Classifying Ventilation Modes and Improving Operator Training with ISO 19223:2019

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The Centers for Disease Control and Prevention has reported that more than 300,000 patients are ventilated in the United States each year.\(^1\) Human factors and communication issues have been cited as the two most common causes of ventilator-related sentinel events, according to reports of patient mortality or severe harm received by The Joint Commission during 2004–15.\(^2,3\)

Over a decade ago, it was determined that the scope of the International Electrotechnical Commission (IEC) standard IEC 60601-1:2005\(^4\) had to be extended to consider equipment usability in its third edition. The Joint Working Group (JWG) of the International Organization for Standardization (ISO) and IEC subcommittees responsible for critical care ventilators (ISO/TC 121/SC 3 and IEC TC/SC 62D/JWG 1) concurred that there was a wide recognition that a key factor adversely affecting lung ventilator usability was the lack of a standardized vocabulary relating to the modes of operation for these devices.

At that time, ISO 4135:2001\(^5\) was the only international standard that included terms related to devices of that type; however, its scope was restricted to defining terms that were used in standards related to the performance of such equipment and therefore did not cover usage factors. The terms in general clinical use had origins in the early days of mechanical ventilation, when the emphasis was on saving the lives of patients who were unable to breathe on their own, with little attention given to patients’ respiratory activity.

Approach to the Challenge

Although ventilators were being continuously improved and becoming progressively more patient interactive, the associated terminology had only become increasingly confusing. Proprietary terms describing alternative means of ventilating patients had been introduced by some manufacturers, and existing terms were used inconsistently. One effect was that clinical orders comprising ventilator settings for one model of ventilator could produce a very different result when applied to another.

Chatburn and colleagues drew attention to the challenges faced by clinicians, educators, and others resulting from the lack of a coherent vocabulary, including difficulty in comparing published studies or reports of clinical trials and a lack of consistency among education programs.\(^6,7\)

When different manufacturers supplied ventilators to the same institution, training resources often were inadequate for all modes of all ventilator brands. From the point of view of manufacturers, it was increasingly difficult to compare the detailed operation of their products with competitors’ devices and adequately educate their sales force and training staff.\(^7,8\)

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**Key Takeaways**

- Confusing, inconsistent terminology associated with different manufacturers’ ventilators has adversely affected lung ventilator usability, challenged healthcare facilities in training clinicians adequately, and made it difficult for manufacturers to compare the detailed operation of their products with competitors’ devices.
- A new International Organization for Standardization (ISO) standard, ISO 19223:2019 (Lung Ventilators and related equipment—Vocabulary and semantics), defines and describes the use of ventilator terminology in a manner that will facilitate the setting of a ventilator and the description and recording of ventilator-patient interactions, without ambiguity, both continuously and at specific points during ventilation.
- A key feature of ISO 19223 is the introduction of ventilation-mode groups, which are “groups of ventilation-modes that share fundamental features with respect to the characteristics of their ventilation-patterns.” This system provides a useful primary classification means for the large number of mode names used by manufacturers.
ISO-IEC JWG 1 agreed that its approach to the problem should be on devising the best means of communicating a rational, functional terminology structure of how the selected settings would determine the interaction between the patient and ventilator. It requested that an initial discussion document be prepared, and in February 2007, a small group of experts (led by Dr. Norman Jones) began preparing a suitable terminological entry for the pending revision of IEC 60601-2-12:2001.\(^9\) (Note: This publication was superseded by ISO 80601-2-12:2011,\(^9\) which currently is in the final stages of a further revision.)

**Development of a Unique International Standard**

In 2008, ISO TC 121/SC 4 (Anaesthetic and Respiratory Equipment—Vocabulary and semantics), which had been responsible for ISO 4135 but dormant for several years, was reactivated. By this time, it had also become clear that the scope of the work on ventilation terminology needed to extend beyond its application to critical care ventilators, to the extent that the production of a separate standard was justified.

Therefore, it was agreed that the working group responsible for this work should be under the purview of ISO/TC 121/Subcommittee (SC) 4 with the objectives of compiling a standardized vocabulary applicable to all types of ventilators, as well as clarifying existing terminology and its use. This new international standard was given the designation ISO 19223.\(^11\) The intent was that the standard would update and replace the ventilator terminology included in ISO 4135:2001,\(^5\) with that standard then undergoing revision as a distinct work item.

SC 4 involved additional experts in its work and established a comprehensive concept system that made extensive use of diagrammatic tools to clearly identify the relationships among various ventilation patterns and the means used to artificially inflate patients’ lungs. This was used as the basis for creating definitions that clarify both common elements and distinctions. The process included extensive review of the scientific and medical literature, manufacturers’ ventilator manuals and literature used to market these devices, and the Food and Drug Administration’s (FDA’s) Manufacturer and User Facility Device Experience (MAUDE) database.\(^12\) The project involved the participation of anesthesiologists, intensive care physicians, respiratory therapists, and educators, as well as information technology, research and development, marketing, and training experts from the lung ventilation industry.

