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Anaesthetic and respiratory equipment — Vocabulary

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

This fourth edition cancels and replaces the third edition (ISO 4135:2001), which has been technically revised.

The main changes compared to the previous edition are as follows:

— Deletion of terms that are no longer relevant to International Standards prepared by ISO/TC 121, or that are defined in more widely applicable International Standards, such as ISO 14971.

— Deletion of terms that are specific to lung ventilators and that are covered in ISO 19223.

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

In this document, the following print types are used:

— Definitions: roman type;

— *Terms defined in this document or as noted: italic type;*

— Informative material appearing outside of tables, such as notes, examples and references: in smaller type.

The primary objective for this document has been to facilitate consistent use of terminology across all the standards relevant to manufacturers, test laboratories and regulatory agencies with an interest in equipment for use in anaesthesiology and respiratory care.

Since the publication of the 3rd edition of ISO 4135 in 2001, many new and updated standards have been published by ISO/TC 121. In many cases, terms defined in the 3rd edition of ISO 4135 have not been found sufficient for the purposes of these standards, resulting in terms being redefined in different standards, or new terms created, such that users of the standards may be confused as to the meaning.

In preparation for this new edition, all the terms defined in ISO/TC 121 documents were reviewed. This new edition is intended to address several objectives:

a) Deletion of terms in the 3rd edition of ISO 4135 that no longer fulfil a purpose, or that are now included in ISO 19223;

b) Addition of terms from other ISO/TC121 standards where these can be of value across multiple standards;

c) Encouragement of consistent use of terminology across ISO/TC 121 standards, in order to minimize the potential for readers to misunderstand intent.

In preparation of this document it became apparent that many terms are defined in standards applicable to medical equipment more widely than the scope of ISO/TC 121, and that redefining these terms in a domain-specific terminology or in a product standard can lead to confusion when users of the standard are familiar with the more generally applicable terminologies.

A number of terms previously defined in the 3rd edition of ISO 4135 or in other ISO/TC 121 standards, particularly those for different categories of lung ventilators and anaesthetic workstations, are now provided in ISO 19223:2019. These are freely available on the ISO online browsing platform (see Clause 3).

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

Terms defined in ISO 19223 have been included in this document where they have applicability outside the scope of mechanical ventilation.

EXAMPLE 1 *Airway pressure* is included in this document because it has applicability in fields such as pulmonary function testing.

EXAMPLE 2 *Airway resistance* is not included in this document because the only context of use of this term is within standards for lung ventilators, for which ISO 19223 is an appropriate source.

Particular emphasis has been placed on the identification of instances where the same term is used for different concepts, or where the same concept is identified by different terms.

This last point is particularly relevant for test laboratories, and for manufacturers using standards from several different subcommittees of ISO/TC 121, or ISO/TC 121 standards alongside IEC/TC 62 standards. When multiple definitions exist, and particularly when terms in the general standard or collaterals are redefined in particular standards, it is all too easy for the user of a standard to reference the wrong definition, and hence misconstrue requirements.

In some cases terms were provided in different sections of the 3rd edition of ISO 4135, with different definitions. The Working Group amended the categorization and in some cases amended term names in order to avoid any instances of terms with distinct definitions.

The terms, names and acronyms listed in this Standard have been described in a manner that formalizes their interpretation to the extent that it minimizes ambiguity and provides a rigid usage discipline for formal data handling and informatics, whilst retaining phraseology that is suitable for user instructions and clinical dialog.

In the application of the vocabulary of this International Standard, the full term should always be used wherever any ambiguity might arise from use of an abbreviated term and where there is no trade-off with conciseness, for example, in the formulation of data bases. However, in many applications the context of use may make some of the parts of a compound preferred term redundant, in which case abbreviations, symbols and permitted terms may be used, as appropriate.

The vocabulary of this document is primarily arranged in a systematic order, with a secondary alphabetical order. An alphabetical index of the terms defined in this document is provided in Annex A.

