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**Anaesthetic and respiratory  
equipment — Breathing sets and  
connectors**

*Matériel d'anesthésie et de réanimation respiratoire — Systèmes  
respiratoires et raccords*

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## 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 on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: [Foreword - Supplementary information](#)

The committee responsible for this document is ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Airways and related equipment*.

This fifth edition cancels and replaces the fourth edition (ISO 5367:2000), which has been technically revised.

The following major changes were made:

- title and scope;
- additional normative references;
- additional terms and definitions;
- additional general requirements, including risk management, usability, clinical and biophysical research;
- requirements for coaxial tubing, revised leakage limits, and testing for flow resistance and compliance;
- revised limits for prevention of electrostatic charges;
- revised requirements for marking of packaging, including the use of symbols, disclosure of intended patient category, flow resistance and compliance;
- added an annex for rationale;
- added an annex for hazard identification for risk assessment;
- revised test method annexes for resistance to flow, security of attachments, leakage and compliance;
- added an annex for compliance with the EU Directives.

## Introduction

This International Standard 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 **compliance** 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 International Standard includes requirements for both single-use and reusable **breathing sets** and **breathing tubes**. Re-usable **breathing sets and breathing tubes** are intended to comply with the requirements of this International Standard for the recommended service life.

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 also take this into account.

Terms defined in this International Standard are set in **bold type**.

Throughout this International Standard, text for which a rationale is provided in [Annex A](#) is indicated by an asterisk (\*).

Throughout this International Standard, 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 cmH<sub>2</sub>O values are given for information only to allow comparison to medical literature and related **breathing system** standards.

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# Anaesthetic and respiratory equipment — Breathing sets and connectors

## 1 Scope

\*This International Standard specifies basic 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.

This International Standard is applicable to **breathing sets** which include special components (e.g. water traps) between the **patient end** and **machine end** which are supplied already assembled.

This International Standard is not applicable to **breathing sets** and **breathing tubes** for special purposes.

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

EXAMPLE 2 High Frequency Oscillatory Ventilation, (HFOV) or High Frequency Jet Ventilation (HFJV).

EXAMPLE 3 **Breathing sets and breathing tubes** with special connectors for neonatal ventilation.

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**.

NOTE 1 Examples of various types of **breathing sets with patient end adaptors** are depicted in [Annex A](#).

Requirements for exhalation valves, exhaust valves, **adjustable pressure-limiting (APL) valves**, heat and moisture exchangers (HMEs), breathing filters, and reservoir bags, if provided, are not covered by this International Standard.

NOTE 2 ISO 80601-2-12, ISO 80601-2-13, ISO 9360-1<sup>[3]</sup>, ISO 23328-2<sup>[4]</sup>, and ISO 5362<sup>[1]</sup> cover these.

NOTE 3 Certain aspects of heated-wire **breathing tubes** are discussed in ISO 8185<sup>[2]</sup>.

## 2 Normative references

\*The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE See [Annex A](#) for information on the use of dated and undated normative references.

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

ISO 7000, *Graphical symbols for use on equipment — Registered symbols*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 14971, *Medical devices — Application of risk management to medical devices*

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ISO 15223-1:2012, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

IEC 60417, *Graphical symbols for use on equipment*

IEC 60601-1:2005, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-6, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*

IEC 62366, *Medical devices — Application of usability engineering to medical devices*

ISO 80601-2-12:2011, *Medical electrical equipment — Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators*

ISO 80601-2-13:2011, *Medical electrical equipment — Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation*

EN 556-1:2001, *Sterilization of medical devices — Requirements for medical devices to be designated “STERILE” — Part 1: Requirements for terminally sterilized medical devices*

EN 1041, *Information supplied by the manufacturer with medical devices*

### 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4135<sup>[5]</sup> and ISO 14971 and the following apply.

**3.1 adaptor**  
specialized connector to establish functional continuity between otherwise disparate or incompatible components

[SOURCE: ISO 4135:2001, 4.2.3.1]

**3.2 anaesthetic breathing system**  
inspiratory and expiratory gas pathways through which anaesthetic gas flows at respiratory pressure between the fresh-gas inlet, the **patient connection port** and an exhaust valve or exhaust port

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

**3.3 antistatic**  
property of a material or procedure that disperses or inhibits the accumulation of electrostatic charges

**3.4 APL valve**  
**adjustable pressure-limiting valve**  
**pop-off valve**  
pressure-limiting valve which releases gas over an adjustable range of pressures

[SOURCE: ISO 4135:2001, 4.3.6, modified]

**3.5 assembled end**  
end of a **breathing tube** incorporating an **adaptor**



**3.6****breathing set**

assembly of **breathing tubes**, connectors and components that form the inspiratory and expiratory limbs of the gas pathways of an **anaesthetic** or **ventilator breathing system** between the ventilator and the patient's airway device

Note 1 to entry: The exhaust valve, heat and moisture exchanger (HME), breathing filter, and reservoir bag are not included.

Note 2 to entry: The **patient connection port** is included.

