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Introduction

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Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/ Figure/Table/Note	Type of comment	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	



DRAFT International Standard

ISO/DIS 19223-3

Lung ventilators and related equipment — Vocabulary and semantics —

Part 3: Respiratory care

ICS: 11.040.10; 01.040.11

ISO/TC 121/SC 4

Secretariat: **ANSI**

Voting begins on:
2024-12-24

Voting terminates on:
2025-03-18

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36 **Foreword**

37 ISO (the International Organization for Standardization) is a worldwide federation of national standards
 38 bodies (ISO member bodies). The work of preparing International Standards is normally carried out
 39 through ISO technical committees. Each member body interested in a subject for which a technical
 40 committee has been established has the right to be represented on that committee. International
 41 organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO
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 43 electrotechnical standardization.

44 The procedures used to develop this document and those intended for its further maintenance are
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 46 different types of ISO documents should be noted. This document was drafted in accordance with the
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57 For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and
 58 expressions related to conformity assessment, as well as information about ISO's adherence to the
 59 World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see
 60 www.iso.org/iso/foreword.html.

61 This document was prepared by Technical Committee ISO/TC121, *Anaesthetic and respiratory*
 62 *equipment, Subcommittee SC4, Vocabulary and semantics, Working Group 3, Respiratory care equipment.*

63 A list of all parts in the ISO 19223 series can be found on the ISO website.

64 Any feedback or questions on this document should be directed to the user's national standards body.
 65 A complete listing of these bodies can be found at www.iso.org/members.html.

66 Introduction

67 In 2019, ISO Technical Committee 121 Subcommittee 4 published the first edition of ISO 19223, Lung
68 ventilators and related equipment—Vocabulary and semantics. ISO Technical Committee 121
69 Subcommittee 4's Working Group 1 published the fifth edition of ISO 4135, Anaesthetic and
70 respiratory equipment—Vocabulary in 2022.

71 The Subcommittee recognized that these new standards did not adequately address vocabulary and
72 semantics for high-frequency and jet lung ventilation or some aspects of respiratory therapy
73 equipment. The Subcommittee resolved during its July 2022 meeting to establish two new SC4
74 Working Groups to undertake development of these specialized vocabularies as additional parts of
75 ISO 19223. The second edition of ISO 19223, Lung ventilators and related equipment—Vocabulary
76 and semantics, would subsequently be published as ISO 19223-1. Subcommittee 4 Working Group 2
77 was established to develop a standard for high-frequency and jet ventilation terminology and
78 Subcommittee 4 Working Group 3 was established to address high flow respiratory therapy, sleep
79 apnoea breathing therapy, as well as other aspects of respiratory care.

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

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

86 In this document, the following print types are used:

87 Definitions: roman type.

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

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

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

93 The verbal forms used in this document conform to the usage described in ISO/IEC Directives, Part 2,
94 Annex H. For the purposes of this document, the auxiliary verb

95 — “shall” means that compliance with a requirement or a test is mandatory for compliance with this
96 document,

97 — “should” means that compliance with a requirement or a test is recommended but is not mandatory
98 for compliance with this document, and

99 — “may” is used to describe a permissible way to achieve compliance with a requirement or test.

100 — “can” means that a given possibility or ability exists.

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

103

104

Lung ventilators and related equipment—Vocabulary and semantics—Part 3: Respiratory care

1 Scope

This document establishes a vocabulary of terms and semantics for respiratory care not addressed in sufficient detail by ISO 19223:2019 or ISO 4135:2022.

It is applicable

- in respiratory high-flow therapy equipment standards
- in sleep apnoea breathing therapy equipment standards
- in sleep apnoea therapy masks and accessories standards
- in ventilatory support equipment 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 excludes mechanical ventilation (defined in ISO 19223:2019), high-frequency and jet ventilation (defined in ISO 19223-2:XXXX), negative pressure ventilation, liquid ventilation, and extracorporeal membrane oxygenation.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4153:2022, ISO 19223:2019, ISO 19223-2:XXXX and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

3.1 General terms

3.1.1

co-therapy

inhalational therapy using a short-acting bronchodilator medication as needed, ancillary to, or in combination with a long-acting bronchodilator drug