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## Contents

<b>Foreword</b> .....	<b>3</b>
<b>Introduction</b> .....	<b>4</b>
<b>1 Scope</b> .....	<b>5</b>
<b>2 Normative references</b> .....	<b>5</b>
<b>3 Terms and definitions</b> .....	<b>6</b>
<b>4 General requirements</b> .....	<b>8</b>
<b>4.1 General</b> .....	<b>8</b>
<b>4.2 Test methods</b> .....	<b>8</b>
<b>4.3 Recommended service life</b> .....	<b>8</b>
<b>5 Materials</b> .....	<b>8</b>
<b>5.1 General</b> .....	<b>8</b>
<b>5.2 *Biological safety testing</b> .....	<b>8</b>
<b>6 Design requirements</b> .....	<b>8</b>
<b>6.1 General</b> .....	<b>8</b>
<b>6.2 Designated length</b> .....	<b>8</b>
<b>6.3 Means of connection</b> .....	<b>9</b>
<b>6.4 Leakage</b> .....	<b>10</b>
<b>6.5 Resistance to flow</b> .....	<b>10</b>
<b>6.6 Compliance</b> .....	<b>11</b>
<b>6.7 *Prevention of electrostatic charges</b> .....	<b>12</b>
<b>7 Requirements for <i>breathing sets</i> and <i>breathing tubes</i> supplied sterile</b> .....	<b>12</b>
<b>8 Packaging</b> .....	<b>12</b>
<b>9 Information supplied by the manufacturer</b> .....	<b>12</b>
<b>9.1 General</b> .....	<b>12</b>
<b>9.2 Marking on the packaging</b> .....	<b>12</b>
<b>9.3 Instructions for use</b> .....	<b>13</b>
<b>Annex A (informative) Rationale</b> .....	<b>15</b>

ISO/FDIS 5367:2022(E)

<b>Annex B (informative) Hazard identification for risk management .....</b>	<b>24</b>
<b>Annex C (normative) Test for security of attachment of <i>plain end</i> to conical connector .....</b>	<b>25</b>
<b>Annex D (normative) Test for security of attachment of <i>adaptor</i> to <i>breathing tube</i> .....</b>	<b>26</b>
<b>Annex E (normative) Test for leakage .....</b>	<b>27</b>
<b>Annex F (normative) Measurement of resistance to flow .....</b>	<b>29</b>
<b>Annex G (normative) Test for increase in flow resistance with bending .....</b>	<b>32</b>
<b>Annex H (normative) Test for <i>compliance</i> .....</b>	<b>34</b>
<b>Bibliography .....</b>	<b>36</b>

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<b>Foreword</b> .....	vii
<b>Introduction</b> .....	ix
<b>1 Scope</b> .....	1
<b>2 Normative references</b> .....	1
<b>3 Terms and definitions</b> .....	1
<b>4 General requirements</b> .....	3
<b>4.1 General</b> .....	3
<b>4.2 Recommended service life</b> .....	3
<b>5 Materials</b> .....	4
<b>5.1 General</b> .....	4
<b>5.2 Biological safety testing</b> .....	4
<b>6 Design requirements</b> .....	4
<b>6.1 General</b> .....	4
<b>6.2 Designated length</b> .....	4
<b>6.3 Breathing tube ends</b> .....	4
<b>6.4 Leakage</b> .....	6
<b>6.5 Resistance to flow</b> .....	6
<b>6.6 Compliance</b> .....	7
<b>6.7 Axial strength of breathing tubes</b> .....	8
<b>7 Requirements for <i>breathing sets</i> and <i>breathing tubes</i> supplied sterile</b> .....	8
<b>8 Packaging</b> .....	8
<b>9 Information supplied by the manufacturer</b> .....	8
<b>9.1 General</b> .....	8
<b>9.2 Marking on the packaging</b> .....	8
<b>9.3 Instructions for use</b> .....	9
<b>Annex A (informative) Rationale</b> .....	11
<b>Annex B (informative) Hazard identification for risk management</b> .....	19
<b>Annex C (normative) Test for security of attachment of <i>plain end</i> to conical connector</b> .....	20

ISO/FDIS 5367:2022(E)