**3.7****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]

**3.8****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]

**3.9****machine end**

that end of the **breathing set** or **breathing tube** 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]

**3.10****patient connection port**

opening at the **patient end** of a **breathing system** intended for connection of an airway device such as a tracheal or tracheostomy tube connector, a face mask, a supralaryngeal airway or a test apparatus

[SOURCE: ISO 4135:2001, 4.2.1.2, modified]

**3.11****patient end**

that end of the **breathing set** or **breathing tube** which is intended to be connected to the **patient end adaptor**, **Y-piece** or other appropriate component near the patient

**3.12****patient end adaptor**

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

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

**3.13****plain end**

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

**3.14****swivel adaptor**

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

**3.15**  
**ventilator breathing system**  
**VBS**

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** and the exhaust port

[SOURCE: ISO 80601-2-12:2011, 201.3.221]

**3.16**  
**Y-piece**

**patient end adaptor** as a three-way connector with a **patient connection port** and two ports for connection to **breathing tubes**

[SOURCE: ISO 4135:2001, 4.2.2.2, modified]

## 4 General requirements

### 4.1 Risk management

**4.1.1** This International Standard specifies requirements that are generally applicable to risks associated with **breathing sets** and **breathing tubes**. An established risk management process shall be applied to the design of the device.

NOTE An informative list of identified hazards is contained in [Annex B](#).

**4.1.2** **Breathing tubes** shall, when transported, stored, installed, operated in normal use and maintained according to the instructions of the manufacturer, present no risks that are not reduced to an acceptable level using risk management procedures in accordance with ISO 14971 and which are connected with their intended application, in normal and in single-fault condition.

NOTE A situation in which a fault is not detected is considered a normal condition. Fault conditions/hazardous situations might remain undetected over a period of time and, as a consequence, might lead to an unacceptable risk. In that case, a subsequently detected fault condition needs to be considered as a single-fault condition. Specific risk control measures need to be determined within the risk management process to deal with such situations.

**4.1.3** It is recognized that the manufacturer may not be able to follow all of the processes identified in this International Standard for each constituent component of the **breathing tube**, such as proprietary components, subsystems of non-medical origin, and legacy devices. In this case, the manufacturer should take special account of the need for additional risk control measures.

**4.1.4** Where requirements of this International Standard refer to freedom from unacceptable risk, acceptability or unacceptability is determined by the manufacturer in accordance with the manufacturer's policy for determining acceptable risk.

*Check compliance by inspection of the risk management file.*

### 4.2 Usability

If required by a competent authority, the manufacturer shall address in a usability engineering process any risks resulting from poor usability (see IEC 60601-1-6 and IEC 62366).

*Check compliance by inspection of the usability engineering file.*

### 4.3 Clinical evaluation

If required by a competent authority, a clinical evaluation shall be performed and documented in the technical documentation of the device.

*Check compliance by inspection of the technical documentation of the device.*

### 4.4 Biophysical or modelling research

If required by a competent authority, and where appropriate, validated biophysical or modelling research shall be carried out.

*Check compliance by inspection of the technical file.*

### 4.5 Test methods

The manufacturer may use type tests different from those detailed within this International Standard, if an equivalent degree of safety is obtained. However, in the event of dispute, the methods specified herein shall be used as the reference methods.

### 4.6 Recommended service life

Re-usable **breathing sets** and **breathing tubes** shall comply with the requirements of this International Standard throughout the recommended service life as required in [8.4.4](#).

*Check compliance by inspection of the manufacturer's technical file.*

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## 5 Specific requirements

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**5.1 Materials** <https://standards.iteh.ai/catalog/standards/sist/788d2d9f-9762-4b58-acff-13e3c80827f7/iso-5367-2014>

**5.1.1 Breathing sets and breathing tubes**, in their ready-for-use condition after any preparation recommended by the manufacturer, shall satisfy appropriate biological safety testing, in accordance with ISO 10993-1.

**5.1.2 Breathing sets and breathing tubes** shall be made of materials suitable for their intended use and, if applicable, shall function in the presence of commonly used concentrations of anaesthetic agents and gases in accordance with their intended use.

**5.1.3** If required by a competent authority and if phthalates are incorporated in parts of the medical devices coming directly or indirectly into contact with the patient, the medical device shall be labelled accordingly.

NOTE Attention is drawn to substances which are carcinogenic, mutagenic or toxic to reproduction.

**5.1.4** If materials that contain natural rubber (latex) are incorporated in parts of the medical devices coming directly or indirectly into contact with the patient, the medical device shall be labelled accordingly.

### 5.2 Length

**5.2.1** The length of a **breathing tube** shall be designated by its nominal overall length, expressed in metres, when measured in the resting condition (without extension), lying on a horizontal surface. **Breathing tubes** intended to be extended when used shall be designated by both the unextended and extended lengths.

5.2.2 The designated length of a **breathing tube** provided attached to a **Y-piece** or **patient end adaptor** shall include the length of the **Y-piece** or **patient end adaptor** and any **assembled ends**.

