratory cycle*

[SOURCE: ISO 80601-2-70:2015, 201.3.203, modified — Rephrased.]

Note 1 to entry: The two levels of *positive airway pressure* (PAP) invoked by the various names that have been given to this *breathing-therapy mode* are typically identified by the terms IPAP (*inspiratory* positive *airway pressure*) and EPAP (*expiratory* positive *airway pressure*), with IPAP representing the *set inspiratory pressure* level during the *patient's inspiratory phase* and EPAP the *set baseline airway pressure* (BAP) during the *patient's expiratory phase*.

Note 2 to entry: This is the generic name for a *breathing-therapy mode* previously identified by the proprietary name BiPAP®[8] (which is not to be confused with the proprietary name BIPAP®[7], a *ventilation-mode*).

Note 3 to entry: Although classed as a *breathing-therapy mode*, this mode has been included in this edition of this document in order to highlight one of the conceptual boundaries between equipment intended for *artificial ventilation* and that intended for *breathing* therapy.

Note 4 to entry: See also *breathing-therapy mode* (3.11.22), *respiratory cycle* (3.4.16), *airway pressure* (3.6.1), *inspiration* (3.2.10), *expiration* (3.2.11), *set* (3.1.19), *inspiratory pressure* (3.6.2), *baseline airway pressure* (3.10.1), *BAP* (3.10.2), *expiratory phase* (3.4.2), *bi-level* AV (3.12.4) and *CPAP* (3.11.15).

3.12.6
BAP time
time-low
duration of a BAP, or *pressure-low*, *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: This term is only relevant to *ventilation-modes* labelled as *bi-level* AV and is only used in combination with the term BAP_H (*pressure-high*) for the designation of the higher *baseline airway pressure*; it may be represented by an appropriate letter symbol, for example, t_L (or t_{BAP}).

Note 3 to entry: See also *baseline airway pressure* (3.10.1), *BAP*$_H$ (3.12.2), *bi-level AV* (3.12.4), *time-high* (3.12.9) and Figures C.22 to C.33 and F.5.

3.12.7
BAP_H
pressure-high
alternatively named higher *baseline airway-pressure* level in *ventilation-modes* labelled as *bi-level* AV

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).

Note 2 to entry: The preferred term is spoken as, BAP-high.

Note 3 to entry: The admitted term is included in this edition of this document based on its common current usage and the possible need for a longer transition time for the changeover to the use of the term BAP_H, should this prove necessary; it may be represented by an appropriate letter symbol, for example, p_H.

Note 4 to entry: The use of this alternative term, or its admitted synonym, in *ventilation-modes* labelled as *bi-level* AV is optional.

Note 5 to entry: See also *BAP* (3.10.2), *bi-level AV* (3.12.4) and Figures C.32, C.33, and F.7a.

3.12.8
BAP$_H$ phase
pressure-high phase
alternatively named *assured-inflation* phase in *ventilation-modes* labelled as *bi-level* AV

Note 1 to entry: The admitted term is included in this edition of this document based on its common current usage and the possible need for a longer transition time for the changeover to the use of the term BAP$_H$ *phase*, should this prove necessary.

Note 2 to entry: The preferred term is spoken as, BAP-*high phase*.

Note 3 to entry: The admitted term may be represented by an appropriate letter symbol, for example, p_H phase.

Note 4 to entry: The use of this alternative term, or its admitted synonym, in *ventilation-modes* labelled as *bi-level* AV is optional.

Note 5 to entry: See also *bi-level AV* (3.12.4), *BAP* (3.10.2) and Figures C.32, C.33, and F.7a.

3.12.9
BAP$_H$ time
time-high
alternatively named duration of a BAP$_H$, or *pressure-high*, *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: This term is only relevant to *ventilation-modes* labelled as *bi-level* AV and is only used in combination with the term BAP$_H$ (or *pressure-high*) for the designation of the higher *baseline airway pressure*; it may be represented by an appropriate letter symbol, for example, t_H, t_{BH} or t_{BAPH}.

Note 3 to entry: With *inflations* that provide synchronized *termination,* the *measured* duration, averaged over several *respiratory cycles*, will be determined by the *set time-high*, even though the duration of any individual BAP$_H$ (or *pressure-high*) *phase* can vary from the *set rate* as allowed by the synchronization algorithm.

Note 4 to entry: The use of this alternative term, or its admitted synonym, in *ventilation-modes* labelled as *bi-level* AV is optional.

Note 5 to entry: See also *bi-level AV* (3.12.4), *baseline airway pressure* (3.10.1), *BAP$_H$* (3.12.7), *BAP$_H$ phase* (3.12.8), *time-low* (3.12.6), *breath synchronization* (3.9.7), D.2.6, Annex F and Figures C.32 and C.33, and F.7.

3.13 Safety limits and alarm terminology

3.13.1
pressure limit
airway-pressure limit
airway-pressure threshold value for the *initiation* of an action to protect the *patient* during *normal use*

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 is a general, pre-coordinated term that is the basic definition for high and low limitation functions and for associated functions such as defining *alarm conditions* and other means of protection.

Note 3 to entry: The *limit* is to be taken to be for a rising pressure unless specified otherwise. This not only accords with common usage but also avoids a possible confusion resulting from the use of the word 'high', which is used in the *limit* and alarm terms in this document with a meaning of 'higher than intended', as distinct from 'the opposite of low'.

Note 4 to entry: See also *normal use* (3.1.24), *limit* (3.1.23) and deprecated terms for *inspiratory pressure* (3.6.2).

3.13.2
pressure-limited
inspiratory pressure limited to the *set pressure limit* during *normal use*, by means of an *inspiratory-pressure relief* function

Note 1 to entry: This limitation is typically used in conjunction with *volume-control inflation-types* where the intention is to *limit* the maximum pressure that can be generated at the *patient-connection port* during *normal use*.

Note 2 to entry: An *inspiratory-pressure-relief* function spills excess regulated flow to atmosphere, if necessary to avoid the *inspiratory pressure* exceeding the *set* level. This can result in a possibly un-quantified loss of the *delivered volume*. See also *inspiratory-pressure relief* (3.6.5).

Note 3 to entry: The term *pressure-limited* may be represented by an appropriate letter symbol, for example, p_{Lim}.

Note 4 to entry: The *initiation* of this *pressure-limitation* is typically associated with an *alarm condition*.

Note 5 to entry: See also *normal use* (3.1.24), *inspiratory-pressure relief* (3.6.5), *airway pressure* (3.6.1), *alarm condition* (Annex J), D.2.3 and Figure C.13 for an example of a *pressure-limited inflation*.

3.13.3
maximum limited pressure
maximum limited airway-pressure
DEPRECATED: maximum circuit pressure limit
highest *airway pressure* that can occur during *normal use* or under *single fault condition*

Note 1 to entry: In addition to its direct reference as a requirement, 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: As with all unqualified *airway pressures*, this limited pressure is that at the *patient-connection port* and relative to ambient pressure.

Note 3 to entry: As this is the highest-level precaution against excessive pressures being applied to the *patient's airway* this *pressure limit* is typically *preset* by the *manufacturer* but can be made adjustable by the *responsible organization* to a lower pressure level.

[SOURCE: ISO 80601-2-12:2011, 201.3.214, modified — Addition of preferred and deprecated terms.]

3.13.4
maximum working airway-pressure
maximum working pressure
highest *airway pressure* that can be generated by the *ventilator* during *intended use* and *normal condition*

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

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

Note 3 to entry: See also *airway pressure* (3.6.1), *intended use* (3.1.25) and *normal condition* (3.1.26).

3.13.5
high-airway-pressure limit
airway pressure threshold value at which a *protection device* prevents any further rise in the *airway pressure*

Note 1 to entry: The *protection device* can maintain the *airway pressure* at a level close to the threshold value, reduce the *airway pressure* to the *set* BAP or *terminate* the *inflation phase*. One or more of these alternatives will be required by the Particular Standard that covers the class of *ventilator* to which the term might be applied.

Note 2 to entry: The *set limit* can be:

— independently adjustable;

— connected to an adjustable *pressure limit*;

— connected to the high airway pressure-*alarm limit*;

— related to the *set inspiratory pressure*.

Note 3 to entry: See also *protection device* (3.13.10) and *inspiratory-pressure relief* (3.6.5)

3.13.6
high-pressure relief limit
high-airway-pressure relief limit
airway pressure threshold value used by a *ventilator* to determine when a *protection device* prevents any further rise in *airway pressure* during *normal use*

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: As with all unqualified *airway pressures*, this limited pressure is that at the *patient-connection port* and relative to ambient pressure.

Note 3 to entry: During an *inflation*, the high *inspiratory-pressure relief protection device* is intended to maintain the *airway pressure* at the threshold value, without *terminating* the *inflation*.

Note 4 to entry: Activation of this form of *airway pressure* limitation can cause a drop in the *inspiratory volume*. *Operator* awareness of this characteristic can be important for *patient* safety.

Note 5 to entry: The *set limit* can be independently adjustable, linked with an *adjustable pressure limit*, related to the *set inspiratory pressure* or determined by an algorithm.

Note 6 to entry: The *set limit* can be associated with an *alarm limit*.

Note 7 to entry: See also *protection device* (3.13.10), *normal use* (3.1.24), *alarm limit* (Annex J) and *high-pressure termination limit* (3.13.7).

3.13.7
high-pressure termination limit
high-airway-pressure termination limit
airway pressure threshold value used by a *ventilator* to determine when a *protection device terminates* the current *inflation phase* during *normal use*

Note 1 to entry: This form of *airway pressure limit*ation can often result in the *delivered volume* falling below that *set*. *Operator* awareness of this characteristic is important for *patient* safety.

Note 2 to entry: As with all unqualified *airway pressure*s, this limited pressure is that at the *patient-connection port* and relative to ambient pressure.

Note 3 to entry: The threshold value can be independently adjustable or connected to an *adjustable pressure limit*, may be related to the *set inspiratory pressure* or determined by an algorithm.

Note 4 to entry: This function can be associated with an *alarm condition*. Particular standards typically have specific requirements.

Note 5 to entry: This *limit* may have the same as or a different threshold from the high *airway pressure-alarm condition*. Particular standards typically have specific requirements.

Note 6 to entry: See also *protection device* (3.13.10), *high-pressure relief limit* (3.13.7), *limit* (3.1.23), *alarm condition* (Annex J) and Figure C.11.

3.13.8
maximum settable inspiratory pressure
highest *inspiratory pressure* that can be *set* by the *operator*

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, which will typically be *preset* by the *manufacturer* or the *responsible organization*

Note 2 to entry: As with all unqualified *airway pressures*, this *inspiratory pressure* is that at the *patient-connection port* and relative to ambient pressure unless prefixed with 'delta' or the symbol Δ.

Note 3 to entry: See also *inspiratory pressure* (3.6.2), *set* (3.1.19), *preset* (3.1.21) and *Δ inspiratory pressure* (3.6.7).

3.13.9
adjustable pressure limit
adjustable airway pressure limit
APL
operator-set limitation on the *airway pressure* under *normal condition*

EXAMPLE APL valve on *anaesthesia breathing system.*

Note 1 to entry: See also *limit* (3.1.23), *normal condition* (3.1.26) and *ventilator breathing system* (3.1.18).

3.13.10
protection device
part or function of a *ventilation* device that, without intervention by the *operator*, protects the *patient* from hazardous output due to incorrect delivery of energy or substances

[SOURCE: ISO 80601-2-12:2011, 201.3.220, modified — Rephrased.]

3.14 Gas port terminology

3.14.1
port
opening(s) for the passage of a fluid through a specified interface

Note 1 to entry: Typical interfaces where ports occur are

— where gas enters a medical device,

— where *operator*-detachable tubing is connected to a medical device, and

— where a *ventilator breathing system* is connected to the *patient* or to an *airway device*.

Note 2 to entry: A *port* can be in the form of a specific connector or designed to not allow connection with any connector.

3.14.2
exhaust port
port of the medical equipment or device from which gas is discharged to the atmosphere during *normal use*, either directly or via an anaesthetic gas scavenging system.

[SOURCE: ISO 80601-2-12:2011, 201.3.205, modified — Restriction to electrical equipment only was removed.]

3.14.3
gas output port
port of the *ventilator* through which gas is delivered at respiratory pressures to an *operator*-detachable part of the *ventilator breathing system*

[SOURCE: ISO 4135:2001, 3.2.8, modified — Rephrased.]

3.14.4
gas return port
port of the *ventilator* through which gas is returned at respiratory pressures through an *operator*-detachable part of the *ventilator breathing system*, from the *patient-connection port*

[SOURCE: ISO 80601-2-12:2011, 201.3.210, modified — Adapted for ventilators.]

3.14.5
patient-connection port
port of a *ventilator breathing system* intended for connection to an *airway device*

[SOURCE: ISO 80601-2-12:2011, 201.3.218, modified — Rephrased.]

Note 1 to entry: The *patient-connection port* is the end of the *ventilator breathing system* proximal to the *patient*.

Note 2 to entry: The *patient-connection port* is typically in the form of a suitable for connection to an *airway device* such as a tracheal or tracheostomy tube, a face mask, or a supralaryngeal airway, or to a test apparatus.

Note 3 to entry: Current particular standards typically specify that the *patient-connection port* is required to be in the form of a specific standardized connector(s), for example, a connector(s) conforming to ISO 5356-1.

Note 4 to entry: In *ventilators* designed to provide NIV (*non-invasive ventilation*) and where the *ventilation* function is dependent upon a design feature of a component that connects the *ventilator* to the *patient's airway*, then the *patient-connection port* typically becomes the contact line of the seal to the *patient's* face and there is no *patient-connection-port* connector.

Note 5 to entry: See also *port* (3.14.1), *ventilator breathing system* (3.1.18), *airway device* (3.1.3), *NIV* (3.1.15) and airway (3.1.2).

Annex A
(informative)

Rationales and guidance

A.1 General guidance

This annex provides rationales for the important clauses of this document and is intended for those who are familiar with its subject but who have not participated in its development. An understanding of the reasons for the main requirements is essential for its proper application. Furthermore, as clinical practice and technology change, it is expected that rationales for the present requirements will facilitate any revision of this document necessitated by those developments.

A.2 Mental model of ventilation as the basis of this document

The Introduction summarizes the factors that led to a comprehensive review of the vocabulary of *artificial ventilation* and the preparation of this document. A key definition in the review was that of *ventilation-mode* because the concepts behind it are fundamental to the conceptual structure underlying the terminology presented in this document. An explanation of how the definitions associated with that key term were derived is, therefore, an essential background to understanding that underlying structure.

Early devices for delivering *automatic ventilation* by means of intermittent positive pressure, operated to a fixed cyclical pattern with a range of *settings* for just the basic parameters. However, with the increasing flexibility offered by electronic control systems, more and more permutations and combinations of the basic elements of gas delivery were devised – to the point where, in the absence of an internationally standardized vocabulary, it was no longer practical to provide every possible *ventilation-pattern* with a meaninfgul unique name.

Today, more than 100 different names for in excess of 30 mutually exclusive *ventilation-modes* make it impossible to teach and learn which mode to use in which clinical situation. Consequently, most users have only been taught just a few of these *ventilation-modes*. Also, it has become very difficult to relate different *manufacturers'* modes to each other – a problem significantly compounded by a lack of consistency in the terminology used to describe them.

An analysis of the structure of these *ventilation-modes* reveals that they all require the selection of both the regulated parameter used to *inflate* the *lungs* and a pattern that determines when and what *inflations* occur; functions that can be conveniently referred to as the *inflation-type* and the *ventilation-pattern*. It also becomes clear that, conceptually and from a clinical perspective, in most cases the choice of *inflation-type* is largely independent of the choice of *ventilation-pattern*.

In the vocabulary of this document, this concept has been formalized, with the *ventilation-mode* becoming a composite of these two independent, *operator*-selectable elements: the *inflation-type* determines how the pressure or flow at the *patient-connection port* will be regulated during an *inflation*, once *initiated*, and the *ventilation-pattern* determines how the *ventilator* will respond to *patient-trigger events* and what it will cause to be delivered, when, irrespective of the *patient's respiratory activity*.

This is seen to be a logical step because most of the clinically distinctive characteristics of the classical *modes*, which still form the foundation of modern *ventilation-modes,* are those that relate to the time-pattern of interactive events between the *ventilator* and the *patient*; characteristics which are largely independent of the delivery-regulation means.

In practice, many *manufacturers* have already, at least partially, intuitively introduced such a separation in the way in which they have labelled their *ventilator* user interfaces and structured their instructions for use.

From this perspective, it is pertinent to note that part of the confusion with respect to *ventilation-modes* has resulted from *manufacturers* labelling their modes with names that feature just one of these attributes; some modes might be labelled SIMV – a *ventilation-pattern*, and others VCV – an *inflation-type*. In accordance with this document both of these *ventilation-mode* labels are incomplete: the correct *ventilation-mode* designation requires an indication of both the *ventilation-pattern* and the *inflation-type*(*s*) being used, with the examples becoming SIMV-PC *or* SIMV-VC and CMV-VC.

The above approach reduces the number of pre-coordinated names required significantly as any of a number of *inflation-types* can be independently selected for use with each *ventilation-pattern*: instead of M x N different *ventilation-mode* names to learn there become just M *ventilation-patterns* plus N *inflation-types*. *Ventilator* operation can therefore be described as if made up from elements of a construction set. As an example, it enabled a list of 58 *ventilation-mode* names, taken from *manufacturers'* literature, to be reduced to just 8 *ventilation-patterns* and 8 *inflation-types* – each of which can be placed into one of an even smaller number of easily remembered groups.

This format, with its focus on the pattern to which *inflations* are *initiated* and on the type of *inflation* that is delivered, is independent of which *ventilation-pattern* and *inflation-type* combination can be used with which *setting*, and for which clinical intention. Its structure not only reduces the number of items to be remembered but also makes them much easier to teach, learn, remember and recognize, thereby improving *ventilator* usability.

With this perception of what constitutes a *ventilation-mode* in current practice, in order to understand how these *ventilation-modes* relate to each other the committee found it to be helpful to create a classification system that groups them in terms of what they have in common and in what way they differ. It was considered that present trends are likely to increasingly disconnect the functional classification of *ventilation patterns* from clinical intentions and that *ventilation-mode* classifications should be based on function alone. When this was done, only four basic groupings, with two further subgroups, were required. These classifications enable teaching to be in terms of the common characteristics of, and mutual differences between, the *ventilation-patterns* in each group, and the appropriate *settings* for each of these *ventilation-patterns* for different clinical intentions.

Additionally, with only four basic families of *inflation-types*, instructions for their use can be centred on the clinical considerations of the alternative methods of generating an *inflation*, and of its *termination*. These instructions can be largely independent of the *ventilation-pattern* with which it will be used although some instruction might be necessary where the selected *inflation-type* could affect the clinical intention of the resultant *ventilation-modes*. Although, conceptually, around 20 standardized types of *inflation* could be made available for *operator* selection to accompany each *ventilation-pattern*, in practice, *manufacturers* will only offer the much more limited range of combinations most likely to be used in clinical practice.

From this perspective, it can be seen that, in the past, many 'new' *ventilation-modes* that have been introduced, with their own proprietary names, have in fact only been an easily described sub-set of a standard *inflation-type*.

With regard to the naming of these *ventilation-patterns* and *inflation types*, there has been full recognition that existing users already have a pertinent vocabulary which they use in the day-to-day operation of current *ventilators*. The confusions have arisen because, in the absence of any comprehensive international agreement, there are invariably several terms in use for each concept and in other cases a single term is being used for a range of concepts with only some similarities.

Because almost all the concepts defined in this document are based on current good practice, and therefore fall within the general range of meanings associated with each of these existing terms it was considered to be more appropriate to retain these terms, wherever possible, and use this document to give them a standardized definition rather than attempt to introduce a completely new term for every concept.

It was seen that with this approach, users will be able to operate *ventilators* conforming to this document in the same way as at present - with no more difficulty than in moving between different *ventilators* - with the advantage that once learnt, it will increasingly be directly applicable to more and more *ventilators* as time progresses. In addition, the named *ventilation-patterns* and *inflation-types* in this document are classified into coherent groups, so those users interested in the differences between *ventilation-modes* will find that these are always explained from the same reference points. These classifications also form the basic framework for the unique identification, by name and code, of any *ventilation-mode* within the scope of this document.

Another challenge that the members of the committee and others have encountered when teaching *ventilator* theory, has been how to distinguish between what the *ventilator* is doing and what is happening to the *patient*. In this document, a *ventilator* can generate *breaths* by cyclically *inflating* the *patient's lungs*, but it is only a *patient* who can *breathe*.

