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Anaesthetic and respiratory equipment — Breathing sets and connectors

Matériel d'anesthésie et de réanimation respiratoire — Ensembles respiratoires et raccords

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Foreword

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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).

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).

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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.

This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Airway devices 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 are as follows:

— the layout now follows the format of ISO 18190:2016;

— 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.

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 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, ISO 23328-2 and ISO 5362. Requirements for heated *breathing tubes* can be found in ISO 80601-2-74.

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_2O equivalent values rounded to the nearest whole cmH_2O.

NOTE 2 Rounded cmH_2O 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 standard for airways and related equipment. The requirements in this device-specific standard take precedence over any conflicting requirements in ISO 18190.

Anaesthetic and respiratory equipment — Breathing sets and connectors

1 Scope

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.

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

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*.

2 Normative references

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.

ISO 4135, *Anaesthetic and respiratory equipment — Vocabulary*

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

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4135 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
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 Figures A.1 to A.5.

3.2
plain end
end of a *breathing tube* designed to fit directly over a cone conical connector conforming to ISO 5356-1

4 General requirements

4.1 General

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 conform to the requirements of this document throughout the recommended service life as required in 9.3.4.

Check conformance by inspection of the manufacturer's technical documentation.

5 Materials

5.1 General

ISO 18190:2016, Clause 5 shall apply.

5.2 Biological safety testing

Breathing sets shall also be evaluated and tested in conformance with ISO 18562-1.

Check conformance by inspection of the manufacturer's technical documentation.

6 Design requirements

6.1 General

ISO 18190:2016, Clause 6 shall apply.

6.2 Designated length

6.2.1 The length of *breathing tubes* shall be designated by their 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.

Check conformance by functional testing.

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

Check conformance by functional testing.

6.2.3 The actual length shall be within ±10 % of the designated length.

Check conformance by functional testing.

6.3 *Breathing tube* ends

6.3.1 *Breathing tubes* shall have *plain ends* or *assembled ends*

Check conformance by inspection.

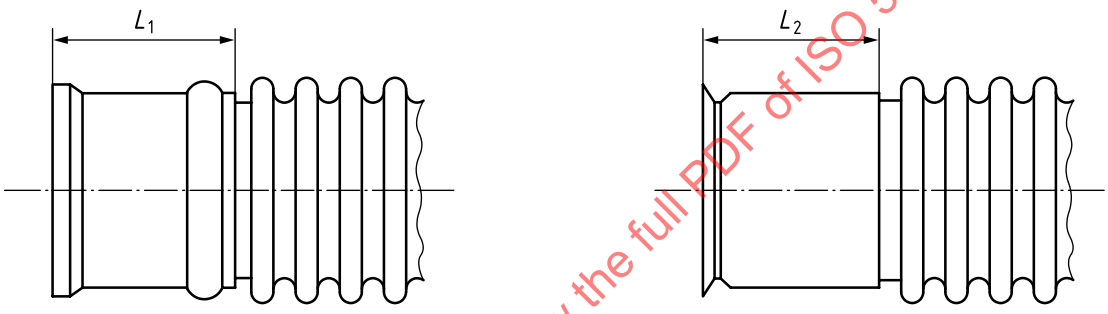
NOTE There is rationale for this subclause in A.3.

6.3.2 Plain ends according to Figure 1 shall have axial lengths as specified in Table 1.

Check conformance by functional testing.

6.3.3 Plain ends shall not become detached from their respective cones when subjected to the axial forces specified in Table 1.

Check conformance by the test given in Annex C.



a) Plain end with recess **b) Plain end without recess**

Figure 1 — Axial length of *plain end* of *breathing tubes*

Table 1 — Breathing tube end specifications

Cone size (mm)	Axial lengths		Axial force (N)
	L_1 (mm)	L_2 (mm)	
22	≥21	≥26,5	≥40
15	≥14	N/A	≥40
11,5	≥10,5	N/A	≥25
NOTE The cone sizes are those specified in ISO 5356-1.			

