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de l'accréditation, de la sécurité et qualité
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ILNAS-EN ISO 4135:2022

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

Anästhesie- und Beatmungsgeräte -
Begriffe (ISO 4135:2022)

02/2022



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ILNAS-EN ISO 4135:2022

EUROPEAN STANDARD **EN ISO 4135**

NORME EUROPÉENNE

EUROPÄISCHE NORM

February 2022

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Supersedes EN ISO 4135:2001

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)

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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of an identical text or by endorsement, at the latest by August 2022, and conflicting national standards shall be withdrawn at the latest by August 2022.

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NORME EUROPÉENNE ^{ILNAS-EN ISO 4135:2022} **EN ISO 4135**
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**Matériel d'anesthésie et de réanimation respiratoire -
Vocabulaire (ISO 4135:2022)**

Anästhesie und Beatmungsgeräte - Begriffe (ISO
4135:2022)

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

La présente Norme européenne a été adoptée par le CEN le 22 août 2021.

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Avant-propos européen

Le présent document (EN ISO 4135:2022) a été élaboré par le Comité Technique ISO/TC 121 « Matériel d'anesthésie et de réanimation respiratoire » en collaboration avec le Comité Technique CEN/TC 215 « Équipement respiratoire et anesthésique » dont le secrétariat est tenu par BSI.

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ILNAS-EN ISO 4135:2022

EUROPÄISCHE NORM **EN ISO 4135**

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Anästhesie- und Beatmungsgeräte - Begriffe (ISO 4135:2022)

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

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

Diese Europäische Norm wurde vom CEN am 22. August 2021 angenommen.

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Europäisches Vorwort

Dieses Dokument (EN ISO 4135:2022) wurde vom Technischen Komitee ISO/TC 121 „Anaesthetic and respiratory equipment“ in Zusammenarbeit mit dem Technischen Komitee CEN/TC 215 „Beatmungs- und Anästhesiegeräte“ erarbeitet, dessen Sekretariat von BSI gehalten wird.

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Anerkennungsnotiz

Der Text von ISO 4135:2022 wurde von CEN als EN ISO 4135:2022 ohne irgendeine Abänderung genehmigt.

**Anaesthetic and respiratory
equipment — Vocabulary**

**Matériel d'anesthésie et de
réanimation respiratoire —
Vocabulaire**

**Anästhesie und Beatmungsgeräte —
Begriffe**



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CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
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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).

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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*.