A further question might be as to where the *trigger* function for *patient-initiation* fits into these classifications. In some previous classification proposals, *initiation* was considered to be a property of the *inflation-type* and so the *triggering*-function was also included in these properties. In the classification system of this document, the *initiation* of an *inflation* is a property of the *ventilation-pattern*, which provides rules defining how the *ventilator* responds to various inputs. Logically, therefore, the *ventilation-pattern* is simply responding to a signal from a *ventilator* detection function indicating that the *measurement* of a *patient* parameter(s) has attained a *set* threshold value. With this concept, the *trigger* function becomes just another *ventilation* monitoring function that provides a signal to the *ventilator* control system. In practice, most major *manufacturers* already treat *patient-triggering* in this way, that is, as an independently-selectable, *settable* monitoring function which provides a signal when the monitored parameter reaches a *set* level, for use by the selected *ventilation-pattern* algorithm as required.

A.3 Guidance followed in the writing of this document

This document is based on the guidance and requirements specified in ISO 704 and ISO 10241-1.

A.4 Rationales for particular clauses and subclauses

The numbering of the following rationales corresponds to the numbering of the clauses in this document. The numbering is, therefore, not consecutive.

1 Scope

Terms pertaining specifically to *breathing*-therapy equipment and high-frequency *ventilation* have not, in general, been specified in this edition of this document as their scope is still evolving with continuing developments in those technologies and their applications. The only exceptions are where it was considered necessary to establish boundaries between bordering concepts. It is the intention of the committee to include such terms in a future amendment or edition of this document.

3 Terms, definitions, symbols, and abbreviated terms

As stated in ISO 704 and ISO 10241-1, a primary function of a standardized terminology is to indicate preferred, admitted, and deprecated terms. In subject fields where there has been no effective standardized terminology, such as is the case with *artificial ventilation*, it is inevitable that there is frequently more than one term in common use for the designation of a given concept.

However, in choosing a preferred term in this document it was recognized that there was often the need to make a compromise between the conflicting requirements of the avoidance of ambiguity and the need for conciseness. In this document, the form of the preferred term, whether the full form of an abbreviation, was selected with priority given to the one that is most generally used. Guidance for corresponding letter symbols is sometimes also provided in notes to entries - for use in appropriate contexts.

Where a term is listed as 'deprecated', this means that it is deprecated as a synonym for the preferred term, although some such terms are used as preferred terms for the designation of other concepts.

In accordance with ISO 10241-1:2011, 6.4.4, the definitions of terms in Clause 3 of this document are intensional definitions. Such definitions are required to consist of a single phrase specifying the concept being designated, and if possible, to reflect the position of the concept in the concept system; containing only information that makes the concept unique. A definition given without an indication of its applicability is to be taken as representing the general meaning of the term. Any additional descriptive information deemed necessary is included in notes to entry or in examples. Notes to terminology entries follow different rules from those integrated into other text in a standard; they provide additional information that supplements the terminological data in the definitions.

Because a *ventilator* is a device that, typically, interacts with a *patient* in accordance with inputs from an *operator*, certain of the concepts of *artificial ventilation* are of quantities with a value that might be either the *actual value* or the intended value as *set*, directly or indirectly, by an *operator*. In these instances, the definition is used to represent the general meaning of the term. If it is, or can be, used to represent either a *set* value or an *actual value* or both, this is stated in a note to entry. An *actual value* exists as a concept whether it can be *measured* or not and is, therefore, unaffected by the accuracy of measurement or the method by which it might be displayed or recorded. For this reason, the vocabulary of this document only addresses *actual values*, *set* values and *measured* values as concepts. It is for particular standards to specify any requirements regarding measurement accuracy and units of measurement.

The terminological entries in Clause 3 are primarily arranged in a systematic order, with a secondary alphabetical order. An alphabetically arranged list of terms is provided in Annex J.

For further information concerning *set*, *measured* and *actual values*, and on how this document is intended to be applied, particularly with respect to context and qualification, and concerning some of the conventions followed in Clause 3, see informative Annexes G and H.

3.4 Time, phase and cycle terminology

The use of terms relating to gas entering and leaving the *patient's lungs* is fundamental to a vocabulary of *artificial ventilation*. In normal speech in English, terms such as inspire, inhale, exhale and expire in their various inflected forms are used for that purpose but each has connotations that makes it less than ideal in at least one of its forms. In particular, inhalation has become associated with drug abuse and many clinicians consider it to be inappropriate to speak of the *patient* expiring, in the presence of the *patient* or those close to them. However, one of the basic objectives of a terminology standard is, wherever possible, to have only one term to represent each concept. After much discussion, the terms *inspiration* and *expiration* were selected for this document but with the recognition that the use of alternative terms can be more appropriate in potentially sensitive situations.

3.5 Rate terminology

The *ventilation* rate terms in this subclause have been grouped into two further subclauses. The first of these groups comprises the terms that are commonly used on the user interfaces of *ventilators.*

The second group comprises those that might be required for specific purposes such as in technical descriptions, clinical papers or data logging. Potentially, there are many such terms but most can be formed as post-coordinations of simpler terms already defined in this document. Four such terms have been entered in 3.5.2, as examples, but, as with some other terms in this document, the purpose of this group is solely to provide guidance in the case of needing to express a respiratory rate in terms of one of a range of related concepts. There is no implied requirement that *manufacturers* should make use of any one of these terms in their labelling or *accompanying documents.*

3.10 Baseline and PEEP terminology

See Annex F, for a rationale for these topics.

3.11 Mode terminology

See A.2.

3.11.5 Ventilation-mode group

The systematic grouping described in this subclause was introduced during the preparation of this document. Its value in helping with the discussion, understanding, memorization and teaching of how the various *ventilation-modes* related to each other regarding their functional characteristics, led to the decision to retain it.

Ventilation-mode groups have been introduced in this document solely to provide a means of classifying *ventilation-modes* in a way that can assist with the understanding and teaching of how the large numbers of such modes currently in use are related to each other. There is no requirement for *manufacturers* to include reference to these groups in product labelling but where this grouping is referred to it is required to be in accordance with this document.

Four *ventilation-mode groups* have been specified, according to their *ventilation-patterns*. Each *ventilation-mode* within the scope of this document falls into one of these groups, the defining characteristics of which are given in 3.11.5. All *alternatively-named modes* and *superordinate modes* also fall into one of these groups, as determined by the underlying *ventilation-pattern* employed.

3.11.6 Assured ventilation

The admitted term, *mandatory ventilation*, is included in this document because it became firmly established over several decades by its use in the *ventilation-mode* names, CMV, IMV and SIMV. In the early implementations of these *ventilation-modes* both the *initiation* and the delivery were imposed on the *patient* but with the modern approach to *artificial ventilation*, which allows *patients* to contribute to their own *ventilation* as much as they are able, the term only makes sense when used to convey the concept of the assured *initiation* of a selected *inflation-type*. This is the only sense in which it is used in this document. However, because the word mandatory is ambiguous when used as a term in this context, in that it can be taken to mean either of these, and because this ambiguity has allowed it to be used to give the appearance of unifying a range of different concepts, the word is only used in this document in reference to the legacy *ventilation-patterns* that have it incorporated into their names. For other purposes, natural language phrases such as 'assured to be' are used to convey the defined concept wherever possible, in preference to the term mandatory or any of its inflected forms.

In the related semantics, the delivery of an *inflation* causes mandatory *ventilation* of the *patient's lungs* but only in the sense that the selected *inflation-type* is assured to be *initiated* - not that the *inflation-type* selected will necessarily deliver an assured volume.

3.11.14 APRV (airway pressure release ventilation)

The rational for the introduction of this *ventilation-mode*, and for its name, was to allow *patients* with acute oxygenation failure to *breathe* with better coordination, improved gas exchange and less barotrauma. The periodic release and near immediate subsequent build-up of *airway pressure* was intended to assist the *patient's* own *breathing* efforts while not allowing the *lungs* to collapse.

Although that rational describes the essential concept of APRV it is recognized that, with this *ventilation-mode* selected, many *manufacturers* now permit the *operator* to *set* the BAP *phase-time* ($\boldsymbol{t}_{\mathrm{L}}$) to values far in excess of any expected *expiratory-flow times*. The justification for this is that the ongoing treatment of a *patient* requiring APRV during an initial acute period might well involve the progressive adjustment of the two BAP levels and also the two phase times, both as individual values and their differentials, in order to provide a step-less continuity of treatment - working towards a single decreasing level of CPAP, without the discontinuity involved in changing over to a different *ventilation-mode*.

3.12 Bi-level terminology

The terminology in this document has been developed taking account of the additional functionality of *ventilators* incorporating an ACAP *adjunct*. This is an advanced regulation function that, unlike conventional pneumatic regulators, maintains a *set airway pressure*, irrespective of the direction of the *airway* flow. It is used not only to enhance the regulation of the *airway pressure* during *pressure-control inflations* but also to maintain the required pressure between *assured inflations*. This makes it possible for the *patient* to *breathe* at any time, both concurrently with an *assured inflation* and during the *expiratory phases* between *assured inflations,* with a minimal imposed addition to the *patient's* work of *breathing*. The *set airway pressure* for this regulation function can be continuously constant, as when used with CPAP, or in the form of a varying pressure waveform with constant portions as is typically generated by either the *inflation-type* algorithm during *inflation phases* or the *expiratory-control algorithm* during BAP *(*or *expiratory) phases*. During BAP *phases*, it maintains a constant pressure when there is no *pressure-support*, available or selected, and in the presence of any leakage.

On *ventilators* equipped with this increased functionality, *manufacturers* have either labelled their *ventilation-modes* as *bi-level modes*, with corresponding terminology for the *settings* and displays, or have retained the classical terminology for their *ventilation-modes*, *settings* and displays, accompanied by a statement indicating that the *patient* is free to *breathe* at any time.

As both approaches appear to have advantages and disadvantages, and as there is not yet any clear consensus as to which is better from a human factors perspective, this document includes terms suitable for both approaches. These terms are in most cases presented in this document as alternatives, but it is expected that they will always be used consistently and in context, according to the *ventilation-mode* designation adopted by the *manufacturer.*

It is anticipated that in future editions of this document more specific guidance will be given on the application of such terms.

Annex B
(informative)

Conceptual relationships between ventilator actions and types of breath

Figure B.1 is a diagrammatical representation of how the terminology of this document is used to describe *patient-ventilator* interactions and the relationship between increases in the volume of gas in the *lung* and *inflations*. In a sequence, these interactions lead to the generation a series of *breaths* of a single or changing type.

In this document, *breaths* are defined from the *patient* perspective. Five types of *breath* are designated by the type of *inspiratory* assistance that might be provided by various means of *artificial ventilation*.

Breaths can be either *initiated* by the *patient* or *ventilator-initiated* after an elapsed time without any *respiratory activity* being detected, as determined by the *ventilation-pattern* that has been selected. The following combinations of *patient* and *ventilator* actions determine the type of *breath* that results.

a) If there is no *respiratory activity* then the selected *assured inflation-type* will be *ventilator-initiated* and will act to increase the volume of gas in the *lung* until one of the *inflation termination* criteria has been reached, at which point the *ventilator* will allow the gas in the *lung* to discharge until the next *breath initiation* occurs. This sequence of events results in a *controlled breath*.

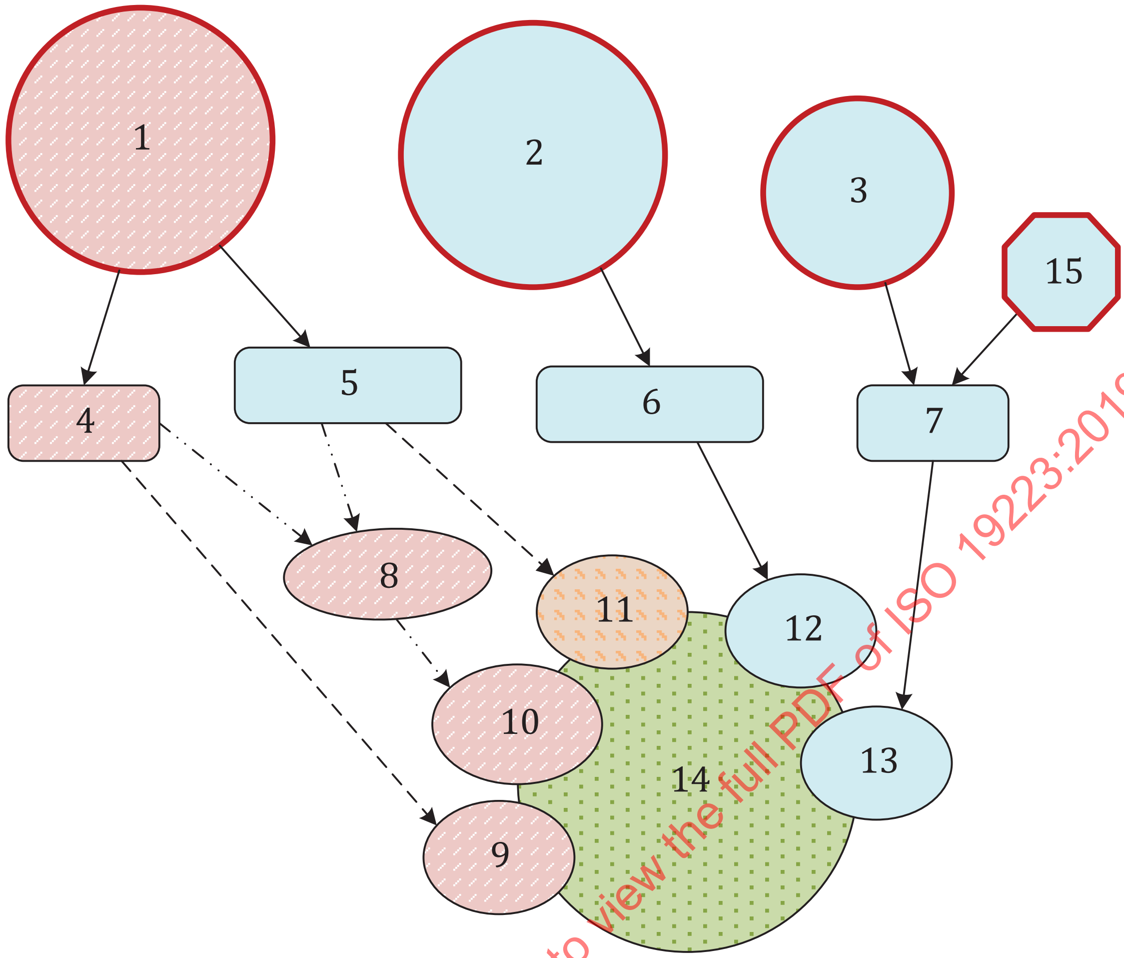
b) If *respiratory activity* occurs during an *expiratory phase* of, or concurrent with, an *assured inflation*, but the selected *ventilation-pattern* is not programmed to *initiate* the next *inflation*, then the *ventilator* might either respond to the *patient* demand by supplying *demand flow,* which matches the demand with little imposed increase in the work of *breathing,* or might have an unspecified delivery, which could cause a significant increase in the work of *breathing*. Either *ventilator* response results in an *unassisted breath*.

c) If a *patient-trigger event* occurs during an *expiratory phase* and the *ventilation-pattern* is programmed to *initiate* the next *assured inflation-type,* then its resulting delivery will assist any further *inspiratory effort.* The volume of gas in the *lung* will increase until respiratory pressures equalize or one of the *inflation termination* criteria is reached. When one of the *inflation termination* criteria is reached the *ventilator* will allow the gas in the *lung* to discharge until the next *breath initiation* occurs. This sequence of events results in an *assisted breath*.

d) If a *patient-trigger event* occurs during a *synchronization window* at the end of an *expiratory phase,* then the next *assured inflation-type* will be *initiated* and this will assist any further *inspiratory effort.* The volume of gas in the *lung* will increase until respiratory pressures equalize or one of the *inflation termination* criteria is reached. When one of the *inflation termination* criteria is reached the *ventilator* will allow the gas in the *lung* to discharge until the next *breath initiation* occurs. This sequence of events results in a *synchronized breath*.

e) If a *patient-trigger event* occurs during an *expiratory phase*, or concurrent with an *assured inflation*, and the selected *ventilation-pattern* is programmed to *initiate* the next *support inflation-type,* then its resulting delivery will support any further *inspiratory effort.* The volume of gas in the *lung* will increase until respiratory pressures equalize or one of the *inflation termination* criteria is reached, at which point the *ventilator* will allow the gas in the *lung* to discharge until the next *breath initiation* occurs. This sequence of events results in a *supported breath*.

It will be clear that the sequence in which any of these specific combinations, and the resultant *breaths*, occur depends on the pattern of *respiratory activity* and the *ventilation-mode* that has been selected.



Key

1 assured inflation-type
2 support inflation-type
3 demand flow
4 time
5 patient-trigger event
6 patient-trigger event
7 patient demand
8 synchronization window
9 controlled
10 synchronized
11 assisted
12 supported
13 unassisted
14 increase in volume of gas in lung
15 unspecified delivery

ventilator delivery functions

means of delivery initiation

outcome

unscheduled

connections showing the relationship for ventilation-modes where the patient is able to increase the assured inflation-type delivery rate above that set

connections showing the relationship for ventilation-modes where patient trigger events do not increase the average assured inflation-type delivery rate above that set

assured rate

more than assured rate

Figure B.1 — Diagrammatical representation of the concepts of the relationship between breath- and inflation-related terms in the vocabulary of this document

Annex C
(informative)

Illustrations of ventilation terms

An important aspect identified in the development of this document is that part of the present confusion in the use of *ventilation* terminology is the lack of distinction between the *setting* perspective and the outcome perspective.

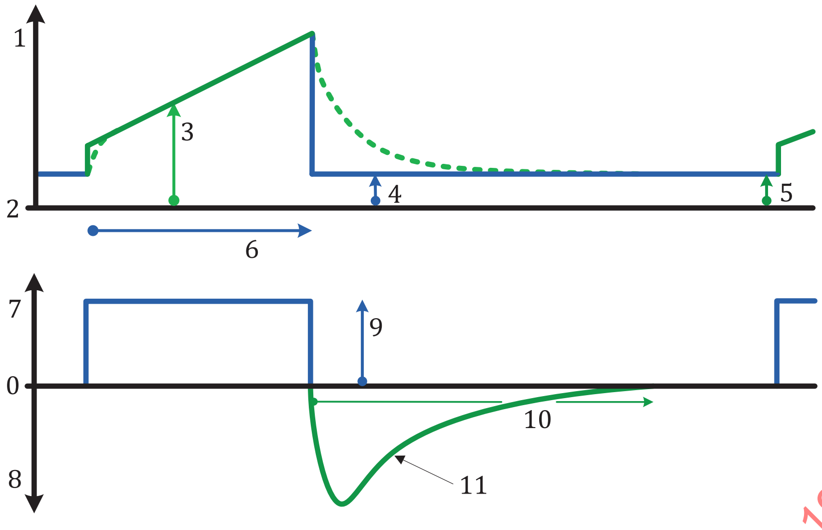
Most current representations of *ventilation-patterns* and *inflations* are based on typical waveforms as seen on user-interface displays, which is inevitably an outcome perspective. This is a helpful approach when describing the interpretation of the function of a specific *ventilator* but inevitably such a display introduces indeterminate artefacts, and these can detract from the clarity of a formal diagrammatical representation of the changes of state that are actually *set* to occur.

Although *set* flow changes can be made to occur almost instantaneously this is not possible with pressure changes because of the resistance and compliance characteristics of a *patient's respiratory system*. With such changes at the *initiation* and *termination* of an *inflation,* where conceptually the *set* value causes a step change, the actual responses are less immediate. In particular, with *pressure-regulation*, *rise times* are typically *operator*-adjustable to enable the avoidance of excessive overshoots and subsequent oscillations.

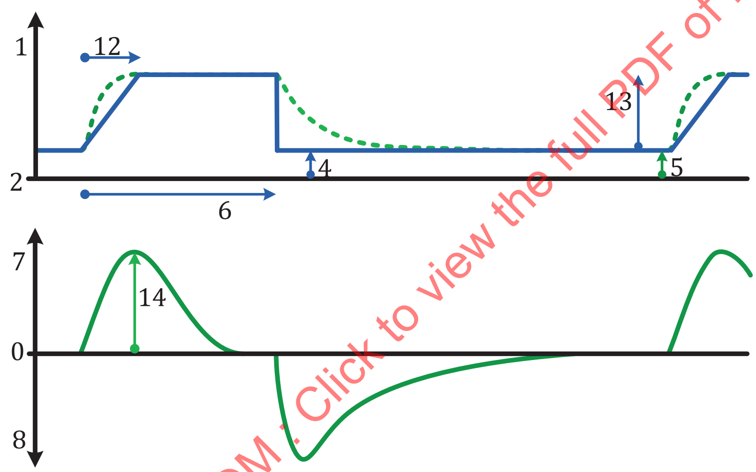
As appropriate, therefore, the diagrammatic representations of both *settings* and *measurements* for typical *ventilation* waveforms shown in the figures in this annex, and Annex F, are sometimes that of an idealized form of the input into the *ventilator* control system and an idealized *patient*, or sometimes that of typical actual waveforms as measured at the *patient-connection port*. They are sometimes combinations of both, depending on the feature that is intended to be highlighted. Figure C.1 has been specifically included to illustrate typical idealized waveforms with the addition of typical artefacts, shown using broken lines, and employing the colour coding detailed in the note to that figure.