6.3.4 *Adaptor*

The end of the *adaptor* that is not intended for attachment to the *breathing tube* shall be a 22 mm or 15 mm or 11,5 mm socket conforming to ISO 5356-1.

Check conformance by inspection of the manufacturer's technical documentation.

6.3.5 *Assembled end*

Adaptors shall not detach from the *breathing tube* at a force of less than:

a) 45 N for 15 mm and 22 mm adaptors; and

b) 30 N for 11,5 mm adaptors.

Adaptors for use in breathing sets or breathing tubes for neonatal ventilation using an 11,5 mm ISO 5356-1 compliant socket conical connector shall not detach from the breathing tube at a force of less than 30 N.

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

Check conformance by the test given in Annex D.

6.3.6 *Patient connection ports*

Patient connection ports shall be one of the following:

a) a coaxial 22 mm cone/15 mm socket;

b) a 15 mm socket;

Check conformance by inspection of the manufacturer's technical documentation.

6.4 Leakage

6.4.1 Leakage from *breathing tubes* shall not exceed 10 ml/min at (60 ± 3) hPa [(60 ± 3) cmH_2O].

Check conformance by the test given in Annex E.

6.4.2 Leakage from complete *breathing sets* shall not exceed the leakage limit listed for the designated patient category in Table 2.

NOTE See also Annex A for rationale.

Check conformance by the test given in Annex E.

Apply 6.4.1 or 6.4.2, as applicable

Table 2 — Leakage limit by patient category

Patient category	Intended delivered volume	Leakage limit ml/min	At pressure hPa (cmH_2O)
Adult	≥ 300 ml	70	60 ± 3
Paediatric	50 ml < 300 ml	40	60 ± 3
Neonatal	≤ 50 ml	30	60 ± 3
NOTE See Annex E.			

6.5 Resistance to flow

6.5.1 For *breathing tubes* supplied to be cut to length, the manufacturer shall determine and disclose [see 9.3.1 a)] the resistance to flow per metre length of tubing at the flow listed for the designated patient category in Table 3. The flow resistance shall not exceed the limit in Table 3.

NOTE See also Annex A for rationale for Tables 3 and 4.

Check conformance by the test given in Annex F.

Table 3 — Flow resistance limit per metre by patient category for *breathing tubes* supplied to be cut to length

Patient category	Intended delivered volume	Flow resistance limit hPa/l/min/m (cmH_2O/l/min/m)	At flow l/min
Adult	≥ 300 ml	0,03	30
Paediatric	50 ml < 300 ml	0,06	15
Neonatal	≤ 50 ml	0,37	2,5
NOTE See Annex F.			

6.5.2 For *breathing tubes* supplied ready for use or for each limb of a *breathing set*, the manufacturer shall determine, mark, and disclose [see 9.2 c) and 9.3.1 b)] the resistance to flow at the flow listed for the designated patient category specified in Table 4.

If the resistance exceeds the limit listed in Table 4 for the designated patient category, the risk shall be assessed in the risk management file and, marked and disclosed [see 9.2 c) and 9.3.1 b)].

Check conformance by the test given in Annex F and, if required, by inspection of the manufacturer's risk management file.

Table 4 — Flow resistance limit by patient category for *breathing sets* and *breathing tubes* supplied ready for use

Patient category	Intended delivered volume	Flow resistance limit hPa/l/min (cmH_2O /l/min)	At flow l/min
Adult	≥ 300 ml	0,06	30
Paediatric	50 ml < 300 ml	0,12	15
Neonatal	≤ 50 ml	0,74	2,5
NOTE See Annex F.			

6.5.3 The increase in flow resistance when *breathing tubes* are suspended over a rigid cylinder shall not exceed 150 % of the value obtained when the tube is straight.

Check conformance by the test given in Annex G.

6.6 *Compliance*

6.6.1 For *breathing tubes* supplied to be cut to length, the manufacturer shall determine and disclose [see 9.3.1 d)] the *compliance* per metre of tubing at the pressure listed for the designated patient category in Table 5. The *compliance* per metre of the tubing shall not exceed the limit in Table 5.

Check conformance by the test given in Annex H.

