

This is a preview of "ISO 19223:2019". [Click here to purchase the full version from the ANSI store.](#)

First edition
2019-07

Lung ventilators and related equipment — Vocabulary and semantics

*Ventilateurs pulmonaires et équipement associé — Vocabulaire et
sémantique*



Reference number
ISO 19223:2019(E)

© ISO 2019

This is a preview of "ISO 19223:2019". [Click here to purchase the full version from the ANSI store.](#)



COPYRIGHT PROTECTED DOCUMENT

© ISO 2019

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

This is a preview of "ISO 19223:2019". [Click here to purchase the full version from the ANSI store.](#)

Contents

	Page
Foreword	iv
Introduction	v
1 * Scope	1
2 Normative references	1
3 * Terms, definitions, symbols, and abbreviated terms	1
3.1 General artificial-ventilation terminology.....	2
3.2 Breath terminology.....	9
3.3 Lung inflation terminology.....	13
3.4 * Time, phase and cycle terminology.....	18
3.5 * Rate terminology.....	23
3.5.1 Preferred rate concepts.....	23
3.5.2 Secondary rate concepts — Rate terms for use if required for specific purposes.....	25
3.6 Pressure terminology.....	26
3.7 Flow terminology.....	30
3.8 Volume terminology.....	34
3.9 Initiation and termination terminology.....	38
3.10 * Baseline and PEEP terminology.....	43
3.11 * Mode terminology.....	48
3.12 * Bi-level terminology.....	60
3.13 Safety limits and alarm terminology.....	64
3.14 Gas port terminology.....	67
Annex A (informative) Rationales and guidance	69
Annex B (informative) Conceptual relationships between ventilator actions and types of breath	75
Annex C (informative) Illustrations of ventilation terms	77
Annex D (informative) Classification of inflation-types	109
Annex E (informative) Classification of ventilation-modes	114
Annex F (informative) Concepts relating to baseline airway pressures and PEEP as used in this document	116
Annex G (informative) Conventions followed in this document	125
Annex H (informative) Implementation guidance for the vocabulary of this document	127
Annex I (informative) Equivalence declaration tables	129
Annex J (informative) Terminology — Alphabetized index of defined terms	132
Bibliography	139

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*.

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.

This is a preview of "ISO 19223:2019". [Click here to purchase the full version from the ANSI store.](#)

Introduction

The characteristics of *ventilation-modes* of current automatic *lung ventilators* are often not well understood. The current terminology used for their description is based on that introduced in the early days of *mechanical ventilation*, but with the advances in *ventilators*, and *ventilation-modes* that have evolved over recent years, the language used has been continuously adapted. In the absence of any effective international coordinating action, this has inevitably led to increasing inconsistencies in the way in which well-established terms and their derivatives are used.

To further compound the difficulties in understanding these complexities, some *ventilator manufacturers* have created new proprietary terms to describe these alternative ways of *ventilating patients*, and others have used existing terms with different meanings in different situations. This has led to *patient safety hazards*, an example being that *lung ventilator clinical orders (settings)* for one model of *ventilator* can be quite different from those required to get the same result from a different *ventilator*.

Recognizing these difficulties, ISO Technical Committee ISO/TC 121 requested its Subcommittee, SC 4, to completely review the terminology and semantics for *patient ventilation* with a view to compiling a standardized vocabulary that is applicable to current and, as far as possible, future practice. The primary objective was to use as much existing terminology as possible, while clarifying its meaning and limiting its potential for misuse by defining it more precisely. New terms were only introduced where there was no alternative, either in order to name new concepts or where the misuse of existing vocabulary has become so widespread that the term has become meaningless or unacceptably ambiguous. Importance was placed on a vocabulary that would communicate a clear mental model of how the selected *settings* would determine the interaction between the *patient* and the *ventilator*.