Additionally, some of the figures in this annex and Annex F illustrate waveforms that result from unusual *settings* of *ventilation-modes* based on classically named *ventilation-patterns* - although these *settings* are within the range made available for use with such modes on currently manufactured *ventilators*. These unusual waveforms are not shown with any intention of advocating the use of such *settings* for a particular treatment, but to demonstrate how actual waveforms can be very different from those that are typically provided to illustrate a *ventilation-mode* function. Such illustrations highlight that the *ventilation* waveforms that can be generated with a specific classical pattern-based mode, but with unusual *settings*, are not necessarily all unique and some could overlap those that can be generated with another of the classical patterns.

Colour coding is employed in the figures of this annex, and of Annex F, for the reasons explained in the Introduction of this document. Unless otherwise stated, **blue** is used to represent *set* parameters and **green** to represent *actual* or *measured* parameters; **orange** broken lines are used to represent *baseline airway-pressure* levels. Waveforms with no specific coding are shown in **grey**. Additional colours are used for other purposes in specific figures. Figures C.14 to C.21 and C.35 have their own keys for their particular use of colours.



a) Flow-regulated inflations



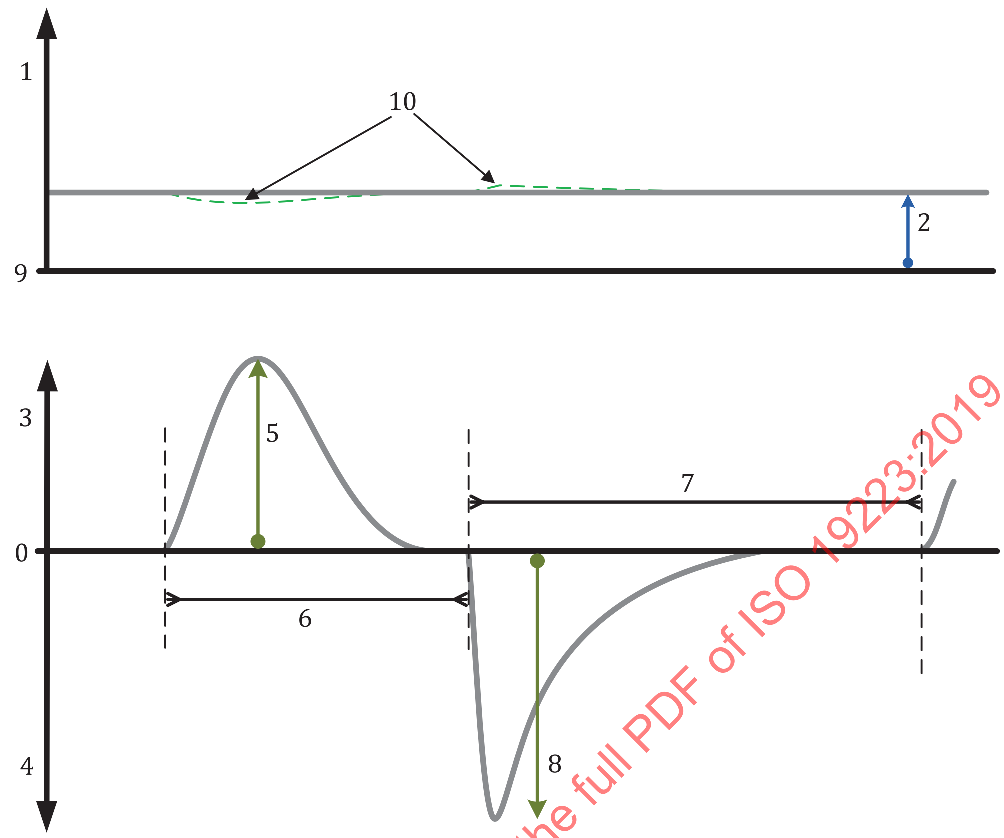
b) Pressure-regulated inflations

Key

1	airway pressure	9	set inspiratory flow
2	ambient pressure	10	expiratory flow time
3	inspiratory pressure	11	expiratory-flow waveform
4	BAP	12	rise time
5	PEEP	13	set Δ inspiratory pressure (if PC); set Δ support pressure (if PS)
6	inspiratory time (setting if VC or PC measurement if PS)	14	peak inspiratory flow
7	inspiratory flow		
8	expiratory flow		

NOTE For this figure only, the colour coding is used to separately identify those portions of the waveforms that are due to settings and those due to measurements. The continuous blue traces are used to represent the idealized waveforms of the ventilator output and the continuous green traces to represent typical actual flows and pressures.

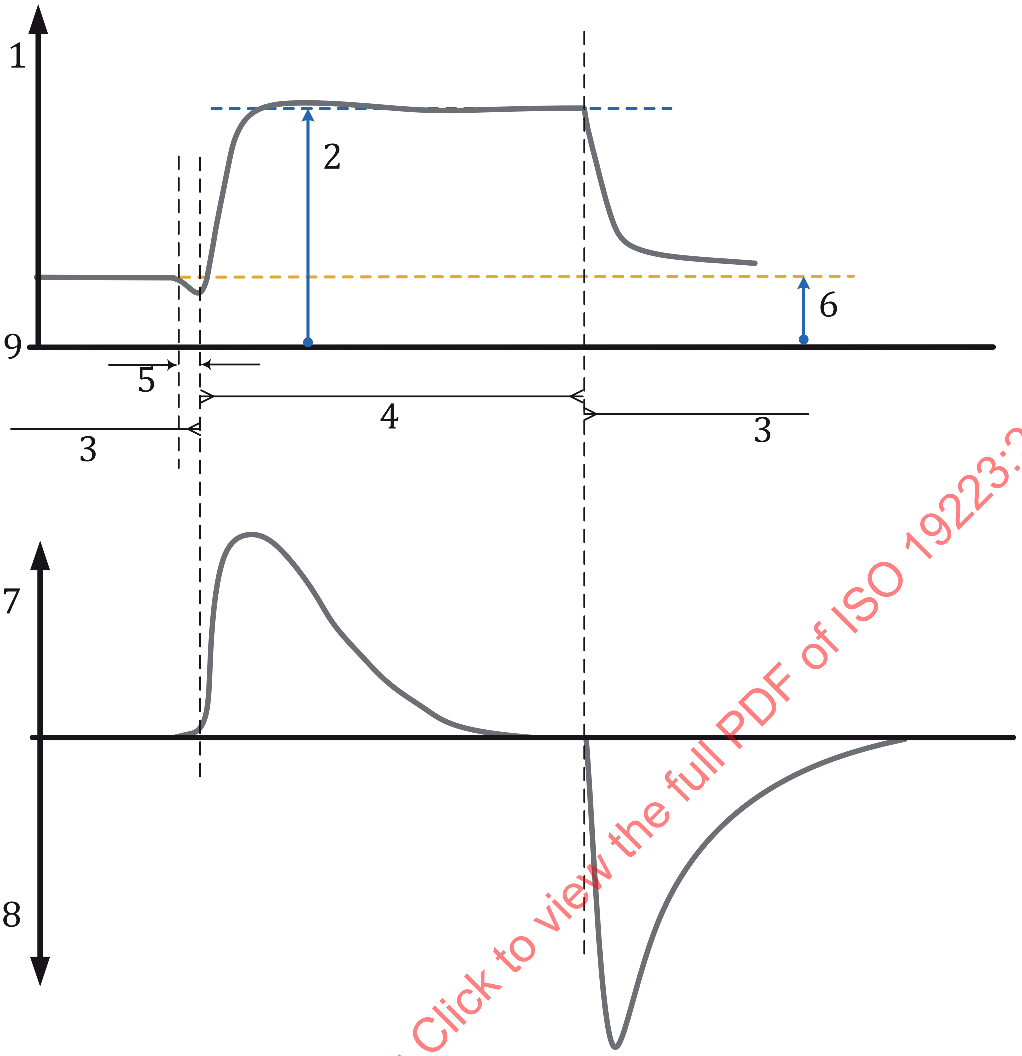
Figure C.1 — Representative ventilation-patterns and inflation-types illustrating the format used in the figures in this annex and Annex F



Key

1 airway pressure
2 CPAP
3 inspiratory flow
4 expiratory flow
5 peak inspiratory flow
6 inspiratory phase
7 expiratory phase
8 peak expiratory flow
9 ambient pressure
10 inevitable pressure deviations

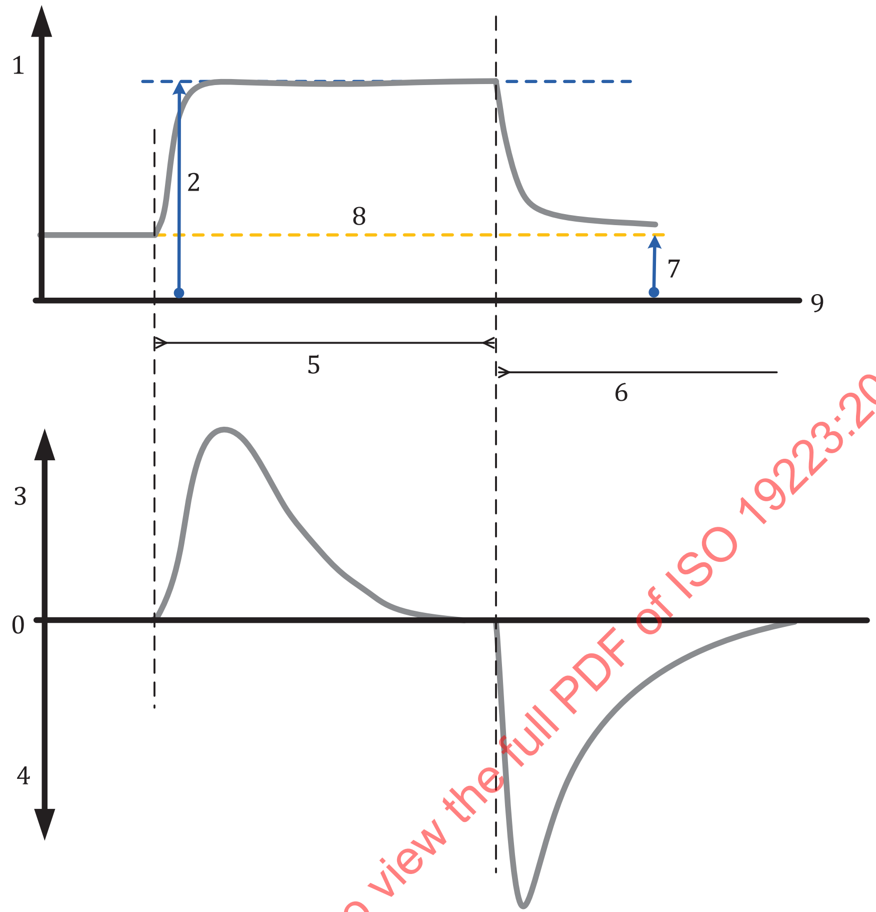
Figure C.2 — The inspiratory and expiratory phases of an unassisted breath, taken with the airway pressure maintained at a set CPAP level



Key

1	airway pressure	6	BAP
2	inspiratory pressure	7	inspiratory flow
3	expiratory phases	8	expiratory flow
4	inflation phase	9	ambient pressure
5	trigger phase		

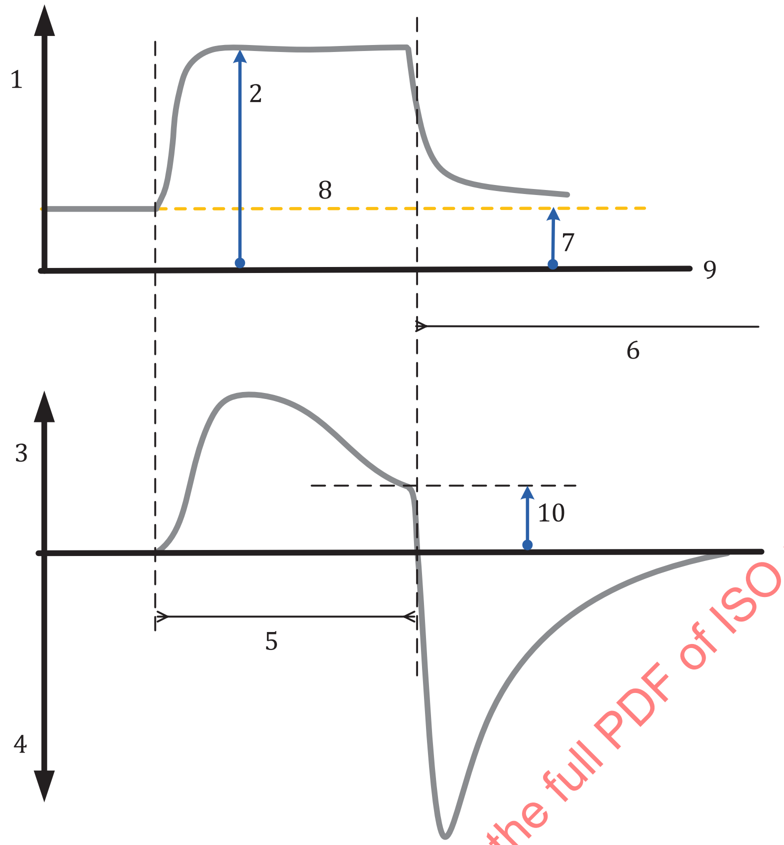
Figure C.3 — The inflation and expiratory phases of a patient-triggered, pressure-control (PC) inflation



Key

1	airway pressure
2	inspiratory pressure
3	inspiratory flow
4	expiratory flow
5	inflation phase
6	expiratory phase
7	BAP
8	baseline airway pressure
9	ambient pressure

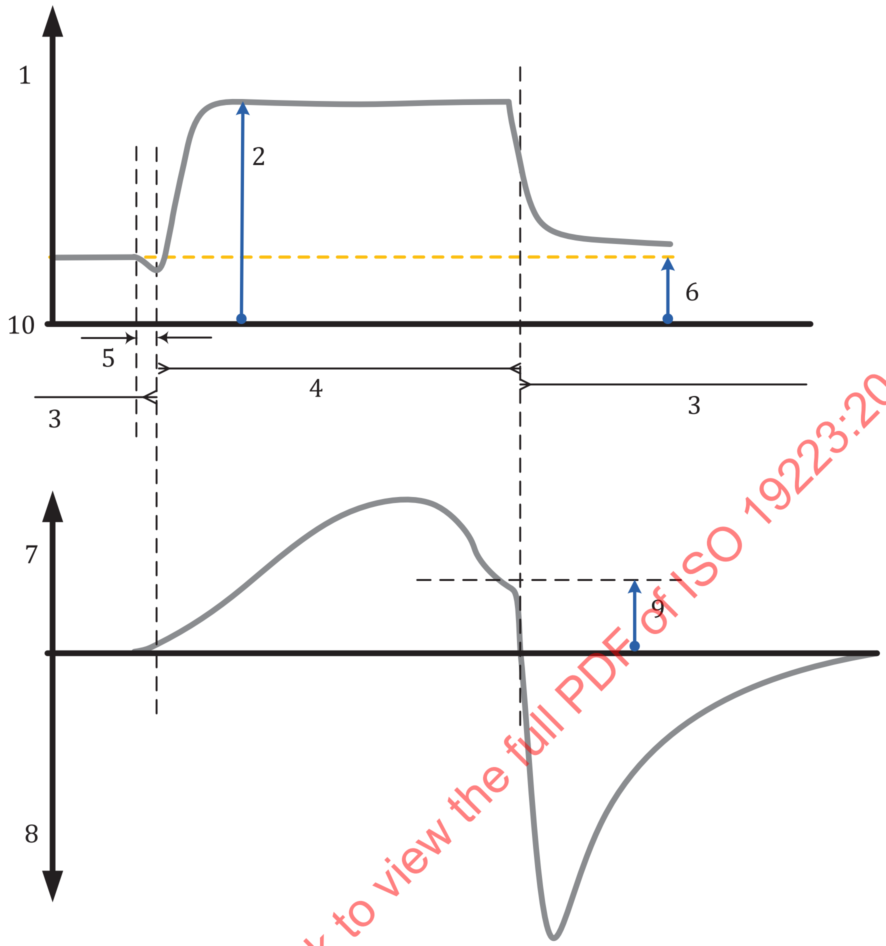
Figure C.4 — The inflation and expiratory phases of a ventilator-initiated, pressure-control (PC) inflation



Key

1	airway pressure	6	expiratory phase
2	inspiratory pressure	7	BAP
3	inspiratory flow	8	baseline airway pressure
4	expiratory flow	9	ambient pressure
5	inflation phase	10	end-inspiratory flow

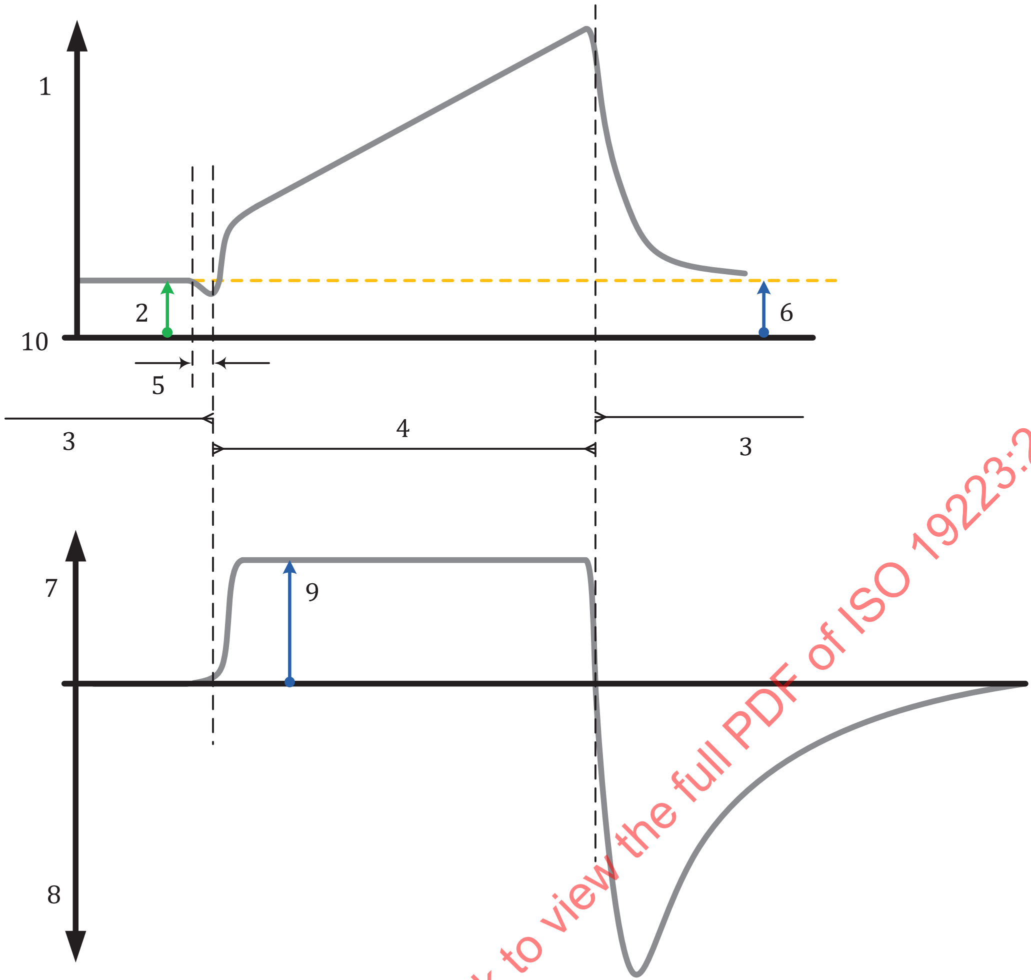
Figure C.5 — The inflation and expiratory phases of a ventilator-initiated, pressure-control (PC) inflation, time-terminated before the cessation of inspiratory flow