Table 5 — *Compliance* limit per metre by patient category for *breathing tubes* supplied to be cut to length

Patient category	Intended delivered volume	Compliance limit ml/hPa/m (ml/ cmH_2O /m)	At pressure hPa (cmH_2O)
Adult	≥ 300 ml	0,8	60 ± 3
Paediatric	50 ml < 300 ml	0,7	60 ± 3
Neonatal	≤ 50 ml	0,3	60 ± 3
NOTE See Annex H.			

6.6.2 For *breathing sets* or *breathing tubes* supplied ready for use, the manufacturer shall determine mark, and disclose [see 9.2 e) and 9.3.1 e)] the total *compliance* at the pressure listed for the designated patient category in Table 5.

NOTE See also Annex A for rationale.

If the *compliance* exceeds the limit listed in Table 6 for the designated patient category, the risk shall be assessed in the risk management file and, if required, marked and disclosed [see 9.2 e) and 9.3.1 e)].

Check conformance by the test given in Annex H and, by inspection of the manufacturer's risk management file.

Table 6 — *Compliance* limit by patient category for *breathing sets* and *breathing tubes* supplied ready for use

Patient category	Intended delivered volume	Compliance limit ml/hPa (ml/ cmH_2O)	At pressure hPa (cmH_2O)
Adult	≥ 300 ml	5	60 ± 3
Paediatric	50 ml < 300 ml	4	60 ± 3
Neonatal	≤ 50 ml	1,5	60 ± 3
NOTE See Annex H.			

6.7 Axial strength of breathing tubes

Breathing tubes shall withstand an axial force of 45 N.

Check conformance by the test given in Annex D.

7 Requirements for *breathing sets* and *breathing tubes* supplied sterile

ISO 18190:2016, Clause 7 shall apply.

8 Packaging

ISO 18190:2016, Clause 8 shall apply.

9 Information supplied by the manufacturer

9.1 General

ISO 18190:2016, Clause 9 shall apply.

9.2 Marking on the packaging

NOTE See also Annex A for rationale.

In addition to the marking requirements specified in 9.1 the packaging shall be marked with the following:

a) the designated length (see 6.2);

b) for *breathing tubes* supplied ready for use, or for each limb of a *breathing set*, the resistance to flow and the test flow in l/min for the designated patient category in accordance with 6.5.2 and, if applicable, the risk assessment disclosure if the flow resistance exceeds the limits listed in Table 3;

EXAMPLE 1 RI @ 30 l/min: 0,08 hPa/l/min (cmH_2O/l/min);

RE @ 30 l/min: 0,07 hPa/l/min (cmH_2O/l/min).

RI: Resistance of the inspiratory limb

RE: Resistance of the expiratory limb

c) if other components (e.g. breathing filters, HMEs) are attached to *breathing sets* or *breathing tubes*, the total resistance to flow and the test flow in l/min for the designated patient category in accordance with 6.5.2 including these attached components;

d) for *breathing tubes* or *breathing sets,* supplied ready for use, the total *compliance* and the test pressure in hPa for the designated patient category in accordance with 6.6.2 and, if applicable, the risk assessment disclosure if the *compliance* exceeds the limits listed in Table 6;

EXAMPLE 2 C @ 60 hPa: 7 ml/hPa (ml/cmH_2O).

C: Compliance

e) if appropriate, the maximum pressure the tubing and connectors can withstand at ambient conditions expressed in Pascals.

Check conformance by visual inspection.