Multiple SC 4 meetings held over the following decade were characterized by scholarly and thoughtful consideration of semantic detail, with the goal of improving the accuracy and consistency of the vocabulary. Terms such as *breath*, *breathe*, *inflation*, *set rate*, *assured inflation*, and *PEEP* (positive end-expiratory pressure) were discussed at length. (Note: From this paragraph forward, terms specifically defined in ISO 19223 appear in italics.) These discussions benefited greatly from a landmark publication in 2012 by Morley and Keszler.\(^13\) Recognition of the importance of this project increased as it progressed, and the development and implementation of a standardized terminology for ventilator technology was identified as a primary concern during the 2014 Association for the Advancement of Medical Instrumentation/FDA Summit on Ventilator Technology.\(^14\)

Published in July 2019, ISO 19223 serves as the outcome of this extensive work. The standard defines and describes the use of ventilator terminology in a manner that will facilitate the setting of a *ventilator* and the description and recording of *ventilator*-patient interactions, without ambiguity, both continuously and at specific points during *ventilation*. Basic concepts such as *baseline airway pressure*, *mandatory*, and *spontaneous breath* are defined clearly. It is expected that the user or operator, when familiar with the application of this new standard, will make the transition from one *ventilator* to another with greater ease and confidence.

As it is formulated according to the requirements of ISO 704\(^15\) and ISO 10241-1,\(^16\) ISO 19223 (when appropriate) includes useful notes to aid in the use of defined terms. These provide immediately accessible supplementary information, not only to the reader of the standard but also to those accessing individual entries on the open-access ISO Online Browsing Platform.\(^17\)
Structure
ISO 19223 is divided into the following sections, according to semantic categories: general artificial-ventilation; breath; lung inflation; time, phase, and cycle; rate; pressure; flow; volume; initiation and termination; baseline and PEEP; mode; bi-level; safety limits and alarms; and gas ports. The standard also includes an informative rationale and guidance annex (Annex A) explaining the mental model of ventilation used as the basis for the standard, nine additional informative annexes (Table 1), and a bibliography.

Mode Terminology
ISO 19223 defines a *ventilation-mode* as the “specified manner in which a ventilator performs its ventilatory function when connected to a patient” (3.11.2). For each *ventilation-mode*, two key characteristics apply: (1) the method used to contribute to, or control, the *inflation* of the patient’s lungs and (2) the pattern with which these contributions occur, based on time intervals or the patient’s own *respiratory activity*. ISO 19223 defines these characteristics separately as *inflation-type* and *ventilation-pattern*, respectively.

Toward the end of the last century, developments in controls and sensors enabled the introduction of adult ventilators with built-in characteristics that enable a patient to make both unrestricted *expirations* and *inspirations* at any time, even during an *inflation* at a constant pressure level. Such a feature, formerly restricted to infant ventilators and unidentified by any specific name, has now been formally designated as an ACAP adjunct. (ACAP stands for “assured constant airway pressure.”)

A key feature of ISO 19223 is the introduction of *ventilation-mode groups* (3.11.5), which are “groups of *ventilation-modes* that share fundamental features with respect to the characteristics of their *ventilation-patterns*” (Table 2). This system was originally introduced in the early stages of the development of the standard as a means of creating a primary classification of the large number of mode names used by manufacturers. As a result of this method being considered a highly useful method of presentation to those being introduced to the concepts adopted in the standard, it was included as the top level of classification. Although manufacturers are not required to refer to these groups in product labeling, if a reference is made, it must be consistent with ISO 19223.

Education and Future Progress
ISO 19223 is expected to enable clinicians, educators, and manufacturers to improve and standardize training, communications, and protocols for patients in institutional, institutional...

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**Table 1.** Informative annexes to ISO 19223: 2019. Abbreviations used: ACAP, assured constant airway pressure; PEEP, positive end-expiratory pressure.
Table 2. Ventilation-mode groups in ISO 19223:2019. Abbreviations used: A/C, assist/control ventilation; BAP, baseline airway pressure; CMV, continuous mandatory ventilation; CPAP, continuous positive airway pressure; CSV, continuous spontaneous ventilation; IMV, intermittent mandatory ventilation; SIMV, synchronized intermittent mandatory ventilation.

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<td>Group 1</td>
<td>One inflation-type can be selected at a time.</td>
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<td>Group 1a</td>
<td>No provision for the selected inflation-type to be initiated by a patient-trigger event (e.g., CMV mode).</td>
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<tr>
<td>Group 1b</td>
<td>Selected inflation-type is assured to be initiated at successive intervals determined by the set rate if not initiated within such an interval by a patient-trigger event (e.g., A/C mode).</td>
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<tr>
<td>Group 2</td>
<td>An inflation-type is selected to be initiated at the set rate, with spontaneous breathing possible between assured inflations (either unassisted or supported by a selected inflation-type).</td>
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<tr>
<td>Group 2a</td>
<td>No provision for the assured inflations to be initiated by a patient-trigger event (e.g., IMV mode).</td>
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<tr>
<td>Group 2b</td>
<td>The initiation of each assured inflation is synchronized with any spontaneous breathing while maintaining the set rate (e.g., SIMV mode).</td>
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<td>Group 3</td>
<td>Each patient-trigger event initiates a selected inflation-type; where a patient-trigger event does not occur within a set time interval, the ventilator initiates a second selected inflation-type.</td>
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<td>Group 4</td>
<td>Ventilation-patterns enable continuous unrestricted breathing or continuous supported breathing, with constant baseline air pressure at the set BAP level.</td>
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<td>Group 4a</td>
<td>Group 4 ventilation-modes with a provision to support each inspiratory activity exceeding a threshold level (e.g., CSV mode).</td>
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<tr>
<td>Group 4b</td>
<td>Group 4 ventilation-modes with no provision to support any inspiratory activity (e.g., CPAP ventilation-mode).</td>
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References


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