Key

1 airway pressure
2 support pressure
3 expiratory phases
4 inflation phase
5 trigger phase
6 BAP
7 inspiratory flow
8 expiratory flow
9 inspiratory-termination flow
10 ambient pressure

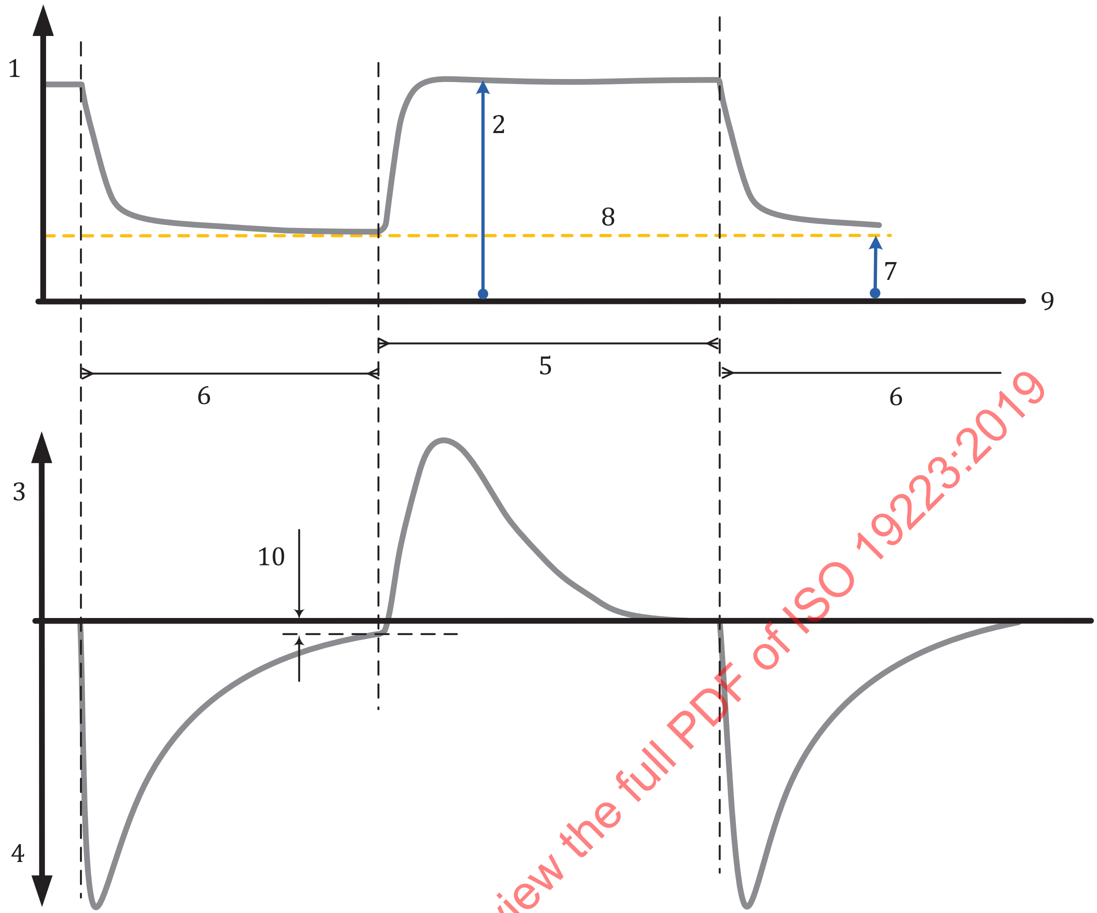
Figure C.6 — The inflation and expiratory phases of a patient-triggered, pressure-support (PS) inflation



Key

1	airway pressure	6	BAP
2	PEEP	7	inspiratory flow
3	expiratory phases	8	expiratory flow
4	inflation phase	9	inspiratory flow
5	trigger phase	10	ambient pressure

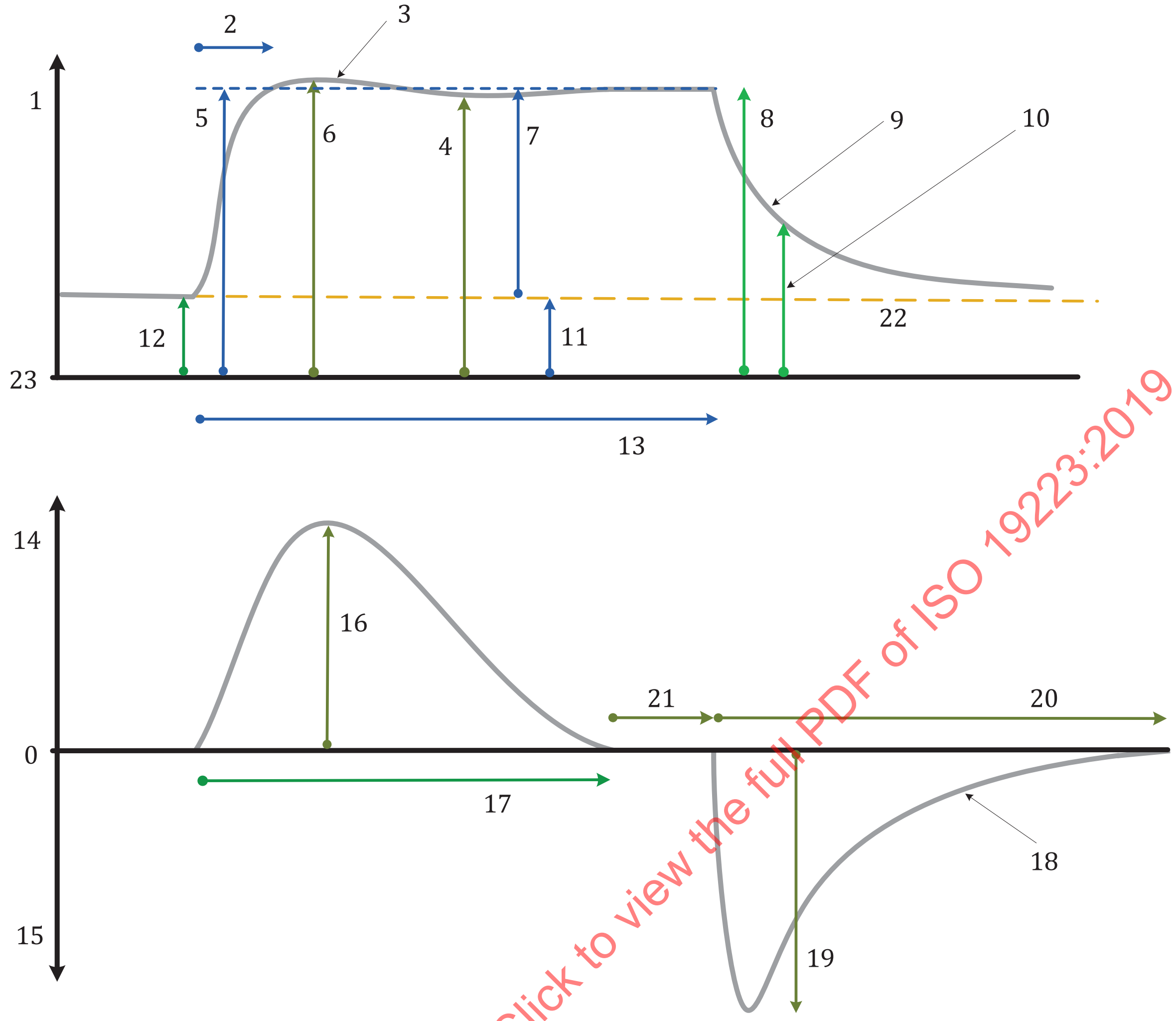
Figure C.7 — The inflation and expiratory phases of a patient-triggered, volume-control (VC) inflation



Key

1	airway pressure	6	expiratory phases
2	inspiratory pressure	7	BAP
3	inspiratory flow	8	baseline airway pressure
4	expiratory flow	9	ambient pressure
5	inflation phase	10	end-expiratory flow

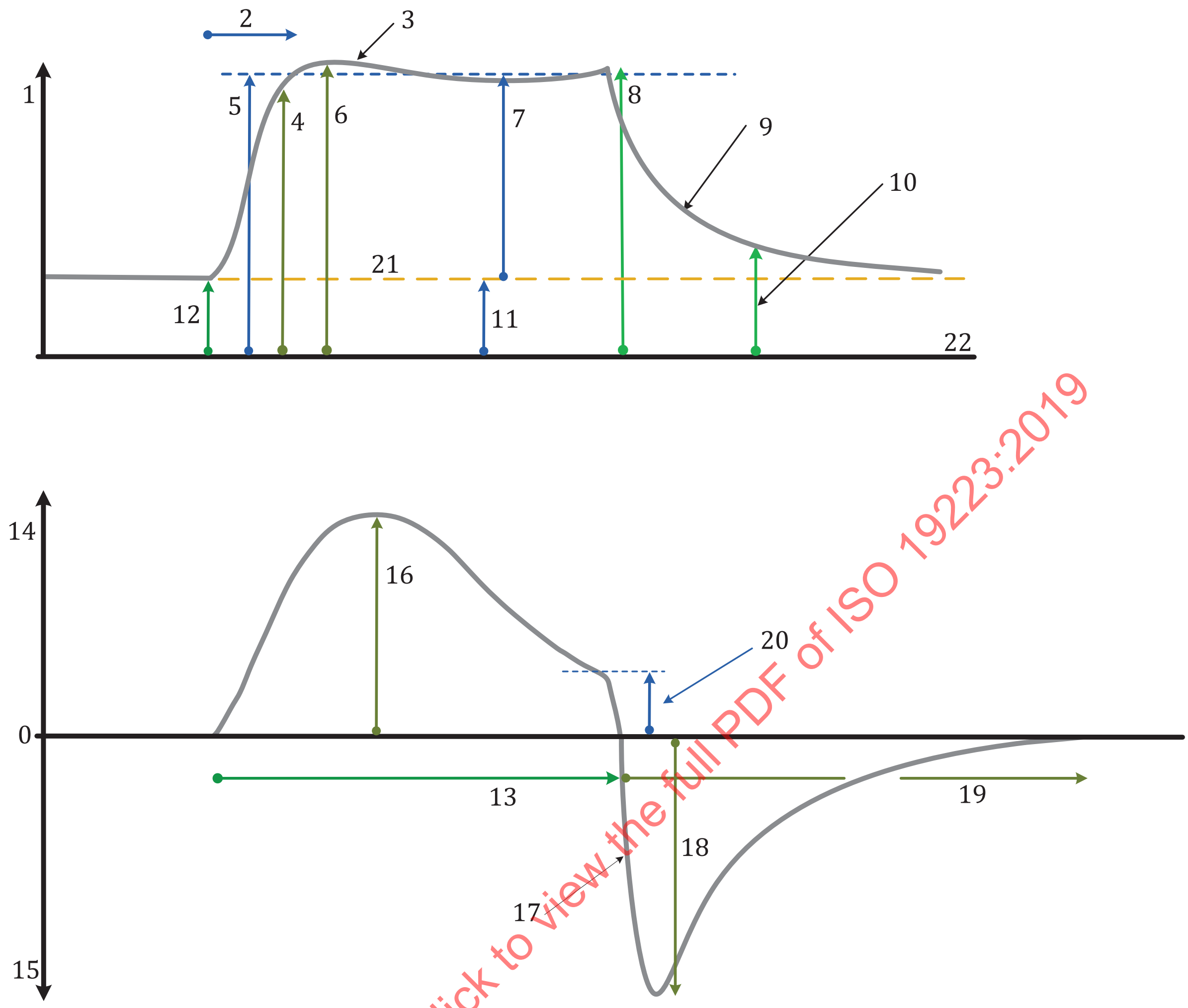
Figure C.8 — The inflation and expiratory phases of a ventilator-initiated, pressure-control (PC) inflation with end-expiratory flow



Key

1 airway pressure
2 rise time
3 inspiratory-pressure waveform
4 instantaneous inspiratory-pressure
5 inspiratory pressure
6 peak inspiratory pressure
7 Δ inspiratory pressure
8 end-inspiratory pressure
9 expiratory-pressure waveform
10 instantaneous expiratory pressure
11 BAP
12 PEEP
13 inspiratory time
14 inspiratory flow
15 expiratory flow
16 peak inspiratory flow
17 inspiratory-flow time
18 expiratory-flow waveform
19 peak expiratory flow
20 expiratory-flow time
21 inspiratory-pause time
22 baseline airway pressure
23 ambient pressure

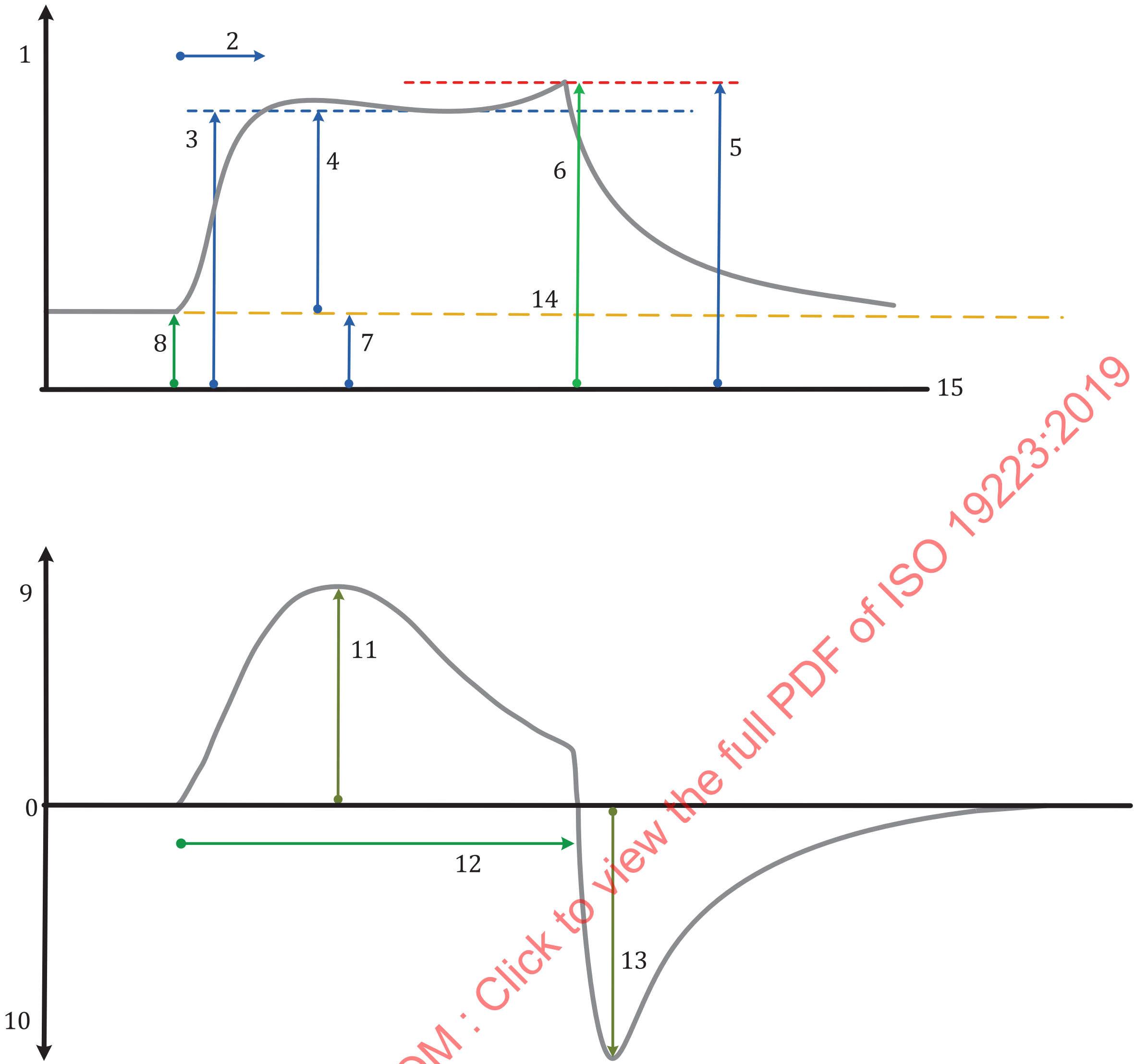
Figure C.9 — Illustrations of the application of defined ventilation terms in designating key features of typical inflation waveforms — Typical airway-pressure and flow waveforms for a pressure-control (PC) inflation



Key

1	airway pressure	12	PEEP
2	rise time	13	inspiratory time
3	inspiratory-pressure waveform	14	inspiratory flow
4	instantaneous inspiratory-pressure	15	expiratory flow
5	inspiratory pressure	16	peak inspiratory flow
6	peak inspiratory pressure	17	expiratory-flow waveform
7	Δ support pressure	18	peak expiratory flow
8	end-inspiratory pressure	19	expiratory-flow time
9	expiratory-pressure waveform	20	termination flow
10	instantaneous expiratory pressure	21	baseline airway pressure
11	BAP	22	ambient pressure

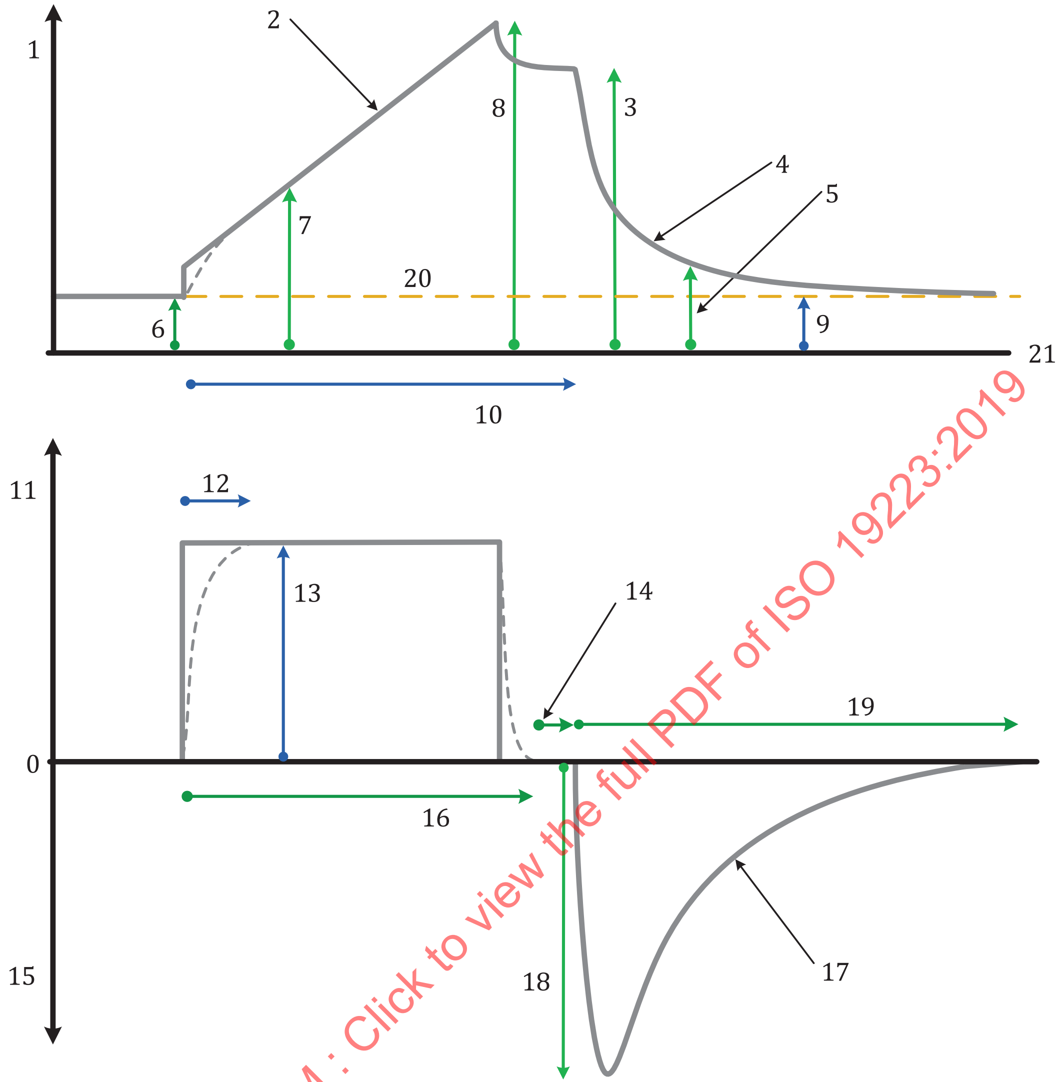
Figure C.10 — Illustrations of the application of defined ventilation terms in designating key features of typical inflation waveforms — Typical airway-pressure and flow waveforms for a pressure-support (PS) inflation