5.2.3 The actual length shall be within  $\pm 10\%$  of the designated length.

### 5.3 Means of connection

#### 5.3.1 General

5.3.1.1 **Breathing tubes** shall have **plain ends** complying with 5.3.2 and/or **assembled ends** with **adaptors** incorporating 22 mm or 15 mm conical connectors complying with ISO 5356-1.

#### 5.3.2 Plain ends of breathing tubes

5.3.2.1 The axial length [ $l_1$  in Figure 1 a)] of the **plain ends** of **breathing tubes**, excluding those specified in 5.3.2.2, shall be not less than 21 mm for **breathing tubes** intended to engage with 22 mm male conical connectors or not less than 14 mm for **breathing tubes** intended to engage with 15 mm male conical connectors.

5.3.2.2 The axial length [ $l_2$  in Figure 1 a)] of the **plain ends** of **breathing tubes** that incorporate an internal ridge [see Figure 1 b)], intended to engage with the recess at the base of a 22 mm male conical connector as specified in ISO 5356-1, shall be not less than 26,5 mm.

5.3.2.3 When tested as described in Annex C, the **plain ends** of **breathing tubes** shall not become detached from the appropriate male conical connector at a force of less than 40 N.

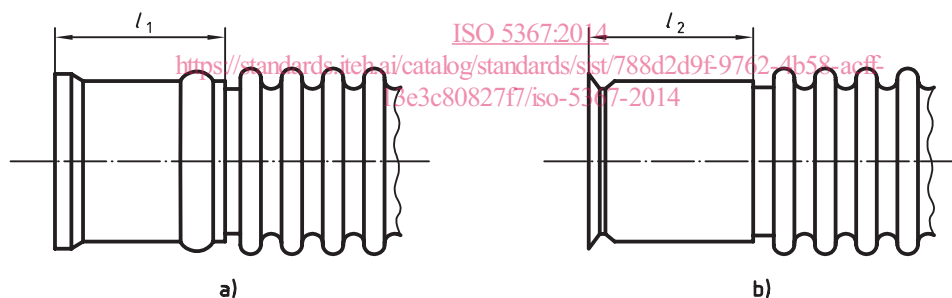


Figure 1 — Axial length of plain end of breathing tube

#### 5.3.3 Adaptor

The end of the **adaptor** that is not intended for attachment to the **breathing tube** shall have a 22 mm or 15 mm **conical connector** complying with ISO 5356-1.

#### 5.3.4 Assembled end

When tested as described in Annex D, the **adaptor** shall not detach from the **breathing tube** at a force of less than 45 N.

NOTE For the purpose of this requirement, a **patient end adaptor** provided securely attached to a **breathing tube** is regarded as an **adaptor**.

### 5.3.5 Breathing tubes securely attached to a patient end adaptor

For **breathing tubes** supplied securely attached to a **patient end adaptor**, the **patient connection port** of that **patient end adaptor** shall be a 22 mm male/15 mm female coaxial or 15 mm female conical connector complying with ISO 5356-1.

### 5.3.6 Coaxial or double lumen breathing tubes securely attached to an adaptor

For coaxial or double-lumen **breathing tubes** supplied securely attached to an **adaptor**, the **patient connection port** attached to or part of that **adaptor** shall be a 22 mm male/15 mm female coaxial or 15 mm female conical connector complying with ISO 5356-1.

## 5.4 Leakage

**5.4.1** Leakage from **breathing tubes** supplied to be cut to length shall not exceed 10 ml/min at  $(60 \pm 3)$  hPa [ $(60 \pm 3)$  cmH<sub>2</sub>O], per metre length of tubing.

*Check compliance by testing in accordance with [Annex E](#).*

**5.4.2** \*Leakage from a single **breathing tube** not intended for use with a **VBS** or **anaesthetic breathing system**, shall not exceed 25 ml/min at  $(60 \pm 3)$  hPa [ $(60 \pm 3)$  cmH<sub>2</sub>O].

*Check compliance by testing in accordance with [Annex E](#).*

**5.4.3** \*Leakage from a complete **breathing set** or **breathing tube** supplied ready for use with a **VBS** or **anaesthetic breathing system** shall not exceed the leakage limit listed for the designated patient category in Table 1.

*Check compliance by testing in accordance with [Annex E](#).*

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**\*Table 1 — Leakage limit by patient category**

Patient category	Intended delivered volume	Leakage limit ml/min	At pressure hPa (cmH <sub>2</sub> O)
Adult	≥ 300 ml	70	60 ± 3
Paediatric	50 ml < 300 ml	40	60 ± 3
Neonatal	≤ 50 ml	30	60 ± 3

NOTE See [Annex E](#).

## 5.5 Resistance to flow

**5.5.1** For **breathing tubes** supplied to be cut to length, the manufacturer shall determine and disclose [see [8.4.1 a](#)] the resistance to flow per metre length of tubing at the flow listed for the designated patient category in Table 2. The flow resistance shall not exceed the limit in Table 2.

*Check compliance by testing in accordance with [Annex F](#).*