For terms that have different definitions in differing contexts, the definition context is specified in <> before the definition.

This document is a “controlled vocabulary”, which includes “pre-coordinated terms”. It is expected that users of this standard may also create “post-coordinated terms” by a process of concatenation as appropriate to the field of use. Within the field of terminology standards, a **pre-coordinated term** is a verbal designation of a concept with more than one root that can be split morphologically into separate components and which is predefined in a controlled vocabulary, for example *minute volume* and *pressure-limiting valve,* while a **post-coordinated term** is a verbal designation of a concept with more than one root, created by a user by combining terms from controlled vocabularies. An example of this would be *supraglottic airway device,* which can be created by combining the two individually defined terms *supraglottic* and *airway device.*

Anaesthetic and respiratory equipment — Vocabulary and semantics

1 Scope

This International Standard establishes a vocabulary of terms used for anaesthetic and respiratory equipment and supplies, related devices and supply systems.

NOTE 1 This document is based on standards and drafts which have been produced by ISO/TC 121 and CEN/TC 215.

NOTE 2 To avoid multiple definitions of the same term in different categories, this document attempts to ensure consistency by the inclusion of a 'general' category, and by use of domain specifiers and unique pre-coordinated domain-specific term names.

NOTE 3 In addition to terms and definitions used in two of the three official ISO languages (English and French), this document gives the equivalent terms in the German language; these are published under the responsibility of the member body for Germany. However, only the terms and definitions given in the official languages can be considered as ISO terms and definitions.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

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/

3.1 General concepts

3.1.1 Properties of gases and materials

3.1.1.1
absolute humidity
mass of water vapour present in a unit volume of gas

Note 1 to entry: In respiratory applications *absolute humidity* is commonly represented in units of milligrams per litre or grams per cubic metre, with volume expressed at BPTS condition.

Note 2 to entry: See also *relative humidity* (3.1.2.4).

3.1.1.2
adiabatic compression
compression process that occurs without transfer of heat into or out of a system

3.1.1.3
aerosol
suspension of liquid or solid particles in a gas

3.1.1.4
air for driving surgical tools
natural or synthetic mixture of gases, mainly composed of oxygen and nitrogen in specified proportions, with defined limits for the concentration of contaminants, and intended to act as a power source for surgical tools

3.1.1.5
anaesthetic gas
gas, which may be the vapour of a volatile anaesthetic agent, or mixture of gases, used in anaesthesia

Note 1 to entry: In parts of an *anaesthetic breathing system* (3.6.1.8), *anaesthetic gas* includes gases exhaled by the patient.

3.1.1.6
auto-ignition temperature
temperature at which a material will spontaneously ignite under specified conditions

3.1.1.7
body temperature and pressure saturated
BTPS
ambient atmospheric pressure, at a temperature of 37 °C, and at a *relative humidity* (3.1.2.4) of 100 %

3.1.1.8
standard temperature and pressure dry
STPD
pressure of 101,325 kPa at a temperature of 20 °C, dry

3.1.1.9
carrier gas
<respiratory therapy> respirable gas that conveys a substance or substances to the patient

EXAMPLE *Medical air* (3.1.1.18) used to convey a bronchodilatory drug.

3.1.1.10
carrier gas
<anaesthesia> respirable gas that conveys one or more *anaesthetic gases* (3.1.1.5) to the patient

EXAMPLE Ambient air and *oxygen* (3.1.1.21) mixture in a *draw-over vaporiser* (3.3.2.3).

3.1.1.11
combustion
rapid oxidation to produce heat and light

3.1.1.12
compliance
change in volume of gas per unit pressure change within an enclosed space

Note 1 to entry: It is deprecated to include the measurement conditions into the definition of *compliance*; in general *compliance* may be expressed at any specified measurement condition.

