

BUREAU OF INDIAN STANDARDS

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भारतीय मानक मसौदा
फेफड़े के वेंटिलेटर और संबंधित उपकरण - शब्दावली और शब्दार्थ

Draft Indian Standard

Lung ventilators and related equipment — Vocabulary and semantics

ICS: 01.040.11, 11.040.10

Anaesthetic, Resuscitation and Allied
Equipment Sectional Committee, MHD-11

Last date for comments 24 August 2024

NATIONAL FOREWORD

(Adoption clause will be added later)

The text of ISO Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are however not identical to those used in Indian Standards. Attention is particularly drawn to the following:

- a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'
- b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test shall be rounded off in accordance with IS 2: 2022 'Rules for rounding off numerical values (revised)'.

This standard also makes a reference to the BIS Certification Marking of the product. Details of which is given in National Annex A.

NATIONAL ANNEX A
(National Foreword)

A-1 BIS CERTIFICATION MARKING

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the BIS Act, 2016 and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.

The technical content of the document has not been enclosed as it is identical with the corresponding ISO standard. For details, please refer to **ISO 19223:2019** or kindly contact:

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SCOPE

This document establishes a vocabulary of terms and semantics for all fields of respiratory care involving *mechanical ventilation*, such as intensive-care *ventilation*, anaesthesia *ventilation*, emergency

and transport *ventilation* and home-care *ventilation*, including *sleep-apnoea breathing-therapy equipment*. It is applicable

- in *lung ventilator* and *breathing-therapy* device standards,
- in health informatics standards,
- for labelling on *medical electrical equipment* and *medical electrical systems*,
- in *medical electrical equipment* and *medical electrical system* instructions for use and *accompanying documents*,
- for *medical electrical equipment* and *medical electrical systems* interoperability, and
- in electronic health records.

This document is also applicable to those accessories intended by their *manufacturer* to be connected to

a *ventilator breathing system* or to a *ventilator*, where the characteristics of those accessories can affect

the basic safety or essential performance of the *ventilator* and *ventilator breathing system*.

NOTE This document can also be used for other applications relating to *lung ventilation*, including nonelectrical

devices and equipment, research, description of critical events, forensic analysis and adverse event

(vigilance) reporting systems.

This document does not specify terms specific to *breathing-therapy* equipment, or to physiologic closedloop

ventilation, high-frequency *ventilation* or *negative-pressure ventilation*; nor to respiratory support

using liquid *ventilation* or extra-corporeal gas exchange, or oxygen, except where it has been considered

necessary to establish boundaries between bordering concepts.