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Anestezijska in dihalna oprema - Slovar in semantika (ISO/DIS 4135:2019)

Anaesthetic and respiratory equipment - Vocabulary and semantics (ISO/DIS 4135:2019)

Anästhesie- und Beatmungsgeräte - Begriffe (ISO/DIS 4135:2019)

Matériel d'anesthésie et de réanimation respiratoire - Vocabulaire (ISO/DIS 4135:2019)

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Anaesthetic and respiratory equipment — Vocabulary and semantics

Matériel d'anesthésie et de réanimation respiratoire — Vocabulaire

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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, WG1 *Respiratory equipment vocabulary*.

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 from ISO 4135 3rd edition that are no longer relevant to standards prepared by ISO/TC 121, or that are defined in more widely applicable standards such as ISO 14971.

— Deletion of terms that are specific to lung ventilators and that are covered in ISO 19223, and that are not relevant outside of the scope of that standard.

— Incorporation of terms from ISO/TC 121 Standards that are applicable beyond their current scope.

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 primary objective for ISO 4135 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 under the auspices of ISO/TC 121. In many cases, terms defined in 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, SC 4 created a working group tasked with reviewing all the terms defined in ISO/TC 121 documents. This new edition is intended to address several objectives:

a) Deletion of terms in the 2001 edition of ISO 4135 that no longer fulfil a purpose, or that are now included in ISO 19223 (where these are not used outside the scope of that standard);

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

c) Encouragement of consistent use of terminology across TC121 standards, in order to minimize the potential for stakeholders to misunderstand intent.

In preparation of this edition of ISO 4135 it became apparent that many terms are defined in standards applicable to medical equipment more widely than the scope of TC121, and that redefining these terms in a domain-specific terminology or in a particular standard can lead to confusion when users of the standard are familiar with the more generally applicable terminologies.

In line with guidance in ISO/IEC Directives, Part 2, Principles and rules for the structure and drafting of ISO and IEC documents, subclause 16.5.5, this document does not include a number of terms that have previously been defined in ISO TC121 deliverables, and yet are also defined in more general ISO/IEC sources. These terms fall within scope of the guidance in ISO/IEC Directives Part 2:

“Common terms, which a qualified user of the document will already know, should not be defined.”

[SOURCE: ISO/IEC Directives, Part 2, subclause 16.5.5]

Sub-committees of ISO TC121 and their working groups are recommended to reference terms in one of these sources rather than including a definition within their deliverable.

The specific list of sources that this Working Group determined to be “widely known to a qualified user” of an ISO TC121 deliverable comprises the following:

ISO Guidance and standards applicable to all medical equipment

— ISO/IEC Guide 63 [1],

— ISO 14971 [2]

— ISO 16142-1 [3].

IEC standards applicable to all medical electrical equipment (or for all within a specified use environment)

— IEC 60601-1 [4],

— IEC 60601-1-2 [5]

— IEC 60601-1-6 [6]

— IEC 60601-1-8 [7]

— IEC 60601-1-9 [8]

— IEC 60601-1-10 [9]

— IEC 60601-1-11 [10]

— IEC 60601-1-12 [11]

— IEC 62366-1 [12]

It has not proven possible to include a list of terms that are defined in these sources into this document.

BOX NOTE

SC4 intends to publish a white paper “Terminologies for Respiratory and Anaesthetic Equipment Standards” prior to the final publication of this edition of ISO 4135.

A number of terms previously defined in ISO 4135 or in other TC 121 standards, particularly those for different categories of lung ventilators and anaesthetic workstations, are now provided in ISO 19223:2019.[13] These are freely available on the ISO online browsing platform,

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

Terms defined in ISO 19223 have not been included into this edition of ISO 4135 unless they have applicability outside the scope of mechanical ventilation.

EXAMPLE 1 *airway pressure* is included in this edition of ISO 4135 because it has applicability in fields such as pulmonary function testing.

EXAMPLE 2 *airway resistance* is not included in this edition of ISO 4135 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 ISO TC121 SCs, or TC121 standards alongside IEC TC62 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 ISO 4135 ed. 3, with different definitions. We have 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 must be avoided 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.

Vocabulary and terminology standards are required by ISO to be prepared considering the guidance of ISO 704, Terminology work - Principles and methods, ISO 10241-1, Terminological entries in standards - Part 1: General requirements and examples of presentation, and the ISO/IEC Directives, Part 2, 2011 -- Rules for the structure and drafting of International Standards.

The following concepts extracted from ISO 704 were considered to be of particular relevance to the formatting of the vocabulary in this International Standard:

> Standardized terminologies should reflect a coherent terminological system that corresponds to the concept system of the subject field in question. The terminology defined in an International Standard should be precise and lead to increased clarity in communication.
>
> A primary function of a standardised terminology is to indicate preferred, admitted and deprecated terms. A term recommended by a technical committee shall be considered a preferred term whereas an admitted term shall represent an acceptable synonym for a preferred term. Deprecated terms are terms that have been rejected. Terms are rejected or deprecated for a number of reasons. A term may be a synonym for the preferred term but is deprecated in the interests of monosemy (having a single meaning). Alternatively a term may be flawed, inaccurate or may be used with a different definition.

[SOURCE: ISO 704 [14]]

In accordance with the ISO 10241-1:2011 Clause 6.4.4, the definitions of terms are intentional 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 entry follow different rules from notes integrated into other text; they provide additional information that supplements the terminological data.