<b><u>Annex D (normative) Test for security of attachment of assembled ends and axial strength of breathing tubes .....</u></b>	<b><u>21</u></b>
<b><u>Annex E (normative) Test for leakage .....</u></b>	<b><u>22</u></b>
<b><u>Annex F (normative) Measurement of resistance to flow .....</u></b>	<b><u>24</u></b>
<b><u>Annex G (normative) Test for increase in flow resistance with bending.....</u></b>	<b><u>27</u></b>
<b><u>Annex H (normative) Test for compliance.....</u></b>	<b><u>29</u></b>
<b><u>Bibliography.....</u></b>	<b><u>31</u></b>

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ISO 5367

<https://standards.iteh.ai/catalog/standards/sist/54cacd42-b717-4093-9e5b-713ceda6635d/iso-5367>

## 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](http://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](http://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](http://www.iso.org/iso/foreword.html).

This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment* Subcommittee SC 2, *Airways and related equipment*, 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 sixth edition cancels and replaces the fifth edition (ISO 5367:2014), which has been technically revised.

The main changes compared to the previous edition are as follows:

- the layout now follows the format of ISO 18190:2016 *General standard for airways and related equipment*;
- the general requirements such as risk management, usability, clinical investigation and some common marking requirements have been removed as they are now in ISO 18190 and cross-referenced in the appropriate clauses of this document;
- the list of normative references, many of which are cited in ISO 18190, has been updated;
- requirements for hose systems for neonatal applications were added (e.g. the 11,5 mm conical connector according to ISO 5356-1).

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](http://www.iso.org/members.html).

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## Introduction

This document contains requirements for *breathing sets*, *breathing tubes* and connectors that are intended to function as accessories to anaesthetic and respiratory equipment. *Breathing sets* and *breathing tubes* are characterized by certain design requirements such as a means of connection and leakage limits. Disclosure requirements for conformance and flow resistance values allow the user to make an informed choice when connecting these accessories to a breathing system. These design requirements are intended to allow operation within the limits of performance of the *anaesthetic breathing systems* and *ventilator breathing systems* with which the accessories are intended to operate.

This document includes requirements for both single-use and reusable *breathing sets* and *breathing tubes*. Reusable *breathing sets* and *breathing tubes* are intended to ~~comply with~~ conform to the requirements of this document for the recommended service life.

**NOTE 1** Examples of various types of *breathing sets* with *patient end adaptors* are depicted in Annex A.

This document is not applicable to *breathing sets* and *breathing tubes* that are intended to be used only for special purposes.

EXAMPLE 1 Ventilators having special *compliance*, pressure or breathing frequency requirements.

EXAMPLE 2 ~~— Patient Interface adapters with special connectors for neonatal ventilation, that are not interfacing to a Tracheal tube.~~

Requirements for breathing system components such as exhalation valves, exhaust valves, *adjustable pressure-limiting (APL) valves*, heat and moisture exchangers (HMEs), breathing filters, and reservoir bags, are not covered by this document but can be found in ISO 80601-2-12, ISO 80601-2-13, ISO 9360-1<sup>[2]</sup>, ISO 23328-2<sup>[3]</sup> and ISO 5362<sup>[4]</sup>. Requirements for heated *breathing tubes* can be found in ISO 80601-2-74<sup>[4]</sup>.

Certain tests are performed under constant pressure to simplify the test methodology. It is recognized that this does not reflect clinical use, where pressure is intermittent and peak pressures occur for short periods. The limits in the test methods take this into account. While such test methods do not address product variability, the limits required do take this into account.

Throughout this document, all pressures are denoted in SI units of hPa with corresponding cmH<sub>2</sub>O equivalent values rounded to the nearest whole cmH<sub>2</sub>O.

**NOTE** ~~The unit cmH<sub>2</sub>O is not an SI notation and is not used in ISO documents; rounded~~ **NOTE 2 Rounded** cmH<sub>2</sub>O values are given for information only to allow comparison to medical literature and related breathing system standards.

This document is written following the format of ISO 18190, ~~which is the general~~ **General** standard for airways and related equipment. The requirements in this device-specific standard take precedence over any conflicting requirements in ~~the general standard~~ **ISO 18190**.

Throughout this document the following print types are used:

- requirements and definitions: roman type;
- informative material appearing outside of tables, such as notes, examples and references: smaller type. The normative text of tables is also in smaller type;
- terms defined in Clause 3: italics.