9.3 Instructions for use

9.3.1 Resistance and *compliance* information shall be supplied:

a) for *breathing tubes* supplied to be cut to length, the resistance to flow per metre length of tubing and the test flow in l/min for the designated patient category in accordance with 6.5.1;

b) for *breathing tubes* supplied ready for use or for each limb of a *breathing set*, the resistance to flow and the test flow in l/min for the designated patient category in accordance with 6.5.2 and, if applicable, the risk assessment disclosure if the flow resistance exceeds the limits listed in Table 3;

c) if other components (e.g. breathing filters, HMEs) are attached to *breathing tubes* or *breathing sets*, the total resistance to flow and the test flow in l/min for the designated patient category, in accordance with 6.5.2 including these attached components;

d) for *breathing tubes* supplied to be cut to length, the *compliance* per metre of tubing and test pressure for the designated patient category in accordance with 6.6.1;

e) for *breathing tubes* and *breathing sets,* supplied ready for use, the total *compliance* and the test pressure in hPa for the designated patient category in accordance with 6.6.2 and, if applicable, the risk assessment disclosure if the *compliance* exceeds the limits listed in Table 5;

f) if other components (e.g. breathing filters, HMEs) are attached to *breathing tubes* or *breathing sets*, the total *compliance* and test pressure for the designated patient category, in accordance with 6.6.2 including these attached components;

9.3.2 The manufacturer shall, when requested, provide information on the recommended maximum working temperature of the *breathing set* or *breathing tube* when attached to a heated humidifier, if breathing set is intended to be used within active humidification;

9.3.3 The manufacturer shall provide the recommended maximum working pressure of *breathing sets* or *breathing tubes*;

9.3.4 Unless *breathing sets* or *breathing tubes* are intended and marked as being for single use, the manufacturer shall provide details of recommended methods of cleaning and disinfection or sterilization, and the maximum number or period of reuses, if processing in accordance with the provided instructions leads to a degree of degradation that will limit the useful life of the medical device. Where such degradation is established, the manufacturer shall provide an indication of the number of reprocessing cycles that can normally be tolerated, or some other indication of the end of the medical device's ability to safely fulfil its intended use;

9.3.5 For coaxial and double-lumen *breathing sets*, the manufacturer shall provide details of recommended user test methods to verify the integrity of the *breathing set* before use;

Specialized equipment that is required to perform this user test shall be supplied with *breathing sets* or available from the manufacturer.

NOTE Particular problems with coaxial tubing or double lumen *breathing sets* with internal components include leakage (to atmosphere and between inspiratory and expiratory tubes), separation, or blockage.

Check conformance by inspection of the instructions for use.

Annex A
(informative)

Rationale

A.1 General

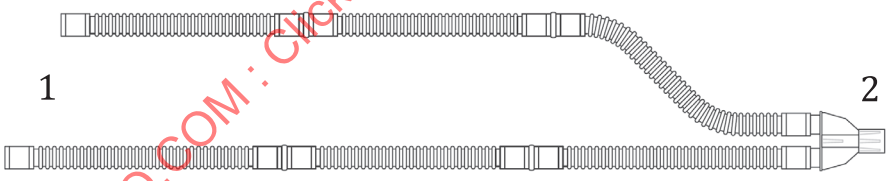
This annex provides a concise rationale for the important requirements of this document and is intended for use by those who are familiar with the subject of this document but who have not participated in its development. An understanding of the reasons for the main requirements is considered essential for its proper application. Furthermore, as clinical practices and technologies change, it is believed that rationales for the present requirements will facilitate any revisions of this document necessitated by those developments.

A.2 Rationale for Clause 1 — Scope

Breathing sets are also commonly known as 'breathing circuits' by clinicians and manufacturers, yet this generic term was eventually deprecated.

Breathing sets are not complete 'circuits' as additional devices and accessories are required to perform the task of ventilation, i.e., an anaesthetic machine, ventilator, absorbers, exhaust/expiratory valves etc., all of which are specifically excluded from the scope of this document.

Examples of several different types of *breathing sets* with various types of *patient end adaptors* are depicted in Figures A.1 to A.5. Other examples (not shown) may also apply.