In order to achieve a vocabulary that is coherent, consistent and applicable to a range of fields such as *patient care*, research, data collection and incident reporting, this document has been developed with the participation, cooperation and assistance of members of other standards development organizations, and of major international *ventilator manufacturers*. The applications include *lung ventilators*, medical data systems facilitating clinical care and research, interoperability, incident reporting and equipment maintenance.

The early work by the subcommittee in establishing how a standardized vocabulary should be structured increasingly led to the conclusion that it would be necessary to revert to first principles. It was recognized that much of the current terminology has its origins in the early use of *automatic ventilation*, when the emphasis was inevitably on how best to save the lives of *patients* who could not *breathe* for themselves and, consequently, only made basic provisions for the *patient's own respiratory activity*. Since that time, *ventilators* have become increasingly interactive with the *patient*, such that it is now necessary to consider their use from a *ventilator-patient* system perspective because it is no longer possible, with any certainty, to predict ahead of time how that interaction will take place.

The terminology in this document is defined and used in a way that makes it capable of facilitating, unambiguously, both the *setting* of a *ventilator* and how to describe and record the resultant *ventilator-patient* interactions, continuously and at defined points within the course of *ventilation*. This includes the result of the complex interactions that occur when *additional breaths* are taken during an *assured-inflation cycle*, as can occur, for example, during APRV (*airway pressure release ventilation*).

This document seeks both to provide a consensus view and the basis for a coherent language for describing *ventilator* function. Now that the fundamental concepts of *artificial ventilation* practice within the scope of this document have matured, it has been possible to review the boundaries between the various concepts of established *ventilation-modes* and the methods of artificially inflating a *patient's lungs* and to formulate definitions that clarify the common elements and the distinctions. In particular, the scopes of several concepts that were appropriate to earlier technology and practice have become inadequate to encompass new developments and it was found necessary to subdivide them. Some of their designating terms have, therefore, had to be deprecated, replaced or constrained using more restrictive definitions, resulting in an inevitable reintroduction of some little-used legacy terms and the need to create a few new terms.

This is a preview of "ISO 19223:2019". [Click here to purchase the full version from the ANSI store.](#)

The overall objective is to encourage a more disciplined use of *ventilator* vocabulary so that *operators* trained in the application of this document will be able to move easily from one *ventilator* to another and operate each one, with confidence, after a minimum amount of training. Although it is recognized that change will not be immediate, it is expected that this discipline will feed through into scientific publications, textbooks and training so that, over time, a standardized basic language of *artificial ventilation* will become internationally established.

Examples of the application of this document are illustrated in the figures of [Annexes C](#) and [F](#) but these are not intended to indicate a requirement, nor to impose any restriction on the design of *artificial ventilation* devices.

Included with many of the terms are notes to entry that provide supplementary information, including explanations of the semantics of the term along with their classification schemes. This format is not only a requirement of ISO 704 but, unlike with such information in an annex, ensures that it remains associated with the term when viewed on the free-to-access ISO Online Browsing Platform.

Some of the terms in this document are principally intended for technical documents, informatics and related applications, and might have little applicability to *ventilator* labelling and instructions for use.

In this document, the following print types are used:

Definitions: roman type.

Material appearing outside of tables, such as notes, examples and references: smaller type.

Terms defined in [Clause 3](#) of this document or as noted, apart from those in the form of acronyms or initialisms or when used in headings or tables: *italic* type.

In this document, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this document conform to the usage described in ISO/IEC Directives, Part 2, [Annex H](#). For the purposes of this document, the auxiliary verb

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this document,
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document, and
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in [Annex A](#).

Colour coding is employed in most of the figures in [Annexes B](#), [C](#) and [F](#) of this document to help distinguish between some of the specific characteristics being illustrated. The coding used for each figure, or set of figures, is provided either in its own specific key or in the introductory text of each annex, as applicable.

NOTE The following figures and tables have been reproduced from Reference [\[34\]](#) with permission:

- Figures: [B.1](#), [C.1](#) to [C.35](#) and [F.1](#) to [F.7](#);
- Tables: [D.1](#) to [D.3](#), [E.1](#) and [E.2](#).