SLOVENSKI STANDARD
oSIST prEN ISO 19223-1:2026

01-oktober-2026

Pljučni ventilatorji in pripadajoča oprema - Slovar in semantika - 1. del: Pljučni ventilatorji (ISO/DIS 19223-1:2026)

Lung ventilators and related equipment - Vocabulary and semantics - Part 1: Lung ventilators (ISO/DIS 19223-1:2026)

Beatmungsgeräte und zugehörige Geräte - Terminologie und Semantik - Teil 1: Beatmungsgeräte (ISO/DIS 19223-1:2026)

Ventilateurs pulmonaires et équipement associé - Vocabulaire et sémantique - Partie 1: Ventilateurs pulmonaires (ISO/DIS 19223-1:2026)

Ta slovenski standard je istoveten z: **prEN ISO 19223-1**

ICS:

01.040.11	Zdravstveno varstvo (Slovarji)	Health care technology (Vocabularies)
11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment

oSIST prEN ISO 19223-1:2026 **en,fr,de**

DRAFT International Standard

ISO/DIS 19223-1

Lung ventilators and related equipment — Vocabulary and semantics —

Part 1: Lung ventilators

ICS: 11.040.10; 01.040.11

ISO/TC **121**/SC **4**

Secretariat: **ANSI**

Voting begins on:
2026-08-04

Voting terminates on:
2026-10-27

ISO/CEN PARALLEL PROCESSING

Reference number
ISO/DIS 19223-1:2026(en)

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Published in Switzerland

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Foreword

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

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

A list of all parts in the ISO 19223 series can be found on the ISO website.

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 ventilators are complex and often not well understood. Some ventilator manufacturers have created proprietary terms to describe ways of ventilating patients, and other manufacturers 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. International standards are necessary to prevent inconsistencies that may result in risks to patients. This document provides standardized terminology and semantics for artificial ventilation. Where possible, terms already in general use have been incorporated, while clearly defining each term and limiting its potential for misuse. New terms and deprecation of previous terms have been necessary to ensure a clear understanding of the interactions between the patient and the ventilator.

This document has been developed with the participation, cooperation and assistance of clinicians, members of other standards development organizations, and major international ventilator manufacturers. The applications include lung ventilators, anaesthesia and respiratory therapy equipment, health informatics systems facilitating clinical care, research, interoperability, incident reporting and equipment maintenance.

Ventilators have become increasingly interactive with the patient, and terminology must take this into account.

The terminology in this document is defined to facilitate 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).

Ventilation-modes of modern ventilators require the selection of both the pattern that determines when and what inflations occur, and the method used to inflate the lungs; functions that can be conveniently referred to as the ventilation-pattern and the inflation-type. In most cases the choice of inflation-type is largely independent of the choice of ventilation-pattern.

In this document, the ventilation-mode is a composite of these two independent, user-selectable elements: 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 and the inflation-type which determines how the pressure or flow at the patient-connection port will be regulated during an inflation, once initiated.

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. The overall objective is to encourage a consistent use of ventilator vocabulary so that users 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.

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

The notes to some definitions refer to post-coordinated terms. These are terms formed by the combination of two defined terms, or of a defined term with a natural language word, to form a new compound term. Usually, the additional term or word qualifies the base term by reference to an alternative site, pressure level or point of occurrence within a *respiratory cycle*. It can place a restriction on the applicability of the base term.

Examples of the application of this document are illustrated in the figures of Annex A and Annex B but these are not intended to indicate a requirement, nor to impose any restriction on the design of artificial

ventilation devices. Colour coding is employed in most of these figures of this document to help distinguish between some of the specific characteristics being illustrated.

NOTE The following figures have been adapted from Reference [1] with permission:

— Figures: Figure A.1 to Figure A.35 and Figure B.1 to Figure B.7.

Lung ventilators and related equipment — Vocabulary and semantics —

Part 1: Lung ventilators

1 Scope

This document defines terms for fields of respiratory care involving artificial ventilation, such as intensive-care ventilation, anaesthesia ventilation, emergency and transport ventilation and home-care ventilation.