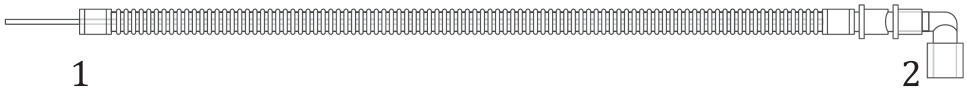


Key

1 *machine end*

2 *patient end*

Figure A.1 — Example of a basic anaesthesia *breathing set*

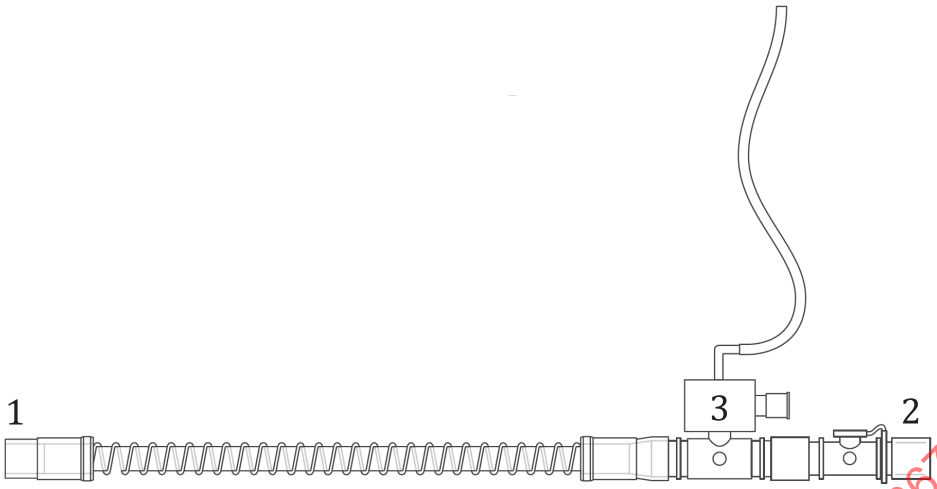


Key

1 *machine end*

2 *patient end*

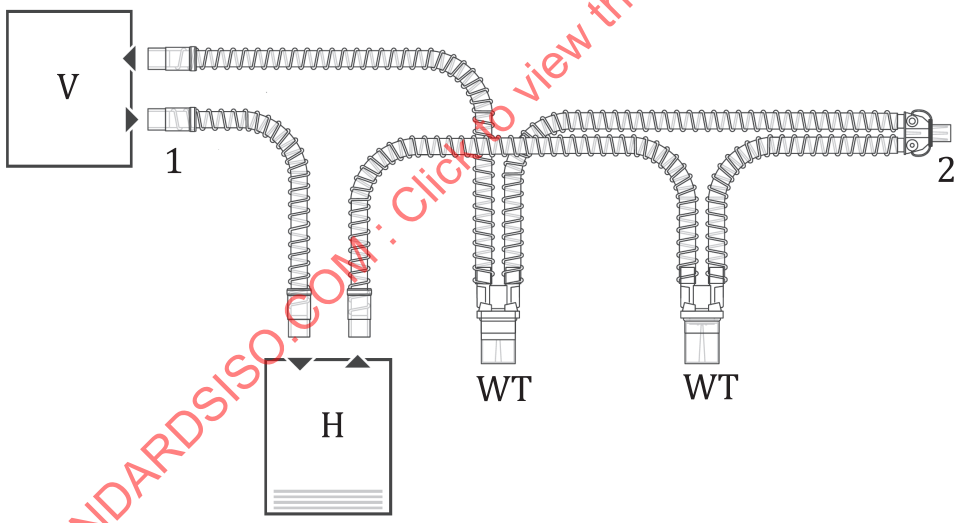
Figure A.2 — Example of a basic coaxial anaesthesia *breathing set*



Key

1 *machine end*
2 *patient end*
3 exhalation valve (see ISO 80601-2-13)

