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BSI Standards Publication

Anaesthetic and respiratory equipment — Vocabulary

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National foreword

This British Standard is the UK implementation of EN ISO 4135:2022. It is identical to ISO 4135:2022. It supersedes BS EN ISO 4135:2001, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/121, Anaesthetic and respiratory equipment.

A list of organizations represented on this committee can be obtained on request to its committee manager.

The UK committee draws users' attention to informative National Annex NA, appended at the back of this document, which provides further guidance to assist users in the application of this standard.

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EUROPÄISCHE NORM

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English Version

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)

This European Standard was approved by CEN on 22 August 2021.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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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.

Any feedback and questions on this document should be directed to the users' national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

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

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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.

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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*.

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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