Key

1	airway pressure
2	rise time
3	inspiratory-pressure
4	Δ inspiratory pressure
5	high-pressure termination limit
6	end-inspiratory pressure
7	BAP
8	PEEP
9	inspiratory flow
10	expiratory flow
11	peak inspiratory flow
12	inspiratory time
13	peak expiratory flow
14	baseline airway pressure
15	ambient pressure

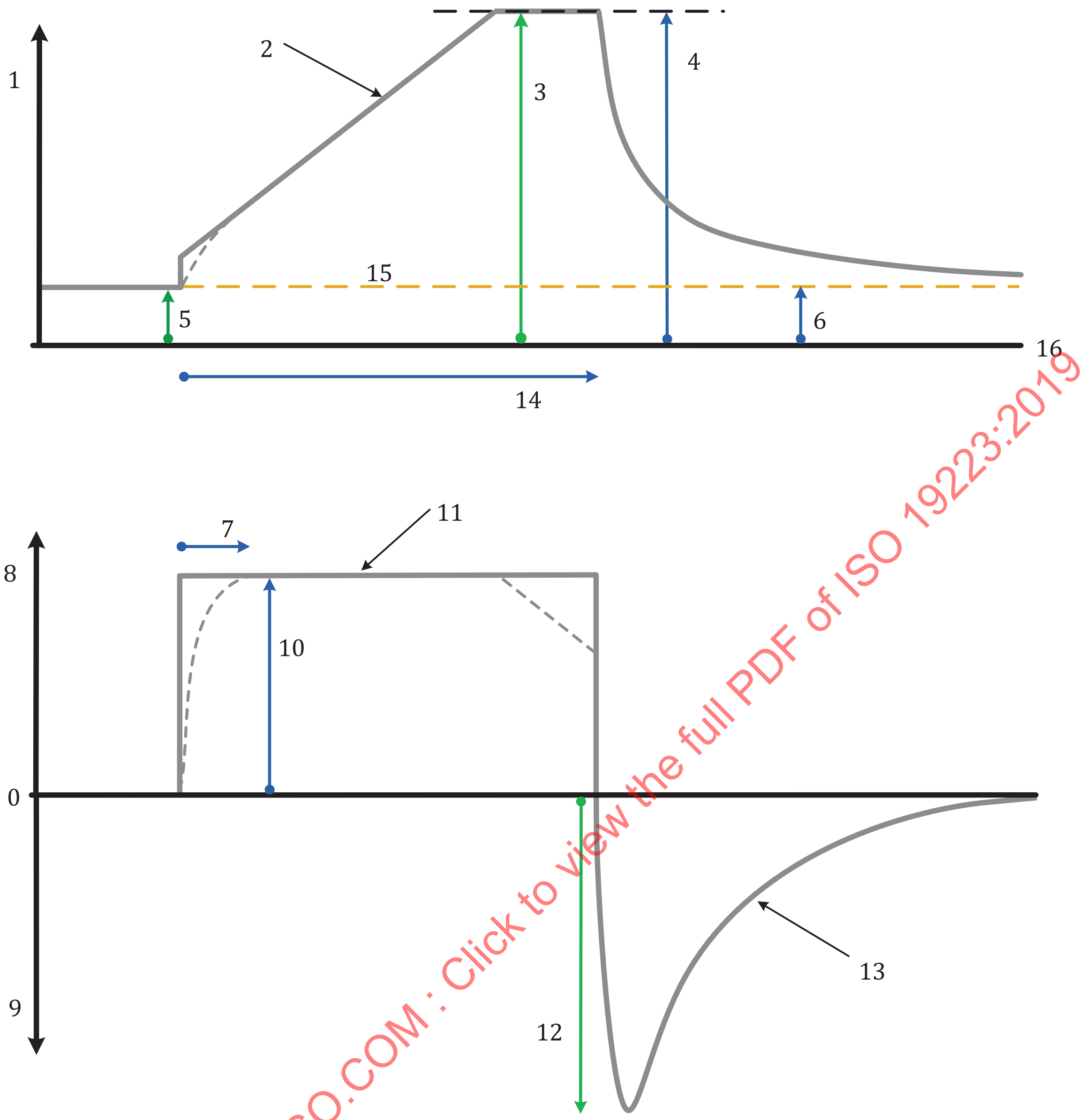
Figure C.11 — Illustrations of the application of ventilation terms in designating key features of typical inflation waveforms — Typical airway-pressure and flow waveforms for a pressure-terminated, pressure-control (PC) inflation



Key

1 airway pressure
2 inspiratory-pressure waveform
3 plateau inspiratory pressure
4 expiratory-pressure waveform
5 instantaneous expiratory pressure
6 PEEP
7 instantaneous inspiratory pressure
8 peak inspiratory pressure
9 BAP
10 inspiratory time
11 inspiratory flow
12 rise time (if applicable)
13 inspiratory flow
14 inspiratory-pause time
15 expiratory flow
16 inspiratory-flow time
17 expiratory-flow waveform
18 peak expiratory flow
19 expiratory-flow time
20 baseline airway pressure
21 ambient pressure

Figure C.12 — Illustrations of the application of ventilation terms in designating key features of typical inflation waveforms — Typical airway-pressure and flow waveforms for volume-control (VC) inflation with inspiratory pause



Key

1 airway pressure
2 inspiratory-pressure waveform
3 peak inspiratory pressure
4 pressure limit
5 PEEP
6 BAP
7 rise time (if applicable)
8 inspiratory flow
9 expiratory flow
10 inspiratory flow
11 inspiratory-flow waveform
12 peak expiratory flow
13 expiratory-flow waveform
14 inspiratory time
15 baseline airway pressure
16 ambient pressure

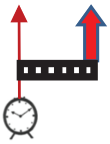
Figure C.13 — Illustrations of the application of ventilation terms in designating key features of typical inflation waveforms — Typical airway-pressure and flow waveforms for a pressure-limited volume-control (VC) inflation

Coloured rectangle representing the *inflation-type* that has been selected for *assured inflations*. The same *inflation-type* may also be initiated by a *patient-trigger event* in accordance with the *ventilation-pattern.*

Red arrow in this symbol represents an assured occurrence and the clock signifies that this is *set* to occur at a timed interval from the previous assured occurrence. This timed interval (1/*Rate*) is determined by the *ventilator set Rate.*

Symbol representing the delay period that has been named as the *synchronization window*

Symbol representing the *ventilator initiation* of the *assured inflation* in the absence of any *patient-trigger event* during the preceding *synchronisation window.*

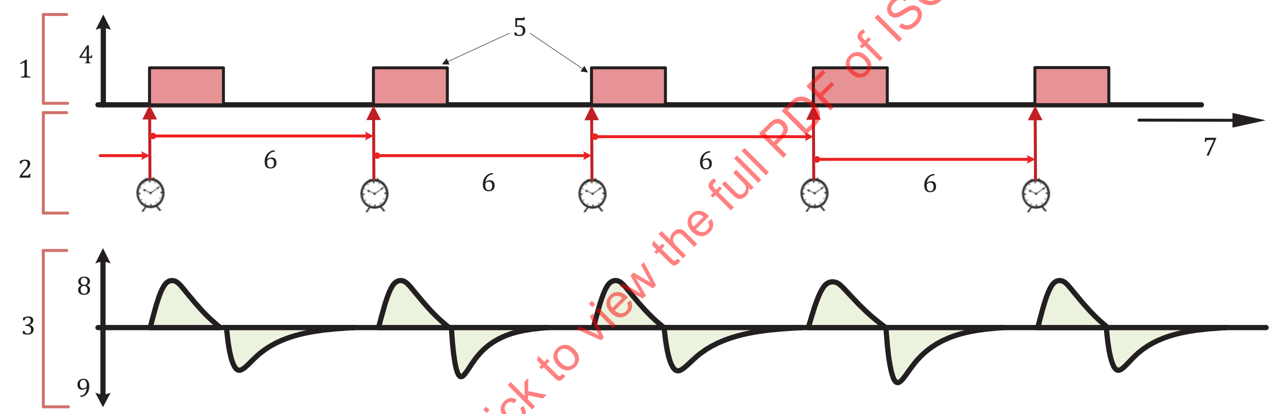


Composite symbol representing the function of the *synchronisation window.* After an assured *initiation* at the timed interval, determined by the *ventilator set Rate,* it provides time for the expiration of any previous inspiration but responds immediately to a *patient-trigger event* by *initiating* the already *assured inflation.*

Coloured rectangle representing the *inflation-type* that has been selected for *initiation* solely in response to a *patient -trigger event.*

Arrow used to represent an envisaged pattern of *patient-trigger events*. They are shown with a broken outline in the following figures because they represent the *setting* perspective of what 'could' happen.

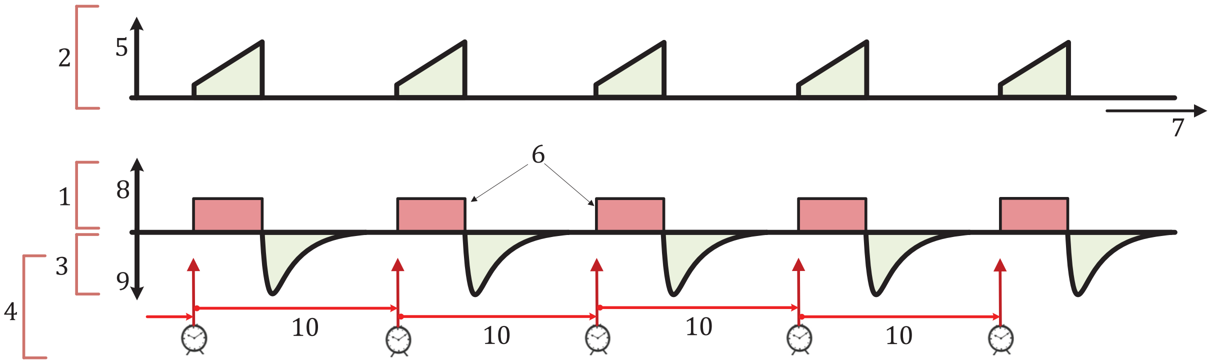
Figure C.14 — Ventilation-patterns: Key to Figures C.15 to C.21



Key

1 setting perspective
2 function of the ventilation-pattern in initiating inflations
3 typical consequent airway-flow waveforms
4 airway pressure
5 representations of pressure-control, assured inflation-types
6 respiratory cycle time (1/set-rate)
7 time
8 inspiratory flow
9 expiratory flow

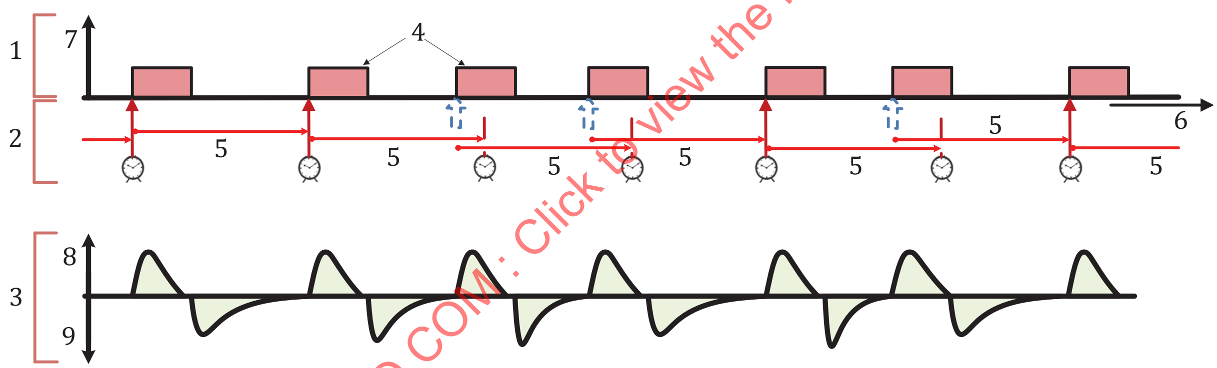
Figure C.15 — Ventilation-patterns: Diagrammatic illustrations of the function of the CMV-pattern in the initiation of inflations, with pressure-control (PC) as the selected inflation-type



Key

1 setting perspective
2 typical consequent airway-pressure waveforms
3 typical consequent airway-flow waveforms
4 function of the ventilation-pattern in initiating inflations
5 airway pressure
6 representations of volume-control, assured inflation-types
7 time
8 inspiratory flow
9 expiratory flow
10 respiratory cycle time (1/set-rate)

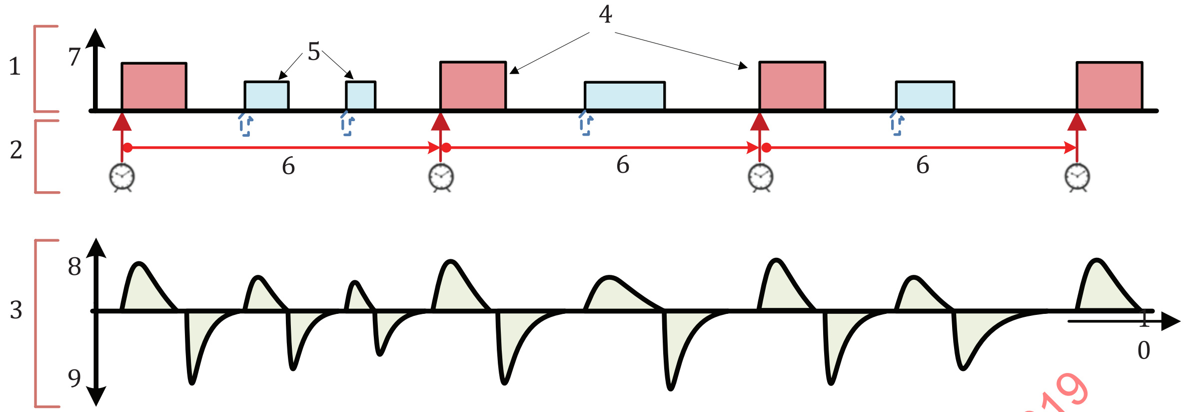
Figure C.16 — Ventilation-patterns: Diagrammatic illustrations of the function of the CMV-pattern in the initiation of inflations, with volume-control (VC) as the selected inflation-type



Key

1 setting perspective
2 function of the ventilation-pattern in initiating inflations
3 typical consequent airway-flow waveforms
4 representations of pressure-control, assured inflation-types
5 respiratory cycle time (1/set-rate)
6 time
7 airway pressure
8 inspiratory flow
9 expiratory flow

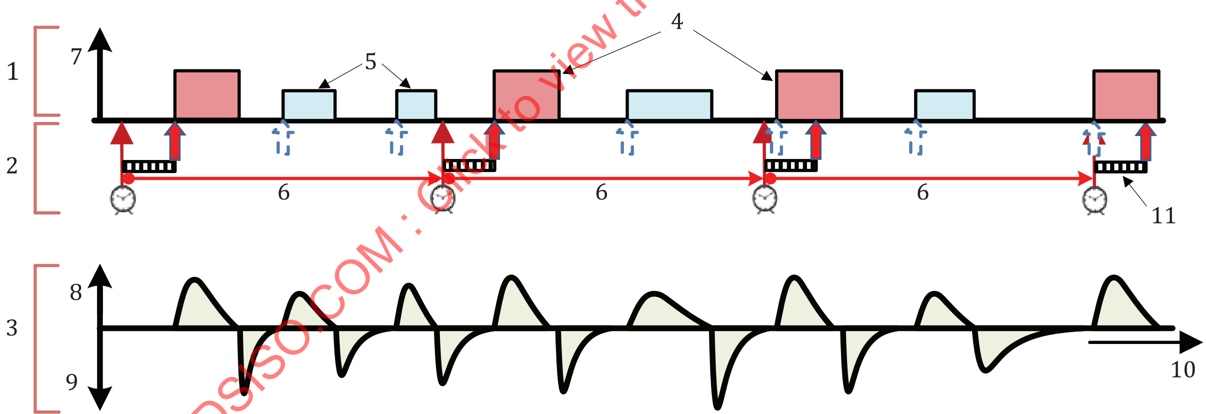
Figure C.17 — Ventilation patterns: Diagrammatic illustrations of the function of the assist/control (A/C) ventilation-pattern in the initiation of inflations



Key

1 setting perspective
2 function of the ventilation-pattern in initiating inflations
3 typical consequent airway-flow waveforms
4 representations of pressure-control, assured inflation-types
5 representations of pressure-support inflation-types
6 respiratory cycle time (1/set-rate)
7 airway pressure
8 inspiratory flow
9 expiratory flow
10 time

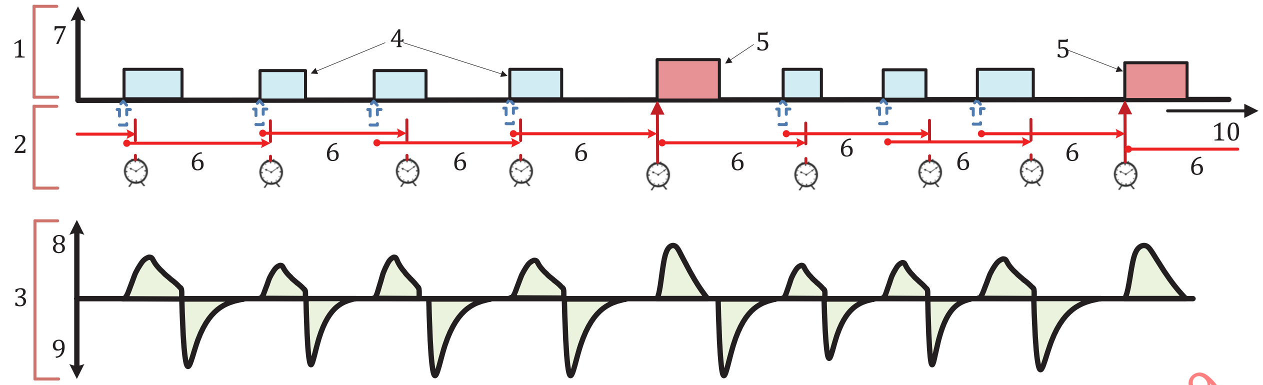
Figure C.18 — Ventilation patterns: Diagrammatic illustrations of the function of the IMV-pattern in the initiation of inflations



Key

1 setting perspective
2 function of the ventilation-pattern in initiating inflations
3 typical consequent airway-flow waveforms
4 representations of pressure-control, assured inflation-types
5 representations of pressure-support inflation-types
6 respiratory cycle time (1/set-rate)
7 airway pressure
8 inspiratory flow
9 expiratory flow
10 time
11 synchronization window

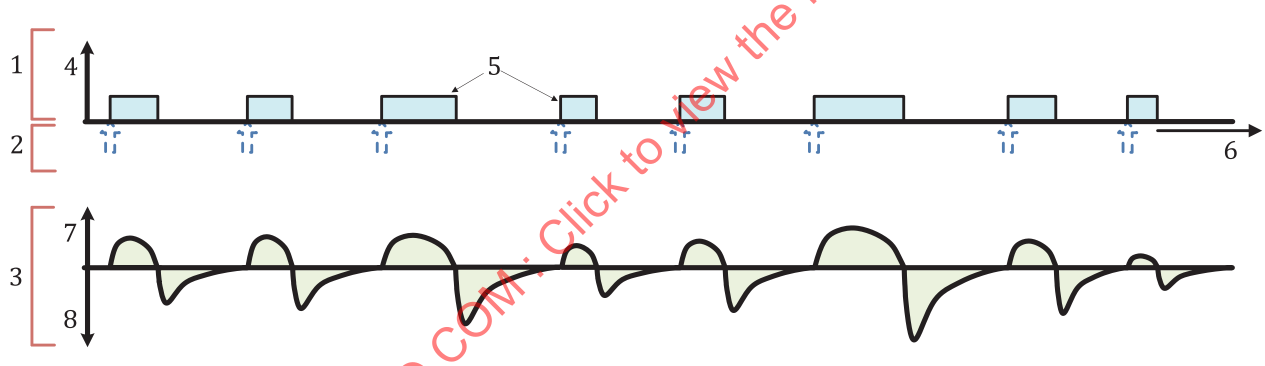
Figure C.19 — Ventilation patterns: Diagrammatic illustrations of the function of the SIMV-pattern in the initiation of inflations



Key

1 setting perspective
2 function of the ventilation-pattern in initiating inflations
3 typical consequent airway-flow waveforms
4 representations of pressure-support inflation-types
5 representations of assured inflation-types
6 respiratory cycle time (1/set-rate)
7 airway pressure
8 inspiratory flow
9 expiratory flow
10 time

