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Anestezijska in dihalna oprema - Slovar (ISO 4135:2022)

Anaesthetic and respiratory equipment - Vocabulary (ISO 4135:2022)

Anästhesie und Beatmungsgeräte - Begriffe (ISO 4135:2022)

Matériel d'anesthésie et de réanimation respiratoire - Vocabulaire (ISO 4135:2022)

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Anaesthetic and respiratory equipment - Vocabulary (ISO 4135:2022)

Matériel d'anesthésie et de réanimation respiratoire - Vocabulaire (ISO 4135:2022)

Anästhesie und Beatmungsgeräte - Begriffe (ISO 4135:2022)

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CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (EN ISO 4135:2022) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment” the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by August 2022, and conflicting national standards shall be withdrawn at the latest by August 2022.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 4135:2001.

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The text of ISO 4135:2022 has been approved by CEN as EN ISO 4135:2022 without any modification.

INTERNATIONAL STANDARD

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Anaesthetic and respiratory equipment — Vocabulary

Anästhesie und Beatmungsgeräte — Begriffe

Matériel d'anesthésie et de réanimation respiratoire — Vocabulaire

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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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

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.

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.

The terms, names and acronyms listed in this document 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 document, 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 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 document 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

1 Scope

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

NOTE 1 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 2 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: 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 FiO_2 (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 an *anaesthetic vaporiser* (3.3.2.2), and it can also include the vapour generated by an *anaesthetic vaporiser*.

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 Liquid gases used for cryoablation.

EXAMPLE 2 Gases used to provide an anaerobic atmosphere.

EXAMPLE 3 Compressed air for hyperbaric chambers.

EXAMPLE 4 Driving gas for surgical tools.

EXAMPLE 5 Inflating gases for laparoscopy.