The terminological entries hereunder are formatted in accordance with the current ISO rules for the presentation of terminology standards. The vocabulary of this International Standard is primarily arranged in a systematic order, with a secondary alphabetical order. An alphabetical list of terms is provided at the end of this document.

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.

pre-coordinated term

verbal designation of a concept with more than one root that can be split morphologically into separate components, which is predefined in a controlled vocabulary

EXAMPLES: *minute volume* and *pressure-limiting valve*

post-coordinated term

verbal designation of a concept with more than one root, created by a user by combining terms from controlled vocabularies

EXAMPLE *supraglottic airway device* can be created by combining the two individually defined terms *supraglottic* and *airway device*

controlled vocabulary

standardized and organized arrangements of terms and their definitions related to one or more subject fields

Different jurisdictions use different distinct definitions for patient populations based on age and weight. In this standard an attempt has been made to define terms for patient groups, recognizing that it is impossible to align with regulations in all jurisdictions. Where a particular standard has a need to refer to a patient cohort by weight, this should be specified explicitly.

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 to entry This International Standard is based on standards and drafts which have been produced by ISO/TC 121 and CEN/TC 215.

Note 2 to entry Contrary to the policy in ISO 4135 3rd edition of allowing 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 to entry In addition to terms and definitions used in two of the three official ISO languages (English and French), this International Standard 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

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

None.

3 Terms and definitions

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 moist gas

Note 1 to entry: In respiratory applications *absolute humidity* is commonly represented in units of milligrams per litre or grams per cubic metre.

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, intended for driving surgical tools

3.1.1.5
anaesthetic gas
gases and, if present, vapour of a volatile anaesthetic agent, used in anaesthesia

Note 1 to entry: In parts of an *anaesthetic breathing system* (3.6.1.7), *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
carrier gas
respirable gas that conveys a substance or substances to the patient

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

EXAMPLE 1 ambient air and oxygen mixture in a drawover vapourizer

EXAMPLE 2 medical air used to convey a bronchodilatory drug

3.1.1.9
combustion
rapid oxidation to produce heat and light

3.1.1.10
compliance
volume added per unit pressure increase when gas is added to 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.

3.1.1.11
delivered gas temperature
temperature of the gas, or *aerosol* or both, being delivered to a patient, referenced to the *patient connection port* (3.1.4.39)

3.1.1.12
delivered oxygen concentration
FiO2
concentration of oxygen in the gas delivered to a patient

3.1.1.13
fresh gas
respirable gas delivered to a *breathing system* (3.6.1.1)

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

Note 2 to entry: In a ventilator, the *fresh gas* is all respirable gas delivered into the VBS (which may be at a point within the ventilator).

3.1.1.14
gas for medicinal use
gas or mixture of gases having properties for treating or preventing disease in human beings which may be used in or administered 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

3.1.1.15
gas level
content of a specific gas in a gaseous mixture

Note 1 to entry: expressed as a volumetric concentration or as a *partial pressure* (3.1.1.21).

3.1.1.16
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

3.1.1.17
medical device gas
gas or mixture of gases intended by the manufacturer to be used for human beings for the purpose of: — diagnosis, prevention, monitoring, treatment or alleviation of disease; — investigation, replacement or modification of the anatomy or of a physiological process; — control of conception; and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means

3.1.1.18
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

3.1.1.19
oxygen
gas for medicinal use where the oxygen concentration is at least the minimum specified in the relevant pharmacopoeia monograph

3.1.1.20
oxygen 93
DEPRECATED: oxygen-enriched air
gas for medicinal use 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).

3.1.1.21
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

3.1.1.22
saturation vapour pressure
partial pressure (3.1.1.21) of water vapour at a given temperature at a liquid-gas interface when dynamic equilibrium between vaporization and condensation is reached

3.1.1.23
suction
application of *vacuum* (3.1.1.25) to remove liquid, solid particles or gas

3.1.1.24
thermal conductivity
rate of heat flow through unit area, per unit temperature gradient, in the direction perpendicular to the area

3.1.1.25
vacuum
pressure less than ambient pressure

3.1.1.26
volume percentage
volume fraction
volume of a gas in a mixture, expressed as a percentage of the total volume

3.1.2 Properties of equipment

3.1.2.1
accessible surface temperature
temperature of any surface of the device which 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 would 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* (3.1.1.25) services and *anaesthetic gas scavenging systems* (3.9.1.1).

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

3.1.2.4
relative humidity
water vapour pressure, expressed as a percentage of the saturation vapour pressure, 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
the degree of closeness of measurements of a quantity to an accepted reference value

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 component.

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

Note 1 to entry: The definition provided has been amended from that in ISO 10524-x to remove the units of measure. Definition of a term to represent a concept but also to specify a unit of measure is deprecated as a potentially hidden requirement.

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

Note 1 to entry: Bias is the total systematic error as contrasted to random error. There can be one or more systematic error components contributing to the bias. A larger systematic difference from the accepted reference value is reflected by a larger bias 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
set of operations that establishes, under specified conditions, the relationship between values of quantities indicated by a measuring instrument, or measuring system, or values represented by a material measure or a reference material and the corresponding values realized by standards

3.1.3.5
calibration range
range of values over which a monitoring device or a control has been tested and calibrated

3.1.3.6
declared range
DEPRECATED: measurement range
that portion of the displayed range 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