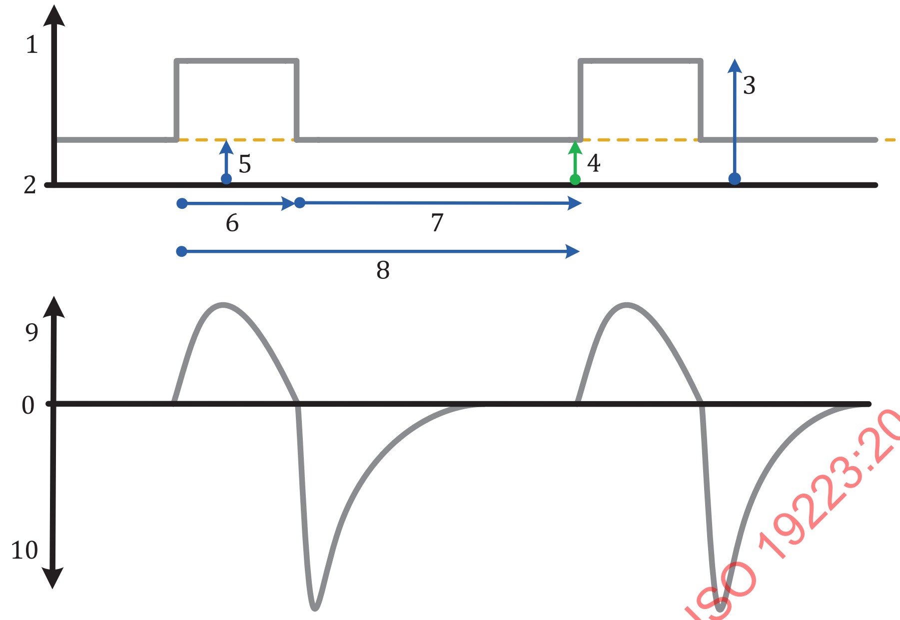
Figure C.20 — Ventilation patterns: Diagrammatic illustrations of the function of the S/T ventilation-pattern in the initiation of inflations



Key

1 setting perspective
2 function of the ventilation-pattern in initiating inflations
3 typical consequent airway-flow waveforms
4 airway pressure
5 representations of pressure-support inflation-types
6 time
7 inspiratory flow
8 expiratory flow

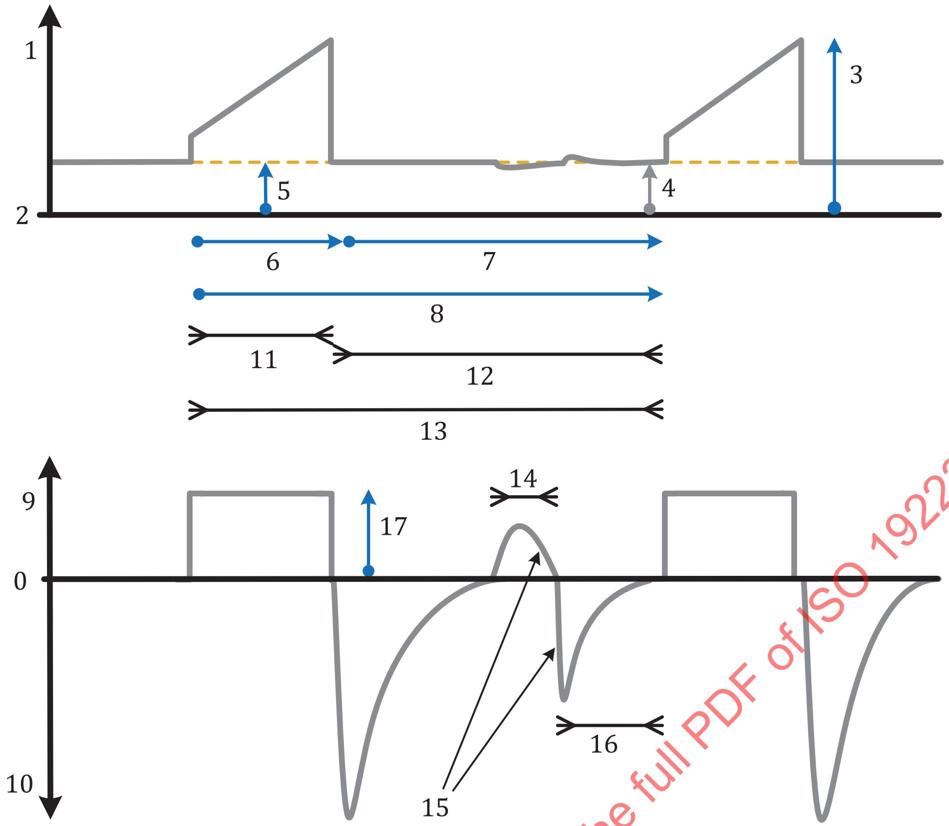
Figure C.21 — Ventilation patterns: Diagrammatic illustrations of the function of the CSV-pattern in the initiation of inflations



Key

1 airway pressure
2 ambient pressure
3 inspiratory pressure
4 PEEP
5 BAP
6 inspiratory time
7 expiratory time or BAP time
8 cycle time (1/set-rate)
9 inspiratory flow
10 expiratory flow

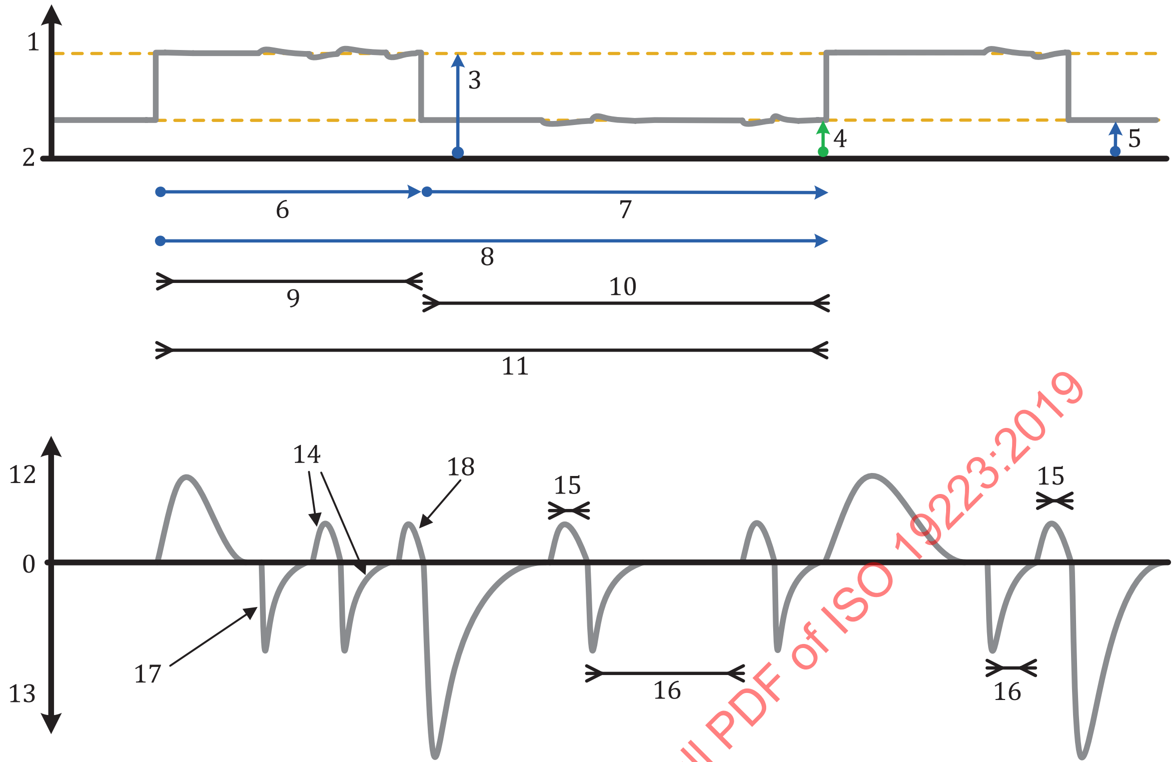
Figure C.22 — Typical airway-pressure and flow waveforms for a CMV-PC ventilation-mode



Key

1	airway pressure
2	ambient pressure
3	peak inspiratory pressure
4	PEEP
5	BAP
6	inspiratory time
7	expiratory time or BAP time
8	cycle time (1/set-rate)
9	inspiratory flow
10	expiratory flow
11	inflation phase
12	expiratory phase or BAP phase
13	respiratory cycle
14	inspiratory phase
15	unassisted breath
16	expiratory phase
17	inspiratory flow

Figure C.23 — Typical airway-pressure and flow waveforms for a CMV-VC <ACAP$_L$> ventilation-mode

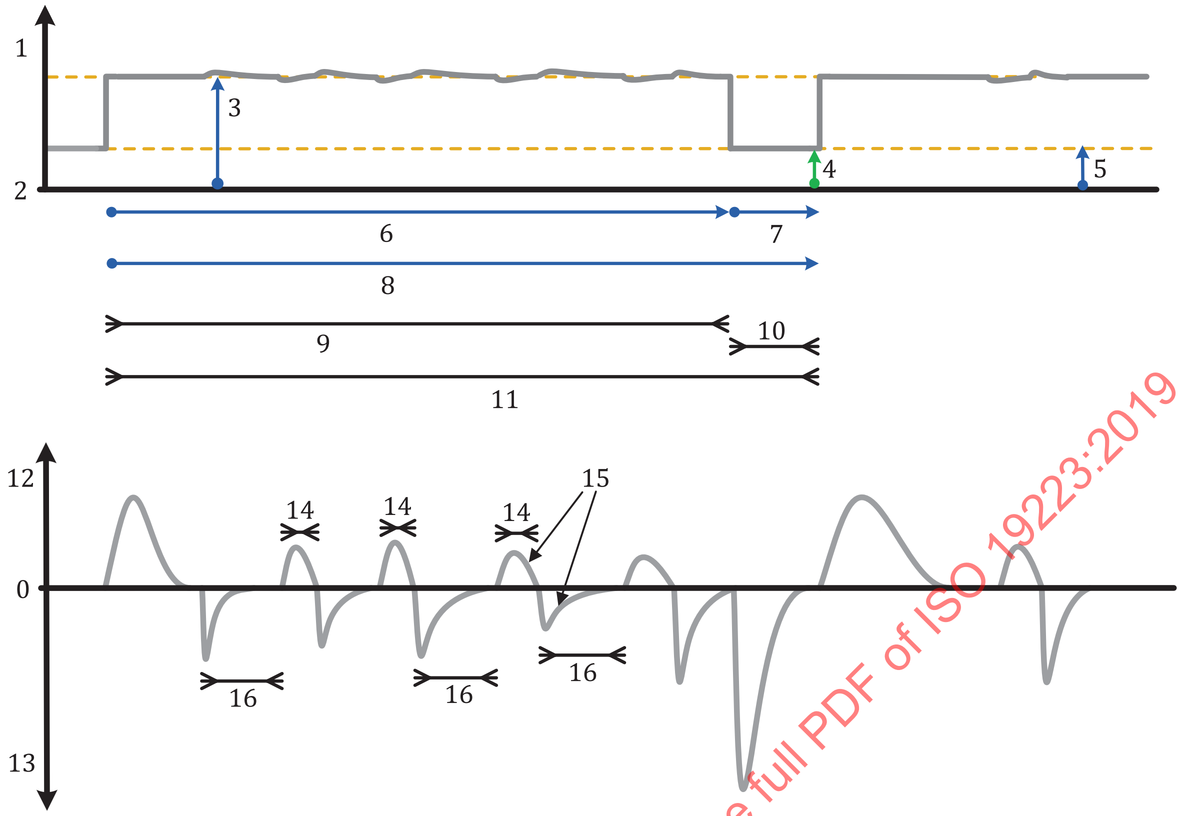


Key

1	airway pressure
2	ambient pressure
3	inspiratory pressure
4	PEEP
5	BAP
6	inspiratory time
7	expiratory time or BAP time
8	respiratory cycle time (1/set-rate)
9	assured-inflation phase
10	expiratory phase or BAP phase
11	assured-inflation cycle
12	inspiratory flow
13	expiratory flow
14	concurrent breath
15	inspiratory phase
16	unassisted breath
17	concurrent expiration
18	concurrent inspiration

Figure C.24 — Typical airway-pressure and flow waveforms for a CMV-PC <ACAP> ventilation-mode, set with extended phase times

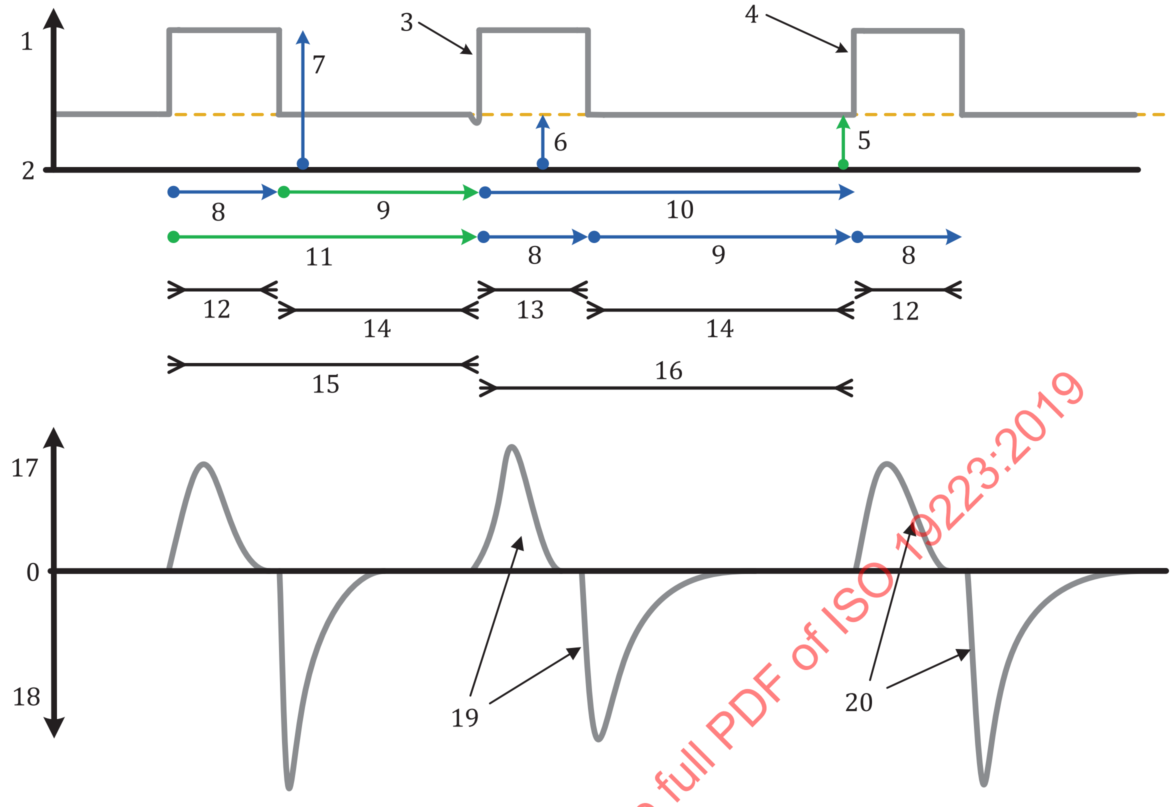
NOTE Figures C.24 and C.25 illustrate unusual *settings* of this *ventilation-mode* which are possible with the range of *settings* available on currently manufactured *ventilators*. As explained in the introduction to this annex (C.1), such illustrations are not shown with the intention of advocating such *settings,* but to demonstrate how actual waveforms can be very different from those normally provided to illustrate a *ventilation-mode* function. Such illustrations highlight that the *ventilation* waveforms that can be generated with a specific classical *ventilation-pattern* based *ventilation-mode*, but with unusual *settings,* are not necessarily all unique and some could overlap those that can be generated with another of these *ventilation-modes*.



Key

1 airway pressure
2 ambient pressure
3 inspiratory pressure
4 PEEP
5 BAP
6 inspiratory time
7 expiratory time or BAP time
8 respiratory cycle time (1/set-rate)
9 assured-inflation phase
10 expiratory phase or BAP phase
11 assured-inflation cycle
12 inspiratory flow
13 expiratory flow
14 inspiratory phases
15 concurrent breath
16 expiratory phases

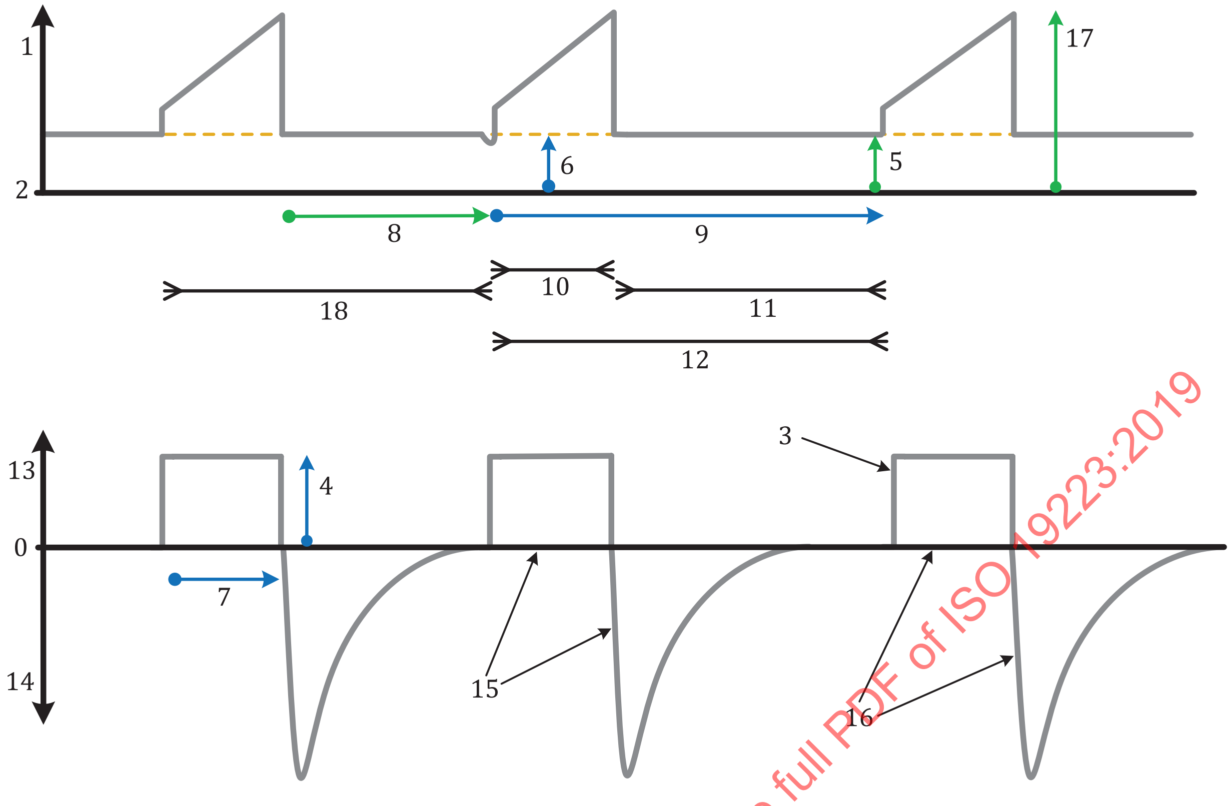
Figure C.25 — Typical airway-pressure and flow waveforms for a CMV-PC <ACAP> ventilation-mode, set with an extreme inverse I:E ratio



Key

1 airway pressure
2 ambient pressure
3 assist inflation (of the assured-inflation type)
4 assured inflation
5 PEEP
6 BAP
7 inspiratory pressure
8 inspiratory time
9 expiratory time or BAP time
10 respiratory cycle time (1/set-rate)
11 respiratory cycle time
12 assured-inflation phase
13 assist-inflation phase
14 expiratory phase or BAP phase
15 assured cycle
16 assist-inflation cycle
17 inspiratory flow
18 expiratory flow
19 assisted breath
20 controlled breath