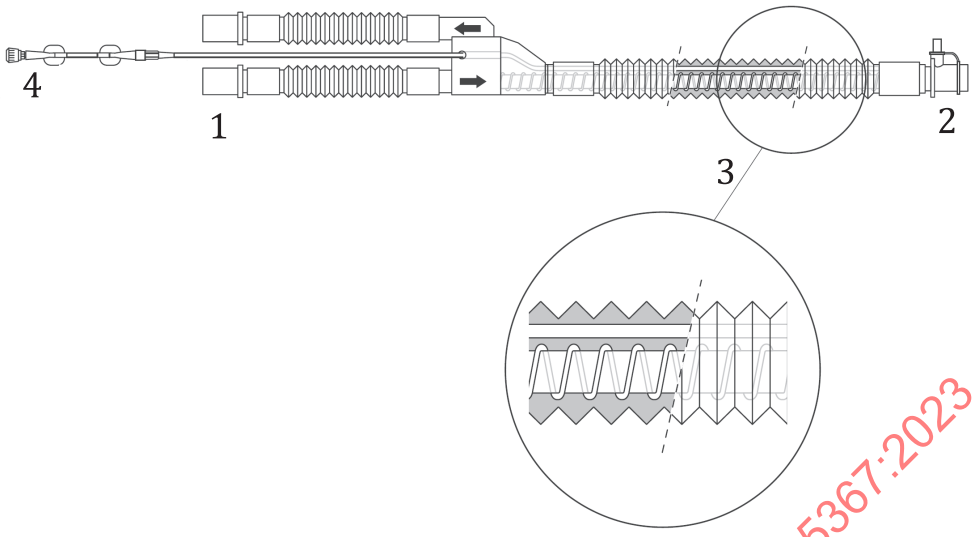
Figure A.3 — Example of a basic single tube *breathing set* with exhalation valve



Key

1 *machine end*
2 *patient end*
V ventilator (see ISO 80601-2-12)
H humidifier (see ISO 80601-2-74)
WT water trap

Figure A.4 — Example of a critical care ventilator *breathing set* with water traps and connections to a humidifier and ventilator



Key

1 ***machine end***

2 ***patient end***

3 multiple lumen coaxial tubing

4 gas sampling tubing

Figure A.5 — Example of a multiple-lumen coaxial *breathing set* with gas sampling tubing

A.3 Rationale for subclause 6.3.1 – Breathing tube ends

The ends of breathing tubes are defined for machine ends and ends towards external interfaces (e.g. patient connection port) if these are intended to be disassembled. This requirement is not applicable if components are permanently attached to the hoses like e.g. water traps in the middle of the hose.

A.4 Rationale for subclause 6.4.2 — Leakage from complete breathing sets

There appears to be no international agreement on the definitions for adult, paediatric, infant, or neonatal body weights, or tidal volumes. Instead, ISO 80601-2-12 and ISO 80601-2-13 agree that patient categories should be replaced with 'relevant delivered volume ranges.'

A.5 Rationale for Table 2 — Leakage limit

Working closely with the developers of the breathing systems standards in an effort to determine reasonable leakage limits for *breathing tubes* and *breathing sets*, it was conservatively decided that *breathing tube* and *breathing set* leakage limits for each patient category in Table 1 should be approximately 30 % of the total system leakage limits for the respective *VBS* and *anaesthetic breathing system* equipment, including accessories, when the breathing systems are tested at the same pressures.

A.6 Rationale for Tables 3 and 4 — Flow resistance

A similar approach was taken with the developers of the breathing systems standards to harmonize the flow resistance test methods between the *breathing sets*, *breathing tubes*, and the various *VBSs* and *anaesthetic breathing systems*. It was conservatively decided that *breathing tube* and *breathing set* resistance limits for each patient category in Table 3 should be approximately 30 % of the total system resistance limit for the respective breathing systems when all are tested at the same flow.

For *breathing tubes* supplied to be cut to length, the 30 % value for each limb of a typical *breathing set* was then expressed on a per metre basis for each patient category in Table 2.

A.7 Rationale for subclause 6.5.2 Resistance to flow

Flow resistance of the total breathing system should not exceed that of the ventilator or anaesthesia workstation of 6 hPa (6 cmH_2O) at the flow rate required to deliver the intended volume (ISO 80601-2-12, ISO 80601-2-13, or other relevant standard that describes total system flow resistance for the intended use of the *breathing set* or *breathing tube*).

The increase in pressure associated with the supplied *breathing set* alone should be limited to the lowest possible value and, ideally, not exceed 1,8 hPa (1,8 cmH_2O) at the flow rate required to deliver the intended volume, because other components added by the user may add flow resistance that will exceed the system limits.