This document is applicable:

— in lung ventilator and *breathing-therapy equipment* 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 information,

— 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 high-frequency ventilation or jet ventilation, which are defined in ISO 19223-2:2025 [2], terms specific to *breathing-therapy equipment*, which are defined in ISO 19223-3:2025 [3], or to physiologic closed-loop ventilation, 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.

This document is structured based on the guidance and requirements specified in ISO 704:2022 [4] and ISO 10241-1:2011 [5].

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 E.

3.1 General artificial-ventilation terminology

3.1.1 Referenced terms

3.1.1.1
normal use
operation, including standby, routine inspection and adjustments by any *user*, in accordance with the *accompanying information* (3.1.1.6) or, for those *medical devices* provided without *accompanying information* (3.1.1.6), with generally accepted practice

Note 1 to entry: ***Normal use*** should not be confused with *intended use* (3.1.1.2). While both include the concept of use as intended by the *manufacturer*, *intended use* (3.1.1.2) focuses on the medical purpose while ***normal use*** incorporates not only the medical purpose, but also matters such as maintenance, transport.

[SOURCE: IEC 60050-880 [6], 880-21-07]

3.1.1.2
intended use
intended purpose
use for which a *product* or *process* is intended according to the specifications, *instructions for use* and other *accompanying information* (3.1.1.6)

[SOURCE: IEC 60050-880 [6], 880-21-06]

Note 1 to entry: ***Intended use*** should not be confused with *normal use* (3.1.1.1). While both include the concept of use as intended by the *manufacturer*, ***intended use*** focuses on the medical purpose while *normal use* (3.1.1.1) incorporates not only the medical purpose, but also such matters as maintenance, service and transport.

3.1.1.3
normal condition
condition of a *medical device* or *accessory* in which all *risk control* measures are intact

[SOURCE: IEC 60050-880 [6], 880-18-11]

3.1.1.4
single fault condition
condition of a *medical device* or *accessory* in which a single *risk control* measure is defective

[SOURCE: IEC 60050-880 [6], 880-18-25.]

3.1.1.5
protection device
part or function of a *medical device* that, without intervention by the *user,* protects against a *hazard* or a *hazardous output*

[SOURCE: IEC 60050-880 [6], 880-16-08.]

3.1.1.6
accompanying information
DEPRECATED: accompanying document
information supplied by the *manufacturer* with or *marked* on a *medical device* or *accessory* for the *user* or the *responsible organization*, particularly regarding safe use

[SOURCE: IEC 60050-880 [6], 880-11-01.]

3.1.1.7
port
fluid port
opening for the passage of a fluid through a specified interface

Note 1 to entry: Typical interfaces where ***ports*** occur are:

— where breathing gas enters a ventilator,

— where water for humidification enters a humidifier,

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

— where a *VBS* (3.1.3.4) is connected to the patient or to an *airway device* (3.1.3.3).

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

[SOURCE: IEC 60050-880 [6], 880-05-02. Modified - added preferred term ***port***]

3.1.2 Qualifiers defined in this document

3.1.2.1
set
setting
allocated a specific value

EXAMPLE 1 A ***set*** pressure *limit* (3.1.2.5).

EXAMPLE 2 The ***set*** *Δ inspiratory pressure* (3.8.6).

Note 1 to entry: ***Set*** is used in this document as a prefix to distinguish an intended value for a controlled *artificial ventilation* (3.1.5.2) variable from a *measured* (3.1.2.2) or *actual value* (3.1.2.4) of the same quantity, if this is not evident from the context of use.

Note 2 to entry: A ***set*** value might be determined directly by the *user* or indirectly by selection of an algorithm that determines the ***setting*** based on other ***set*** or *measured* (3.1.2.2) values.

Note 3 to entry: See also the references to ***settings*** in Annex A and Annex C.

3.1.2.2
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* (3.1.2.4) or *set* (3.1.2.1) value of the same quantity, if this is not evident from the context of use.

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

3.1.2.3
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* (3.1.3.1)

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 *user* password,

— voice recognition, or

— biometric means.

3.1.2.4
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* (3.1.2.1) values are the means by which an user informs the *ventilator* (3.1.3.1) of the intended ***actual value***, and *measured* (3.1.2.2) values are displays or records of the ***actual value***, to the accuracy and resolution of the measuring system.

3.1.2.5
limit
point or level beyond which the value of a parameter cannot pass without an action by the *ventilator* (3.1.3.1)

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* (3.1.5.1) parameters.