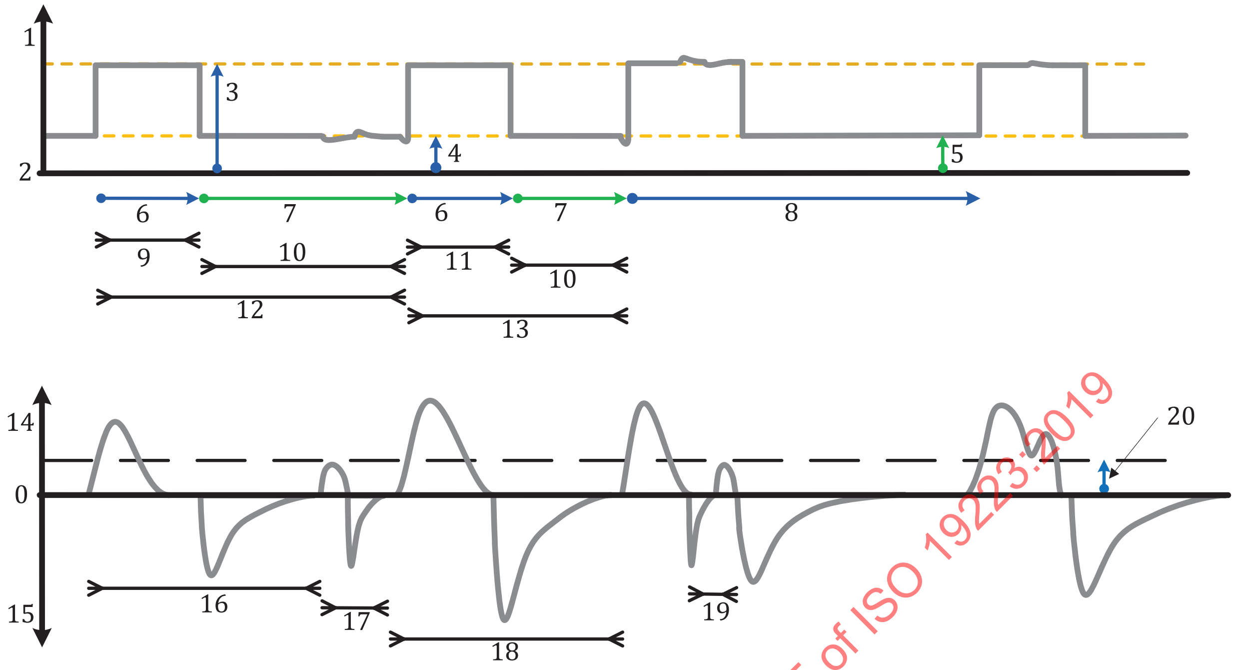
Figure C.26 — Typical airway-pressure and flow waveforms for an A/C-PC ventilation-mode



Key

1 airway pressure
2 ambient pressure
3 assured inflation
4 inspiratory flow
5 PEEP
6 BAP
7 inspiratory time
8 expiratory time or BAP time
9 respiratory cycle time (1/set-rate)
10 assist-inflation phase
11 expiratory phase or BAP phase
12 assist-inflation cycle
13 inspiratory flow
14 expiratory flow
15 assisted breath
16 controlled breath
17 peak inspiratory pressure
18 assured-inflation cycle

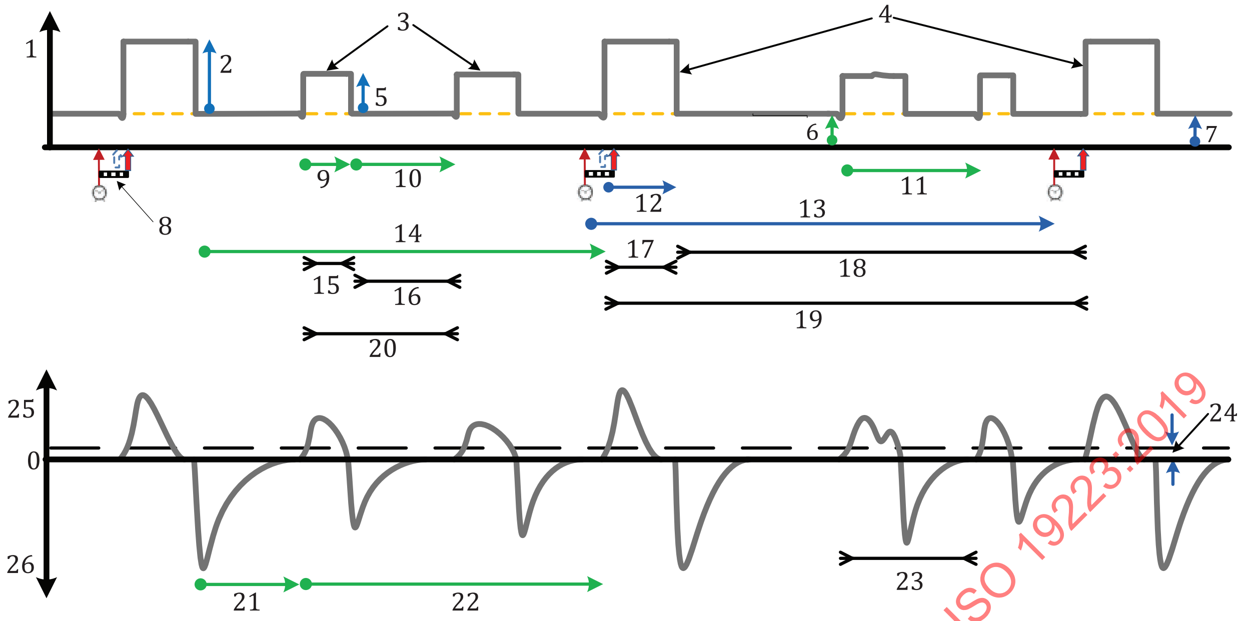
Figure C.27 — Typical airway-pressure and flow waveforms for an A/C–VC ventilation-mode



Key

1	airway pressure	12	assured-inflation cycle
2	ambient pressure	13	assist-inflation cycle
3	inspiratory pressure	14	inspiratory flow
4	BAP	15	expiratory flow
5	PEEP	16	controlled breath
6	inspiratory time	17	unrestricted breath
7	expiratory time or BAP time	18	assisted breath
8	respiratory-cycle time (1/set-rate)	19	concurrent unrestricted expiration followed by unassisted inspiration
9	assured-inflation phase	20	flow trigger level
10	expiratory phase or BAP phase		
11	assist-inflation phase		

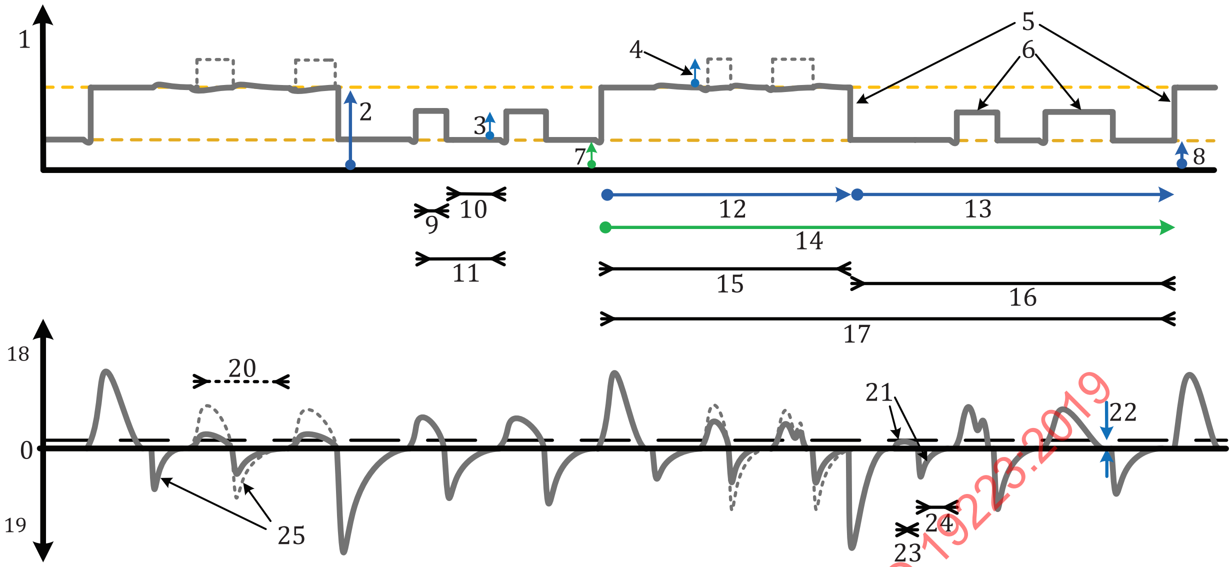
Figure C.28 — Typical airway-pressure and flow waveforms for an A/C–PC <ACAP> ventilation-mode



Key

1 airway pressure
2 Δ inspiratory pressure
3 support inflations
4 assured inflations
5 Δ support pressure
6 PEEP
7 BAP
8 synchronization window
9 support-inflation inspiratory time
10 expiratory time (of support-inflation cycle)
11 support-inflation cycle time
12 inspiratory time (of assured inflation-type)
13 respiratory cycle time (1/set-rate)
14 BAP time
15 support-inflation phase
16 expiratory phase
17 assured-inflation phase
18 BAP phase
19 assured-inflation cycle
20 support-inflation cycle
21 assured-inflation expiratory flow time
22 assured-inflation expiratory pause time
23 supported breath
24 flow-trigger level
25 inspiratory flow
26 expiratory flow

Figure C.29 — Typical airway-pressure and flow waveforms for an SIMV-PC\PS ventilation-mode

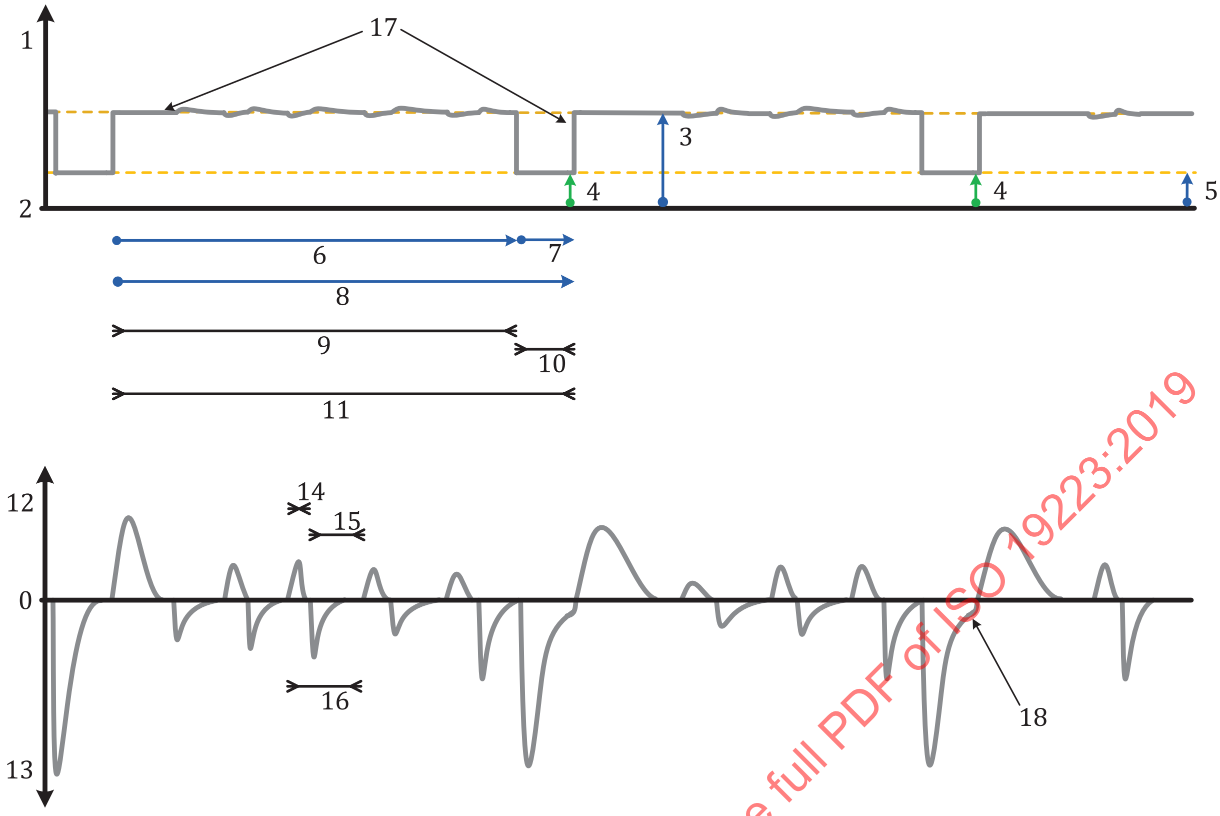


Key

1	airway pressure
2	inspiratory pressure
3	Δ support pressure
4	Δ_H support pressure
5	assured inflations
6	support inflations
7	PEEP
8	BAP
9	support inflation
10	expiratory phase (of support-inflation cycle)
11	support-inflation cycle
12	inspiratory time
13	BAP time
14	assured-inflation cycle time
15	assured-inflation phase
16	BAP phase of assured-inflation cycle
17	assured-inflation cycle
18	inspiratory flow
19	expiratory flow
20	concurrent supported breath
21	unassisted breath
22	flow-trigger level
23	inspiratory phase
24	expiratory phase
25	unrestricted concurrent expirations

NOTE Synchronization windows are not illustrated in this figure.

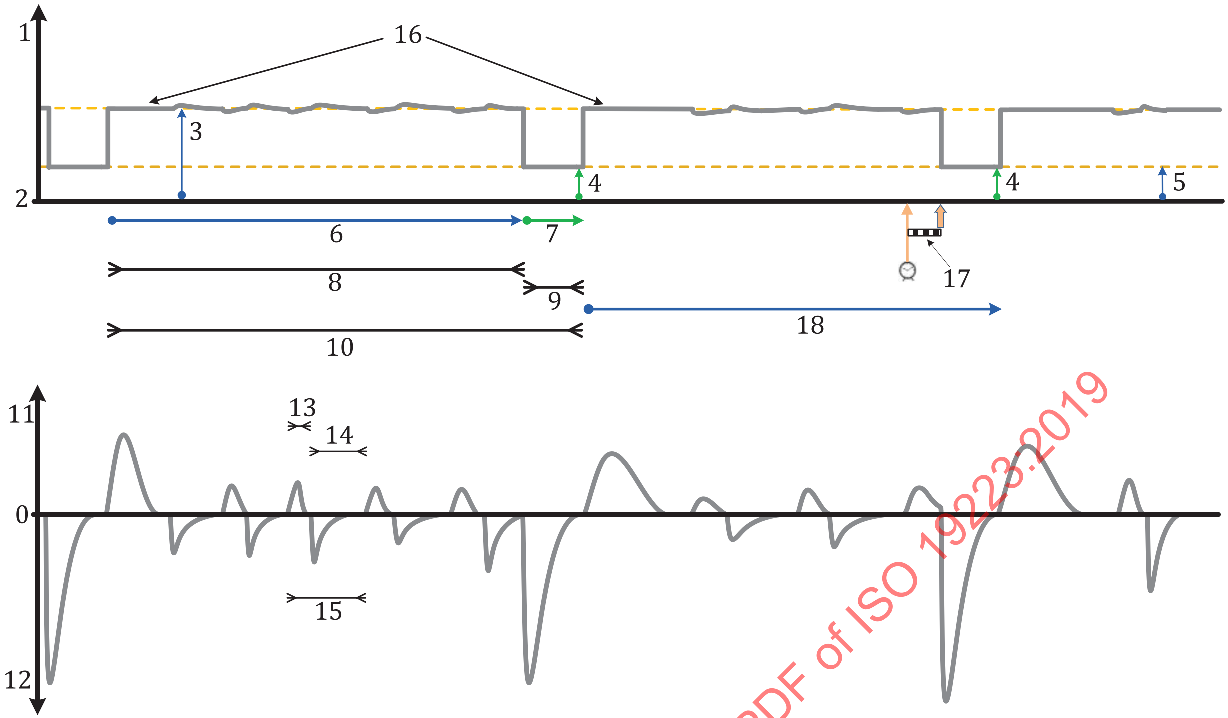
Figure C.30 — Typical airway-pressure and flow waveforms for variations on an SIMV-PC\PS\PS <ACAP> ventilation-mode, with typical settings for a bi-level AV mode



Key

1 airway pressure
2 ambient pressure
3 inspiratory pressure
4 PEEP
5 BAP
6 inspiratory time
7 BAP time
8 respiratory cycle time (1/set-rate)
9 assured-inflation phase
10 BAP phase
11 assured-inflation cycle
12 inspiratory flow
13 expiratory flow
14 inspiratory phase
15 expiratory phase
16 concurrent unassisted breath
17 assured inflations
18 incomplete expiration, typically intentionally achieved by use of insufficient expiratory time

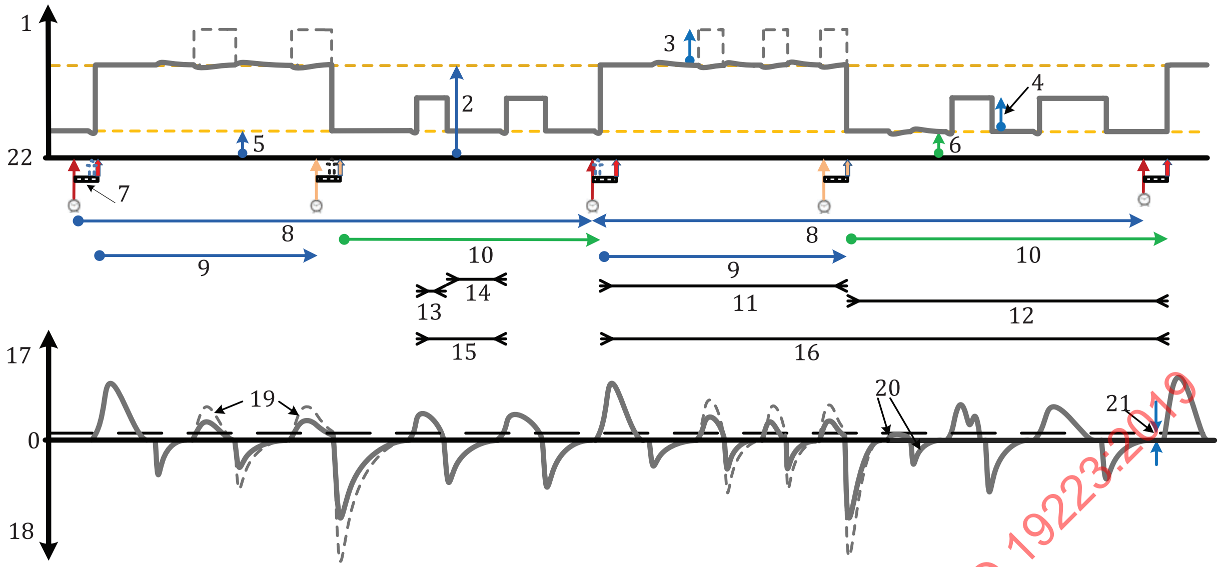
Figure C.31 — Typical airway-pressure and flow waveforms for variations on an IMV-PC\PS\PS <ACAP> ventilation-mode, with typical APRV settings



Key

1 airway pressure
2 ambient pressure
3 BAP_H or p_H
4 PEEP
5 BAP or p_L
6 BAP_H time or t_H
7 BAP time or t_L
8 BAP_H phase
9 BAP phase
10 bi-level AV cycle
11 inspiratory flow
12 expiratory flow
13 inspiratory phase
14 expiratory phase
15 concurrent unassisted breath
16 assured inflations
17 synchronized termination (typical)
18 respiratory cycle time (1/set-rate)