Note 2 to entry: to entry. ISO 19223 provides definitions for pulmonary *compliance*, respiratory system *compliance*, static *compliance* and dynamic *compliance*, all of which relate to the patient. Various other standards from ISO/TC 121 reference *compliance* with respect to items of equipment such as *breathing tubes* (3.1.4.4) and reservoir bags.

3.1.1.13
delivered gas temperature
temperature of the gas, or *aerosol* (3.1.1.3) or both, being delivered to a patient, referenced to the *patient-connection port* (3.1.4.41)

3.1.1.14
delivered oxygen concentration
concentration of oxygen in the gas delivered at a specified location

EXAMPLE In a closed *anaesthetic breathing system* (3.6.1.8), 100 % oxygen can be added to the *breathing system* (3.6.1.1) to match the patient's oxygen consumption, with the *respiratory gas monitor* (3.11.2.1) at the *patient-connection port* (3.1.4.41) measuring a much lower value for *FiO2* (3.1.1.15).

3.1.1.15
FiO_2
fraction of inspired oxygen
concentration of oxygen in the gas inspired by a patient

Note 1 to entry: The measurement site for FiO_2 should be specified by the equipment manufacturer but should be referenced to the concentration of oxygen in the gas that is intended to be inspired.

EXAMPLE In a closed *anaesthetic breathing system* (3.6.1.8), 100 % oxygen can be added to the *breathing system* (3.6.1.1) to match the patient's oxygen consumption, with the *respiratory gas monitor* (3.11.2.1) at the *patient-connection port* (3.1.4.41) measuring a much lower value for FiO_2.

3.1.1.16
fresh gas
respirable gas delivered to a *breathing system* (3.6.1.1)

Note 1 to entry: In a *circle breathing system* (3.6.1.8.1), the *fresh gas* is all respirable gas delivered into the *circle breathing system* (including *anaesthetic gases* (3.1.1.5) and vapours). This can include *oxygen* (3.1.1.21) or air delivered into a vaporiser, and it can also include the vapour generated by a *vaporiser* (3.3.2.2).

Note 2 to entry: In an open *breathing system* (3.6.1.1), the *fresh gas* is all respirable gas delivered into the *breathing system* (which can be at any point within the *breathing system*).

3.1.1.17
gas for medicinal use
gas or mixture of gases that can be used either with a view to restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action, or to make a medical diagnosis

3.1.1.18
medical air
natural or synthetic mixture of gases, mainly composed of oxygen and nitrogen in specified proportions, with defined limits for the concentration of contaminants, intended for administration to patients

3.1.1.19
medical device gas
gas or mixture of gases intended by the manufacturer to be used as a medical device or as an accessory to a medical device

Note 1 to entry: This encompasses uses for investigation or modification of the anatomy or of a physiological process, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

Note 2 to entry: In some countries, *medical device gases* may be regulated as a medical device, a drug or not subject to regulation.

EXAMPLE 1 EXAMPLES:

EXAMPLE 2 Liquid gases used for cryoablation.

EXAMPLE 3 Gases used to provide an anaerobic atmosphere.

EXAMPLE 4 Compressed air for hyperbaric chambers.

EXAMPLE 5 Driving gas for surgical tools.

EXAMPLE 6 Inflating gases for laparoscopy.

3.1.1.20
medical gas
any gas or mixture of gases intended for administration to patients for anaesthetic, therapeutic, diagnostic or prophylactic purposes, or as a source of pneumatic power for medical or surgical tools

3.1.1.21
oxygen
gas for medicinal use (3.1.1.17) where the oxygen concentration is at least the minimum specified in the relevant pharmacopoeia monograph

3.1.1.22
oxygen 93
DEPRECATED: oxygen-enriched air
gas for medicinal use (3.1.1.17) where the oxygen concentration is at least the minimum specified in the relevant pharmacopoeial monograph for oxygen 93

Note 1 to entry: *Oxygen 93* is usually manufactured at the healthcare provider site by a pressure-swing adsorption *oxygen concentrator* (3.2.1.3.7).