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

Note 4 to entry: See also Annex E and safety limits and alarm terminology (3.15).

3.1.2.6
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* (3.11.1) 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* (3.4.1.1) can be ***initiated*** by, for example:

— a *patient-trigger event* (3.11.5);

— a timed signal;

— a manual input;

— a conditional *termination* (3.11.12) of an *expiratory phase* (3.5.6);

— a signal from a remote device.

Note 2 to entry: In this document, an *inflation* (3.4.1.1) that is ***initiated*** by a timed signal may be referred to as being *ventilator-initiation* (3.11.9).

Note 3 to entry: A conditional *termination* (3.11.12) of an *expiratory phase* (3.5.6) is typically achieved by establishing an *expiratory flow* (3.9.5) threshold at which the next *inflation* (3.4.1.1) is ***initiated***. An ***initiation*** of this type is sometimes used, for example, to optimize the *expiratory time* (3.6.6) in an *APRV* (3.13.3.9) mode. Such a threshold flow is typically expressed as either a *set* (3.1.2.1) *expiratory flow* (3.9.5) or a *set* (3.1.2.1) percentage of the peak *expiratory flow* (3.9.5).

3.1.2.7
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* (3.1.5.2) but, because of its ambiguity, it can denote either 'total control' or, as in this definition, 'required to occur'. In early *artificial ventilation* (3.1.5.2) practice, it was usual for all aspects of the patient's *ventilation* (3.1.5.1) to be taken over by the *ventilator* (3.1.3.1) and so every *breath* (3.2.1) could be described as mandatory in its broadest sense. Since then, with the introduction of *breath synchronization* (3.11.6) and the concept of support for *spontaneous breaths* (3.2.3), only a small percentage of *patients* currently have their *ventilation* (3.1.5.1) totally controlled. However, there remains a mandatory component to all forms of *artificial ventilation* (3.1.5.2) but a key aspect for an *user* when setting a contemporary *ventilator* (3.1.3.1) is being assured that, when a selected *inflation-type* (3.4.1.2) is delivered within the selected *ventilation-pattern* (3.13.1.3), it will provide at least a minimum level of assistance and, in the case of apnoea, that the *ventilation* (3.1.5.1) will be totally controlled.

These developments have led *manufacturers* to increasingly restrict the use of the term 'mandatory' to the context of *ventilation* (3.1.5.1) that is assured to occur by the programmed delivery of a selected *inflation-type* (3.4.1.2), in predetermined patterns, at a rate that is independent of the patient's *respiratory activity* (3.2.6). 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 *continuous mandatory ventilation* (3.13.3.2), *intermittent mandatory ventilation* (3.13.3.4) and *synchronized intermittent mandatory ventilation* (3.13.3.5). For other purposes, wherever possible, the word assured is used in its place.

3.1.2.8
rise time
indication of the time for the regulated parameter to rise to a *set* (3.1.2.1) value following the *initiation* (3.1.2.6) of an *inflation* (3.4.1.1)

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* (3.3.2), this is the time to reach a *set* (3.1.2.1) *inspiratory pressure* (3.8.2), for *flow-regulation* (3.3.1) it is the time to reach a *set* (3.1.2.1) *inspiratory flow* (3.9.2).

Note 3 to entry: See also Figure A.1 and Figure A.9 to Figure A.13.

3.1.2.9
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 pressure* (3.8.2) or *expiratory pressure* (3.8.8) to denote when it is referenced to a *baseline airway pressure* (3.12.1) 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 Figure A.1, Figure A.9, Figure A.10, Figure A.29, Figure A.30 and Figure A.33.

3.1.3 Ventilation equipment terms

3.1.3.1
ventilator
lung ventilator
DEPRECATED: respirator
medical device or *medical electrical equipment* intended to provide *artificial ventilation* (3.1.5.2)

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

3.1.3.2
airway
patient airway
connected, gas-containing cavities and passages within the *respiratory system* (3.1.4.2), that conduct gas between the alveoli and the oral and nasal orifices on the surface of the face, or the *patient-connection port* (3.1.3.9) if an *airway device* (3.1.3.3) 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 admitted term ***patient airway***.