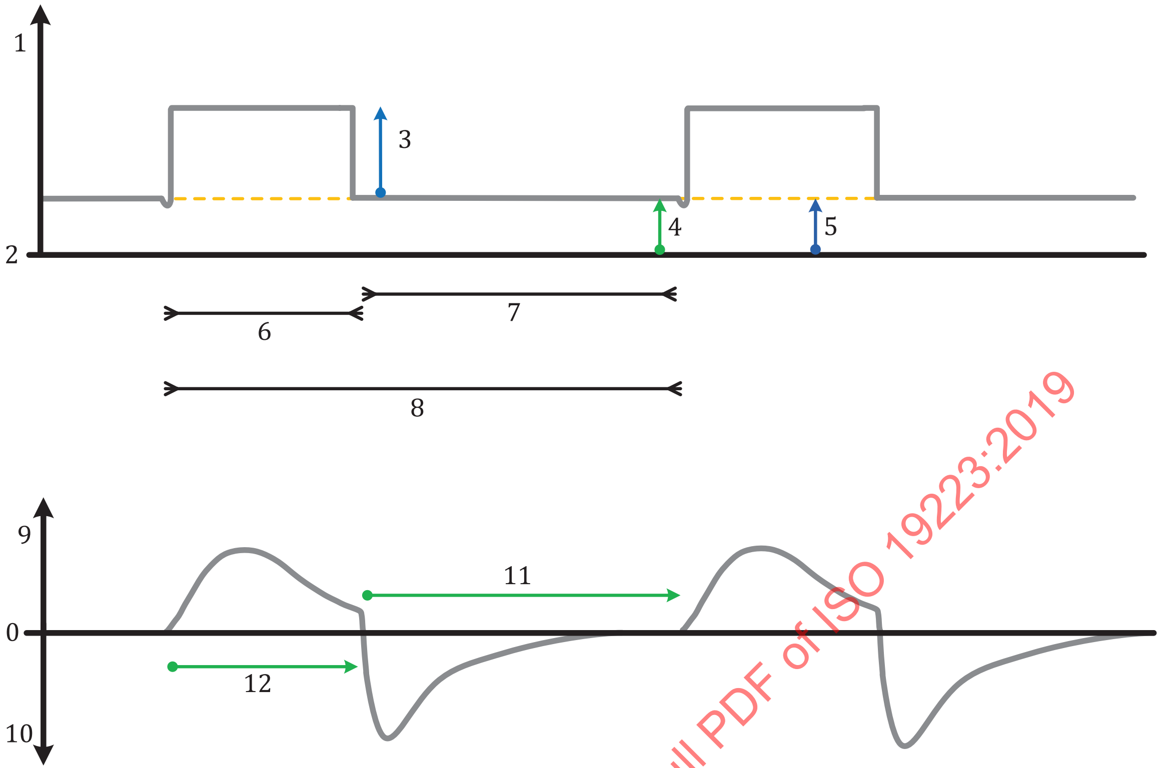
Figure C.32 — Typical airway pressure and flow waveforms for variations on an IMV-PC\PS\PS <ACAP> ventilation-mode, with a PC{S} assured inflation-type, both support-pressures set to zero and optionally labelled as intended for APRV (airway pressure release ventilation)



Key

1 airway pressure
2 BAP_H or p_H
3 Δ_H support pressure
4 Δ support pressure
5 BAP or p_L
6 PEEP
7 synchronization window
8 respiratory cycle time (1/set-rate)
9 BAP_H time or t_H
10 BAP time or t_L
11 BAP_H phase
12 BAP phase
13 support-inflation phase
14 expiratory phase
15 support-inflation cycle
16 assured-inflation cycle
17 inspiratory flow
18 expiratory flow
19 supported concurrent inspirations (if support available or selected)
20 unassisted breath
21 flow-trigger level
22 ambient pressure

Figure C.33 — Typical airway pressure and flow waveforms for variations on an SIMV-PC\PS\PS <ACAP> mode, with a PC{S} assured inflation-type and optionally labelled as a bi-level AV mode



Key

1	airway pressure	7	expiratory phase
2	ambient pressure	8	support-inflation cycle
3	Δ support pressure	9	inspiratory flow
4	PEEP	10	expiratory flow
5	BAP	11	expiratory time
6	inspiratory phase	12	inspiratory time

Figure C.34 — Typical airway pressure and flow waveforms for a CSV-PS ventilation-mode

Previous figures have already shown waveforms for *pressure-control inflation-type* deliveries on a *ventilator* with an ACAP *adjunct*, and with illustrative *concurrent spontaneous breaths*. In practice there could be several *concurrent breaths* and they could take many forms. On the right are shown other possible flow waveforms and these raise the question of what constitutes a *breath* in such a scenario.

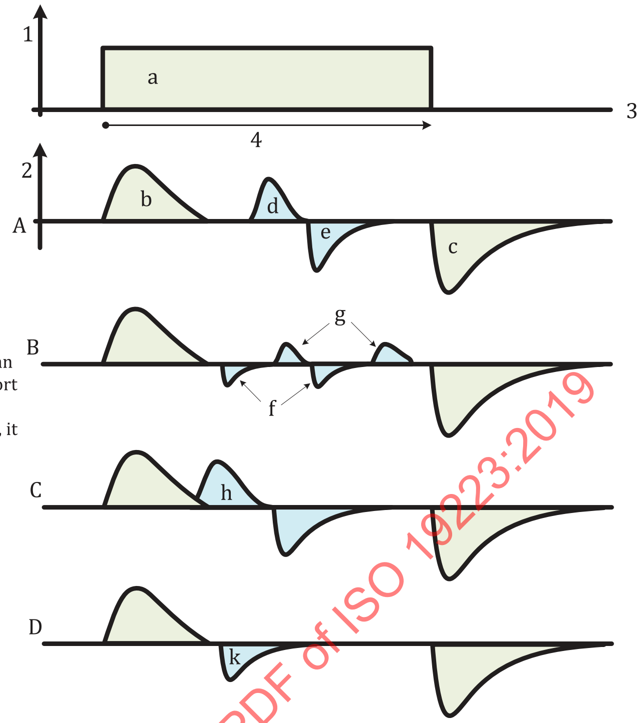
The flow waveform, A, shows the *inspiratory volume*, as a result of the elevated pressure of the *inflation*, a, as the area, b. It can be seen that the *set inspiratory time* greatly exceeds the *inspiratory-flow time* and so there is an *inspiratory pause* before the *inspiratory volume* is *expired*. The *expired* volume is represented by the area, c. It is therefore clear that b and c represent the *breath* resulting from the *inflation*, a, and that d and e represent a *concurrent spontaneous breath*.

Waveform, B, shows a concurrent *spontaneous expiration*, f, occurring before an *inspiration*, g. To do this the *patient* might have had to make an *expiratory* effort but this is a possible occurrence. However, although the volume of this *expiration* is accounted for in the *minute volume* of that *assured-inflation cycle*, it is only the detection of the *initiation* of the two concurrent *inspirations* that contribute to the *total respiratory rate*.

Waveform, C, shows the *patient's inspiratory efforts* augmenting the *inspiratory volume* resulting from the *inflation*, and subsequently *expiring* it, but there is no *spontaneous breath* because the *inspiratory* component, h, is not independent of the *ventilator*-imposed component.

Waveform, D, shows a reflexive *expiration* during the *flow pause* following the imposed *inspiratory volume*. As in the previous example because, k, is not associated with a specific *inspiration* it does not constitute part of a separate, *spontaneous breath*.

From these examples it can be seen that, a *concurrent breath* is one in which an *inspiratory flow* is detected either following a period with no *airway* flow or following an *expiratory flow*.



Key

1 airway pressure
2 inspiratory flow
3 ambient pressure
4 inspiratory time

Figure C.35 — Characteristics of a concurrent breath

Annex D
(informative)

Classification of inflation-types

D.1 General

The principle individual terms relating to currently available *inflation-types* are defined in 3.3. However, there are many possible variations on these waveforms and Tables D.1 and D.2 have been included in order to demonstrate how the defined *inflation-types*, and their known variations, are systematically identified by both name and associated code. Table D.3 has been included to demonstrate the structure of the schematic coding scheme that has been used and to provide a template for the schematic coding of future *inflation-types* and those that are not already specifically designated. Although Table D.3 also includes examples of systematic codes, for a more complete list see Tables D.1 and D.2.

Following convention, the primary classification of *inflation-types* in this document has been founded on the two basic *ventilation* parameters that can be conveniently regulated - pressure and flow – along with a hierarchy of letters used to codify how an *inflation* will be managed, after *initiation*.

The core elements of the systematic naming and encoding scheme are those that have been universally adopted in current *ventilation* terminology, and which are defined in 3.3, that is, *volume-control* (VC), *pressure-control* (PC) and *pressure-support* (PS), although the name *effort-support* (ES) has also been added to enable the classification of certain newer developments. In this document, these names, each in isolation, represent an *inflation-type* that, once *initiated* in accordance with the selected *ventilation-pattern,* regulate the delivered flow or pressure to the *set* value or pattern until *terminated* by time, flow, pressure, volume or other criteria.

Significant variations from the defined conditions for each name are designated by the attachment of a supplements to the name or code. In the case of a code, the attachment is made using leading lower-case letters and contained trailing letters – the containment being by means of round brackets for *termination* parameters, curly brackets for conditional *termination* means and square brackets for additional regulation parameters. Relevant suffixes and prefixes are a necessary part of the full coded form of the systematic *ventilation-mode name* that should always be declared in *a ventilator's accompanying documents.* For other purposes, they are not always needed provided the selection of the represented function is otherwise indicated in the *accompanying documents* or by a separate indication on the user interface.

In the particular case of *volume-control* (VC) *inflations*, although these are always *flow-regulated* six alternative means that have been used to achieve the required gas delivery are listed in Tables D.1 and D.2. Because no particular names have evolved to make a distinction between these alternative means and they all control the gas delivery largely independently of the *patient* no further supplementary coding has been introduced in this document to specifically designate those distinctions. However, it is expected that *manufacturers* will explain the means utilized in achieving *volume-control* on their *ventilators* in their *accompanying documents*, using the vocabulary of this document.

In these classifications, wherever the primary means of *inflation termination* is shown to be other than by time, safety considerations dictate that there will always be some sort of ultimate time *limit* on every *inflation*. This might be a factory-*set* default or an *operator-settable* value with a *limit* on the maximum *setting*, but such secondary time *limits* are not included in the coding in order to keep them as concise as possible.

Provision has also been made to accommodate the possibility of switching between regulated parameters during an *inflation phase*.

D.2 Supplementary explanatory notes for the systematic coding scheme defined in the applicable entries of Clause 3 and tabulated in Tables D.1, D.2 and D.3.

D.2.1

volume-control (See also 3.3.3)

Inflation-types that are all *flow-regulated* to a constant value (or a specified *decreasing flow pattern*) and *time-terminated*, which, by convention, have been identified under their more generally applicable name of *volume-control*, with the abbreviation, VC. There are various ways of achieving a required *tidal volume* within these restraints and most of these have their distinctive characteristics individually described in separate rows in Table D.1. In practical use, the differences will typically be evident from the method by which the volume is *set* but will be of secondary significance to most *operators*. For this reason and following current practice, in this document all these listed alternative possibilities are taken to fall within the scope of this name [*volume-control* (VC)]. However, the specific characteristics that identify the differences as explained in this document should be always described in the *accompanying documents*.

Inflation-types that are *flow-regulated* to a *constantly decreasing* value and *time-terminated*, which, by convention, have also been identified under their more generally applicable name of *volume-control*, with the abbreviation, VC, are identified with the prefix df or cdf.

All *volume-control inflations* delivering *leak compensated* volumes may be identified with the suffix LC although this is not necessary if this feature has been separately identified as an *adjunct*.

D.2.2

volume-targeted (See also 3.3.15 and 3.3.9)

Inflation-types, which unlike *volume-control* (VC), do not control the *delivered volume* directly but which target a *set* volume by adjusting the *inspiratory settings* of a *pressure-regulated inflation,* typically *inflation*-to-*inflation*, depending on *measurements* of previous deliveries.

D.2.3

pressure-limited volume-control (See also 3.13.2, 3.3.3 and 3.3.9)

Variant of *volume-control* (VC) in which, when the *inspiratory pressure* attains a *set* level during normal operation, excess regulated flow is spilt to atmosphere, if this is necessary to avoid the *inspiratory pressure* exceeding the *set* level. This can result in a possibly un-quantified loss of the *delivered volume*. This variant is indicated by the addition of the trailing code [$\boldsymbol{p}_{\mathrm{LIM}}$]. As this loss is part of the normal operation of this *inflation-type* an *alarm condition* might not be generated, but if there is any loss of *delivered volume patient* safety considerations dictate that it should be indicated. If the pressure is limited by *pressure-regulation,* then the code becomes VC→PC (see 3.3.5).

D.2.4

pressure-control (See also 3.3.4)

Inflation-type that, after an initial *rise time*, is *pressure-regulated* to a constant value and *time-terminated*. By convention, it has been identified with the name *pressure-control*, with the abbreviation, PC.

D.2.5

pressure-support or **flow-terminated pressure-control** (See also 3.3.6, 3.9.15 and 3.3.4)

Pressure-control (PC) *inflation-type* that is intended to be *terminated* by patient *respiratory activity* reducing the flow to a *set* flow level before the *set time-termination*, and which is only used with *ventilation-patterns* in which it can only be *initiated* by a *patient-trigger event*, has become identified with the name *pressure-support*, with the abbreviation, PS. If used with a *ventilation- pattern* in which it could be time-*initiated* its code reverts to that of a variant of PC, that is, PC(***q***).

D.2.6

synchronized-termination (See also 3.9.7, 3.9.8 and 3.12.9)

Pressure-control inflation-type, intended for use with ACAP or ACAP$_H$ *adjuncts*, where the patient can *expire* spontaneously during the *set inflation phase* without *terminating* the delivery. It then uses a *synchronization window* to modulate the actual *termination* point of each *inflation* to coincide with the patient's *expiratory* activity (3.2.6). The presence of this feature is indicated by the conditional-*termination* variation trailing code {S}, spoken as '*pressure-control* with synchronized-*termination*'.

D.2.7

effort-support (See also 3.3.7)

Variant of a *pressure-support inflation-type* that is *pressure-regulated* to a non-constant waveform that is dependent upon the instantaneous value of a *patient* variable(s) that indicates the *patient* effort at that point in time, with the intention of providing support to the *breathing* that is always proportion to the respiratory effort. The variables used are typically either those relating to the loads imposed by *airway resistance* and the *lung* elastance or the neural signals that determine respiratory effort. The concept is identified with the name *effort-support*, with the abbreviation, ES. The full systematic name for an *effort-support inflation-type* will include a reference to which of these indicators of specific *patient* efforts are supported, that is, change in *lung* volume [***v***], *airway* flow [***q***], change in *lung* volume and *airway* flow [***q+v***], or the electromyographic activity of the diaphragm and intercostal muscles [EMG].

D.2.8

Note There are currently no agreed names to designate these following, additional regulation parameters, other than the use of a verbal description. D.2.8.1 to D.2.8.5 provide cross references to their corresponding entries in Table D.3.

D.2.8.1

flow-regulated, pressure-terminated (See also 3.3.8 and 3.9.16)

Flow-regulated inflation that is *pressure-terminated* and with which, as a consequence, there is no direct correlation between the *setting* and the *delivered volume*. It is not, therefore, a variant of VC and is classified as a *flow-regulated, pressure-terminated inflation-type*. This *inflation-type* is not currently used in mainstream *ventilators* but is still sometimes used in low-cost, gas-powered resuscitators. These devices are commonly known as 'pressure-cycled resuscitators', on the basis that each phase change is *initiated* when a *measured airway-pressure* in the *ventilator breathing system* reaches a *set* level, although they are sometimes *flow*- or *time-terminated*.

D.2.8.2

volume-terminated, pressure-control (See also 3.3.4 and 3.9.14)

Variant of a *pressure-control inflation-type* in which the *inflation* is *terminated* after a *set* volume has been delivered. As a variant, it is coded as PC(***v***).

D.2.8.3

dual-control (See also 3.3.5)

Hybrid *inflation-type* that starts with the first *inflation-type* but under specified conditions will be changed to an alternative type during the course of the delivery. These changes may be conditionally bi-directional or unidirectional as indicated by the coupling arrows.

D.2.8.4

volume-assured pressure-support (See also 3.3.5 and 3.3.6)

Specific example of *dual-control* in which a *pressure-support* (PS) *inflation-type* is extended by the maintenance of the *termination* flow if the *delivered volume* has not by then attained the *set* volume-assured value. The transition to constant flow can alternatively be *initiated* earlier in the phase if the control algorithm anticipates that the *set* minimum value will not otherwise be attained. This example of *dual-control* is commonly referred to as "volume assured pressure support", with the acronym VAPS, but its abbreviated systematic designation is PC→VC.

D.2.8.5

pressure-control with ACAP or ACAP$_H$ (See also 3.3.4 and 3.12.1)

Conceptually, this is a *pressure-control* (PC) *assured inflation-type* on a *ventilator* provided with an ACAP *adjunct* that is active at the higher, *inspiratory-pressure baseline airway-pressure* level (BAP$_H$). It facilitates concurrent *expirations* in addition to unrestricted *inspirations*.

Table D.1 — Coding scheme for inflation-types

Operator's primary intent	Regulated parameter	Secondary intent(s)	Consequent requirements	Coded form of full systematic name	See clause:	Primary classification	Secondary classification	Associated set parameters
Deliver a specified volume through the patient connection port	Flow	Time-termination	**See Table D.1b for options for consequent requirements**	FR(***t***) which becomes VC	D.2.1	VC		At least two of: required volume, inspiratory flow and inspiratory time
		Constant flow at set value	Time becomes dependent variable	FR(***v***) which becomes VC		VC		
	Pressure	Time-termination	If inspiratory pressure is adjusted inflation-to-inflation the outcome is volume targetted not VC	vtPC	D.2.2	vtPC		Tidal volume and inspiratory time
		Flow-termination of a pressure-support inflation	If inspiratory pressure is adjusted inflation-to-inflation the outcome is volume targetted not VC	vtPS		vtPS		Tidal volume and termination-flow
Deliver a specified flowrate through the patient connection port	Flow	Time-termination	Adjustable pressure limitation during normal operation	VC[p_{Lim}]	D.2.3	VC	p_{Lim}	Inspiratory flow & time and pressure limit
		Time-termination	Adjustable pressure limit but only with alarm condition	FR(***t***) which becomes VC	D.2.1	VC		Delivered flow and inspiratory time
Deliver a specified inflation pressure	Pressure	Time-termination		PR(***t***) which becomes PC	D.2.4	PC		Inspiratory pressure and time
		Flow-termination	May only be used in a ventilation-mode where it can only be patient-intiated	PR(***q***) which becomes PS	D.2.5	PS		Inspiratory pressure and termination-flow
		Flow-terminated	For use in ventilation-modes where it can be time-initiated	PR(***q***) which becomes PC(***q***)		PC	***q***	Inspiratory pressure and termination-flow
		Assured minimum volume	Inspiratory time is extended	PC→VC	D.2.11	PC→VC		Inspiratory pressure and flow, and delivered volume
		Facilitate concurrent expiration	Provision of either ACAP or, at least, ACAP$_H$ as mode adjunct	PC	D.2.12	PC		Inspiratory pressure and time
		Facilitate concurrent expiration and flow-termination	Provision of either ACAP or, at least, ACAP$_H$ as mode adjunct	PC{S}	D.2.6	PC	S	Inspiratory pressure and time
Support patient effort	Pressure	Not otherwise specified	Parameters determined by settings	ES	D.2.7	ES		Proportion of effort parameter-value to be supported
		Support as proportion of a specified patient effort parameter(s)	Measurement of EMG signals	ES[EMG]		ES	EMG	
			Measurement and integration of inspiratory flow	ES[***q+v***], ES[***q***] **or** ES[***v***]		ES	***q+v***, ***q*** or ***v***	

Key to abbreviations:				
	VC	volume-control	***t***	time
	PC	pressure-control	***p***	airway pressure
	PS	pressure-support	***q***	inspiratory flow
	ES	effort-support	***v***	cumulated delivered flow in each inflation
	FR	flow-regulated	p_{Lim}	pressure-limited
	PR	pressure-regulated	vt	volume-targeted
	ACAP	assured constant airway pressure	df	decreasing-flow pattern
	LC	leak compensated	cdf	concave decreasing-flow pattern
	EMG	electromyography	S	synchronised

Note 1: The primary classification and the set parameters, are what will typically be presented as separate selections on the user interface. For guidance on the use of secondary classifications in the labelling and documentation of ventilators, see D.1.

Note 2: On ventilators offering leakage compensation, this is typically selected globally, as an adjunct. If neccessary, to specify its presence on a specific code, in isolation, this may be denoted by the appendage of the letters, LC, as a subscript.

Table D.2 — Coding scheme for variants of Volume-control Inflation-types

Operator's primary intent	Regulated parameter	Secondary intent(s)	Consequent requirements	Coded form of full systematic name	See Clause:	Primary classification	Secondary classification(s)	Set parameters
Deliver a set volume to a specified part of the ventilator breathing system	Flow	Time termination; Constant flow	Set constant-flow is automatically offset to compensate for repeatable deviations due to, e.g., flow rise time & back pressure	VC	D.2.1	VC		At least two of: delivered or inspiratory volume, delivered or inspiratory flow, or inspiratory time
		Time termination; Set constant flow	Flow may be set to less than necessary to achieve volume in set time, thereby providing an inspiratory pause.	VC		VC		
		Time termination; Substantially constant flow	Continuous intra-inflation correction of set flow so as to achieve delivered volume in set time	VC		VC		
		Constant flow at set value	Time becomes dependent variable	VC		VC		
		Time terminated; Descending-ramp flow pattern		dfVC		VC	df	
		Time terminated; Concave decreasing-flow pattern		cdfVC		VC	cdf	

NOTE: On ventilators offering leakage compensation, this is typically selected globally, as an adjunct. If neccessary, to specify its presence on a specific code, in isolation, this may be denoted by the appendage of the letters, LC, as a subscript.