3.1.1.23
partial pressure
pressure that each gas in a gas mixture would exert if it alone occupied the volume of the mixture at the same temperature

3.1.1.24
saturation vapour pressure
partial pressure (3.1.1.23) of water vapour at a given temperature at a liquid-gas interface when a dynamic equilibrium between vaporisation and condensation is reached

3.1.1.25
suction
application of *vacuum* (3.1.1.27) to remove liquid, solid particles, *aerosol* (3.1.1.3) or gas

3.1.1.26
thermal conductivity
rate of heat flow through a unit area, per unit temperature gradient, in the direction perpendicular to the area

3.1.1.27
vacuum
pressure less than ambient pressure

3.1.1.28
volume fraction
volume percent
volume of a gas in a mixture, expressed as a proportion of the total volume

Note 1 to entry: *Volume fraction* can be expressed as a percentage or as a fraction.

Note 2 to entry: The synonym *volume percent* is reserved for the expression of *volume fraction* as a percentage.

3.1.2 Properties of equipment

3.1.2.1
accessible surface temperature
temperature of any surface of the device that can come into contact with any part of the human body during normal use, including during maintenance operations that occur during clinical use

Note 1 to entry: Maintenance operations include refilling a reservoir with water or medication; cleaning and decontamination; and replacement of batteries.

3.1.2.2
antistatic
property of a material or procedure that disperses or inhibits the accumulation of electrostatic charges

3.1.2.3
gas-specific
having characteristics which prevent connections between different gas services, *vacuum* (3.1.1.27) services and *anaesthetic gas scavenging systems* (3.9.1.1).

Note 1 to entry: *Terminal units* (3.2.2.1), cylinder *outlets* (3.1.4.40), *low-pressure hose assemblies* (3.2.3.1), and equipment gas *inlets* (3.1.4.26) and *outlets* (3.1.4.40) are examples of gas services.

3.1.2.4
relative humidity
water vapour pressure, expressed as a percentage of the *saturation vapour pressure* (3.1.1.24), at a particular temperature

Note 1 to entry: See also *absolute humidity* (3.1.1.1).

3.1.3 Metrology concepts

3.1.3.1
accuracy

measurement accuracy
DEPRECATED: accuracy of measurement
closeness of agreement between a measured quantity and a true quantity value of a measurand

[SOURCE: ISO/IEC Guide 99 “International vocabulary of metrology – Basic and general concepts and associated terms (VIM)” definition 2.13]

Note 1 to entry: The term *accuracy*, when applied to a set of test results, involves a combination of a random component and of a common systematic error or *bias error* (3.1.3.3) component.

Note 2 to entry: In practical terms, a reference value is commonly used with an assumption that it represents the true quantity value.

3.1.3.2
accuracy of flow
difference between the indicated flow and the actual flow

[SOURCE: ISO 10524-1, amended to remove the units of measure, as definition of a term to represent both a concept and a specific unit of measure is discouraged as it represents a potentially hidden requirement.]

3.1.3.3
bias error
DEPRECATED: bias
difference between the expectation of the test results and an accepted reference value

Note 1 to entry: *Bias error* is the total systematic error as contrasted to random error. There can be one or more systematic error components contributing to the *bias error*. A larger systematic difference from the accepted reference value is reflected by a larger *bias error* value.

Note 2 to entry: Expectation is a statistical term which can be interpreted approximately as the mean of the values that would be obtained if the measurement were made many times.