3.1.3.3
airway device
device intended for use as an interface between the *patient-connection port* (3.1.3.9) of a *ventilator* (3.1.3.1) and the patient's *airway* (3.1.3.2), and which has no auxiliary features on which the *ventilator* (3.1.3.1) 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* (3.1.3.2) 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* (3.1.3.4) and therefore not an ***airway device***. With that arrangement, the face seal of the mask becomes the *patient-connection port* (3.1.3.9) and there is no *patient-connection port* (3.1.3.9) connector, nor an ***airway device***.

3.1.3.4
VBS
ventilator breathing system
anaesthesia breathing system
pathways through which gas flows to or from the *patient* at respiratory pressures, bounded by the *port* (3.1.1.7) through which respirable gas enters, the *patient-connection port* (3.1.3.9) and the gas *exhaust port* (3.1.3.6)

Note 1 to entry: These pathways typically extend within and outside the body of the *ventilator* (3.1.3.1), with those outside being *user*-detachable.

Note 2 to entry: The *port* (3.1.1.7) of entry of a respirable gas into the ***ventilator breathing system*** can be inside the body of the *ventilator* (3.1.3.1) and should not be confused with an external connection *port* (3.1.1.7) into which respirable gas enters before being reduced to respirable pressures.

Note 3 to entry: The admitted term is included in this document for use in reference to the specific class of *ventilator* (3.1.3.1) that are configured to ventilate *patients* with an anaesthetic gas mixture. With this application, the 'respirable gas' is 'anaesthetic gases' and the '*port* (3.1.1.7) through which respirable gas enters' can be referred to as the 'fresh-gas inlet'.

3.1.3.5
sleep-apnoea breathing-therapy equipment
medical equipment intended to alleviate the symptoms of a *patient* who suffers from sleep apnoea by delivering a therapeutic *baseline airway pressure* (3.12.1) to the *patient*

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

3.1.3.6
exhaust port
port (3.1.1.7) of the medical equipment or device from which gas is discharged to the atmosphere during *normal use* (3.1.1.1), either directly or via an anaesthetic gas scavenging system

3.1.3.7
gas output port
port (3.1.1.7) of the *ventilator* (3.1.3.1) through which gas is delivered at respiratory pressures to an *user*-detachable part of the *VBS* (3.1.3.4)

3.1.3.8
gas return port
port (3.1.1.7) of the *ventilator* (3.1.3.1) through which gas is returned at respiratory pressures through an *user*-detachable part of the *VBS* (3.1.3.4) from the *patient-connection port* (3.1.3.9)

3.1.3.9
patient-connection port
port (3.1.1.7) of a *VBS* (3.1.3.4) intended for connection to an *airway device* (3.1.3.3)

Note 1 to entry: The ***patient-connection port*** is the end of the *ventilator breathing system* (3.1.3.4) 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* (3.1.3.3) 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* (3.1.3.1) designed to provide *NIV* (3.1.5.7) and where the *artificial ventilation* (3.1.5.2) function is dependent upon a design feature of a component that connects the *ventilator* (3.1.3.1) to the patient's *airway* (3.1.3.2), 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.

3.1.3.10
fraction of inspired oxygen
FiO_2
concentration of oxygen in the breathing gas provided to a patient

Note 1 to entry: The ***fraction of inspired oxygen*** is conventionally measured and expressed as a volume fraction in the dry breathing gas mixture, prior to any humidification of the breathing gas.

Note 2 to entry: The ***fraction of inspired oxygen*** is reported either as a fraction (in the range 0.21 to 1.00) or as a percentage value.

3.1.3.11
heliox
breathing gas mixture comprising oxygen and helium

Note 1 to entry: Heliox with a *fraction of inspired oxygen* (3.1.3.10) in the range 0.20 to 0.40, and with the balance being helium, is used in some cases of restricted airway disease as the lower density of helium compared with nitrogen results in more laminar flow, and consequent reduction in *airway resistance* (3.1.4.3).

3.1.4 Respiratory mechanics

3.1.4.1
lung
each of the pair of compliant organs within the ribcage (thorax), bounded by the terminal bronchiole and the visceral pleura, which during *ventilation* (3.1.5.1) 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 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* (3.1.4.2), consisting of the *airway* (3.1.3.2) 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 2 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***.