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# Anaesthetic and respiratory equipment - Breathing sets and connectors

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## 1 Scope

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This document specifies minimum requirements for *breathing sets* and *breathing tubes* intended to be used with *anaesthetic breathing systems*, *ventilator breathing systems*, humidifiers or nebulizers. It applies to *breathing sets* and *breathing tubes* and *patient end adaptors* supplied already assembled and to those supplied as components and assembled in accordance with the manufacturer's instructions.

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This document is applicable to *breathing sets* which include special components (e.g., water traps) between the *patient end* and *machine end*.

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Provision is made for coaxial and related bifurcated, double-lumen, or multiple-lumen *breathing sets* and *breathing tubes* suitable for use with *patient end adaptors*.

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## 2 Normative references

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The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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ISO 4135, *Anaesthetic and respiratory equipment — Vocabulary*

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ISO 5356-1, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*

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ISO 18190:2016, *Anaesthetic and respiratory equipment — General requirements for airways and related equipment*

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## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4135 and the following apply.

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— ISO Online browsing platform: available at <https://www.iso.org/obp>

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— IEC Electropedia: available at <https://www.electropedia.org/>

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### 3.1

#### anaesthetic breathing system

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inspiratory and expiratory gas pathways through which anaesthetic gas flows at respiratory pressure between the fresh gas inlet, the patient connection port (3.9) and an exhaust valve or exhaust port

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[SOURCE: ISO 80601-2-13:2011, 201.3.203]

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### 3.3

#### APL valve

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**adjustable pressure-limiting valve**

pressure-limiting valve which releases gas over an adjustable range of pressures

[SOURCE: ISO 4135:2022, 3.6.3.5, modified]

**3.4**

**assembled end**

end of a *breathing tube* (3.6) incorporating an adaptor

**3.5**

**breathing set**

assembly of *breathing tubes*, (3.6) connectors and components that form the gas pathways of a *breathing system*

Note 1 to entry: Exhaust valves, APL valves, heat and moisture exchangers (HME), breathing system filters, nebulizers and reservoir bags are not included.

**3.6**

**breathing tube**

non-rigid tube used to convey gases and/or vapours between components of a breathing system

[SOURCE: ISO 4135:2001, 4.1.2]

**3.7**

**compliance**

volume added per unit pressure increase when gas is added to an enclosed space, expressed at the temperature and humidity of that enclosed space and at ambient atmospheric pressure

[SOURCE: ISO 4135:2001, 3.1.5]

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**3.8  
machine end**

end of the *breathing set* (3.5) or *breathing tube* (3.6) intended to be connected to the anaesthetic workstation, ventilator or other breathing system component furthest from the patient  
[SOURCE: ISO 4135:2001, 4.2.3.2, modified]

**3.9  
patient connection port**

opening intended for connection to an airway device  
EXAMPLES: e.g., tracheal or tracheostomy tube, face mask, supralaryngeal airway  
[SOURCE: ISO 4135:2001, 4.2.1.2, modified]

**3.10  
patient end**

end of the *breathing set* (3.5) or *breathing tube* (3.6) which is intended to be connected to the *patient end adaptor*, *Y piece* or other appropriate component near the patient

**3.11  
patient end adaptor**

tubular connector with multiple ports, one of which is a *patient connection port* (3.9)

Note 1 to entry: Examples of *patient end adaptors* include a Y-piece, a *swivel adaptor* (3.13) and other specialized adaptors for coaxial, multiple tubes, and bifurcated tubes. See also Annex A, Figures A.1 to A.5.

**3.12  
plain end**

end of a *breathing tube* (3.6) designed to fit directly over a male conical connector complying with conforming to ISO 5356-1

**3.13  
swivel adaptor**

specialized *adaptor* (3.1) which allows variation in the position of its ports relative to each other

**3.14  
ventilator breathing system**

inspiratory or expiratory gas pathways through which gas flows at respiratory pressures and bounded by the port through which fresh gas enters, the *patient connection port* (3.9) and the exhaust port  
[SOURCE: ISO 80601-2-12:2011, 201.3.221]

**4 General requirements**

**4.1 General**

The applicable requirements of ISO 18190:2016, Clause 4 shall apply.

NOTE An informative list of identified hazards is contained in Annex B.

**4.2 Recommended service life**

Re-usable *breathing sets* and *breathing tubes* shall comply with conform to the requirements of this document throughout the recommended service life as required in 9.3.4.

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