3.1.3.4
calibration
operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication

[SOURCE: ISO/IEC Guide 99 “International vocabulary of metrology – Basic and general concepts and associated terms (VIM)” definition 2.39]

3.1.3.5
calibration range
range of values over which a monitoring device or a control should be tested and verified

3.1.3.6
declared range
DEPRECATED: measurement range
portion of the *displayed range* (3.1.3.10) of measured values over which there is specified *accuracy* (3.1.3.1)

3.1.3.7
display
visual representation of quantitative or qualitative information

3.1.3.8
display update period
duration of time, or number of events (e.g. pulses), between possible changes in the displayed values

3.1.3.9
data update period
duration of time, or number of events (e.g. pulses), between possible changes in the data provided by a *monitoring equipment* (3.11.1.3) algorithm to the *display* (3.1.3.7) or to the signal input/output part

Note 1 to entry: This definition does not refer to any regular refresh period of the *display* (3.1.3.7), but rather to the output of new values of the monitored parameter. The definition encompasses both that the measurement may be taken at asynchronous intervals, and also that the data transmitted to another device may be queued asynchronously due to communication bandwidth or other issues.

Note 2 to entry: A device can have more than one signal input/output part, each with its own specified *data update period*.

3.1.3.10
displayed range
range of values that can be displayed for a specific parameter

Note 1 to entry: The *displayed range* can extend beyond the *declared range* (3.1.3.6).

3.1.3.11
drift
change in the reading of a measuring instrument over a stated period of time, under reference conditions that remain constant, where the quantity or property that is measured remains the same

3.1.3.12
laboratory accuracy
closeness of agreement between the output of a measuring device under laboratory conditions and the true value of the measurand.

Note 1 to entry: *Laboratory accuracy* is a qualitative concept. For a quantitative description, the term 'uncertainty' should be used.

3.1.3.13
long-term automatic mode
mode in which a timer, set by the user, initiates multiple *intermittent* (3.11.1.2) measurements

3.1.3.14
measuring site
part of a patient or equipment where a quantity is measured

EXAMPLE Pulmonary artery, distal oesophagus, sublingual space in the mouth, rectum, ear canal, axilla (armpit), forehead skin, *ventilator breathing system* (3.4.1.9).

Note 1 to entry: See also *reference body site* (3.1.3.17).

3.1.3.15
normalized
displayed at constant amplitude, independent of the actual magnitude of the signal being displayed

3.1.3.16
precision
closeness of agreement between indications or measured quantity values obtained by replicate measurements on the same or similar objects under specified conditions

[SOURCE: ISO/IEC Guide 99 "International vocabulary of metrology – Basic and general concepts and associated terms (VIM)" definition 2.15]

Note 1 to entry: Measurement *precision* is usually expressed numerically by measures of imprecision, such as standard deviation, variance, or coefficient of variation under the specified conditions of measurement.

Note 2 to entry: The 'specified conditions' can be, for example, *repeatability* (3.1.3.18) conditions of measurement, intermediate precision conditions of measurement, or reproducibility conditions of measurement (see ISO 5725-1:1994) .

Note 3 to entry: Measurement *precision* is used to define measurement *repeatability* (3.1.3.18), intermediate measurement precision, and measurement reproducibility.

Note 4 to entry: Sometimes "measurement *precision*" is erroneously used to mean *measurement accuracy* (3.1.3.1).

Note 5 to entry: *Precision* depends on random errors and does not relate to the true value or the specified value.

Note 6 to entry: "Independent test results" means results obtained in a manner not influenced by any previous result on the same or similar test object. Quantitative measures of precision depend critically on the stipulated conditions. *Repeatability* (3.1.3.18) and reproducibility conditions are particular sets of extreme stipulated conditions.

3.1.3.17
reference body site
part of a patient to which the indicated quantity refers

Note 1 to entry: A clinical measuring device may estimate a parameter such as core temperature based on measurements from a different *measuring site* (3.1.3.14), such as the ear canal.

3.1.3.18
repeatability
precision (3.1.3.16) of the same measurand carried out under the same conditions of measurement

3.1.3.19
self-measurement automatic mode
mode in which a user action initiates a limited number of *intermittent* (3.11.1.2) measurements

3.1.3.20
short-term automatic mode
mode in which a user action initiates a sequence of repetitive automatic *intermittent* (3.11.1.2) measurements within a specified time period