The committee agreed that flow resistance should include that added by turbulent flow within the components. Expiratory flow resistance is the most critical value to control. Special characteristics of coaxial tubes may require separate disclosure of both inspiratory and expiratory flow resistance. This is important when the machine fails and when the patient is forced to inhale and exhale spontaneously through the components and valves. Normal upper airway flow resistance is approximately 3 hPa (3 cmH_2O) at the flow rate required to deliver the intended volume. Heat and moisture exchangers (HMEs), filters, and other components add significant flow resistance. Therefore, *breathing sets* should not increase this flow resistance, if possible.

The committee also agreed to add requirements to disclose flow resistance values for *breathing sets* and *breathing tubes* intended for neonatal and paediatric patient categories. While there was no agreement on the definitions for adult, paediatric, infant, or neonatal categories defined by body weight or tidal volume, the committee agreed to harmonize the patient categories with those described in ISO 80601-2-12 and ISO 80601-2-13 as 'relevant delivered volume ranges.' It was understood that the patient categories should be further classified, if necessary, to those relating to 'invasive' and 'non-invasive' ventilation requirements, because the performance of many non-invasive ventilation applications of *breathing sets* are less critical.

A.8 Rationale for subclause 6.6.2 *Compliance*

The committee agreed that testing and marking the total *compliance* of the *breathing set* and *breathing tube* is clinically useful because the value may be additive to the *compliance* values for the other accessories and help provide the user with a clearer understanding the total *compliance* of the *VBS* or *anaesthetic breathing system*.

Compliance limits will vary greatly with patient category. Neonatal and paediatric *breathing sets* must have lower *compliance* values in order to function within the ventilator's *compliance* tolerance limits. Errors in the estimation of the total breathing system *compliance* will greatly affect the accuracy of delivered gas volumes.

A.9 Rationale for subclause 9.2 Marking on the packaging

a) designated length: the designated length includes the *patient end adaptor* and any *assembled ends.* For asymmetric systems the designated length is the shortest distance between device and *patient end adapter* (e.g. the expiratory limb of a heated hose system for active humidification with an additional non - heated hose and a water chamber in the inspiratory limb).

A.10 Rationale for subclause 9.3.5 Coaxial *breathing set* user test methods

User testing of coaxial *breathing sets* for the integrity of the internal circuit prior to use on a patient may be required because the security of the inner tubing may not be visible to the user. Manufacturers

need to instruct the operator on how to ascertain the integrity of the internal lumen to reduce the risk of a faulty connection leading to rebreathing of carbon dioxide and other problems.

The following tests have been described for use with a coaxial Mapleson D circuit (e.g. Bain circuit),[6] however, these tests are not applicable for use with circle systems and may be unreliable with Bain circuits:

— observation of a decrement in flow when the distal orifice of the internal circuit was occluded, and

— observation of an accelerated deflation of the reservoir bag by a venturi effect with a high flow through the inner tube.

Annex B
(informative)

Hazard identification for risk management

NOTE Annex B is not an exhaustive or inclusive list of all known hazards and serves only as a guide for developers and users of *breathing sets* and *breathing tubes*.

a) Emission of harmful gases: attention is drawn to the absorption of inhalational anaesthetic agents and other substances by *breathing tubes*. These agents and substances may be subsequently liberated and may pose a hazard.

b) Delamination, leading to increased flow resistance: for *breathing tubes* of a laminated construction, there is a risk of internal de-lamination and bubble formation when they are exposed to inhalational anaesthetic agents.

c) Kinking.

d) Disconnection.

e) Obstruction.

f) Detachment of connector.

g) Hole in the inner tube of a coaxial tube or septum of a double-lumen tube.

h) High flow resistance.

i) Alteration of anaesthetic gases by dissolving substances from the hose material to the breathing gas [e.g. plasticizers, like phthalates, di(2-ethylhexyl) phthalate (DEHP)].

j) Insufficient ventilation of the patient by using tubing with excessive *compliance*.

k) Insufficient ventilation of the patient due to inability to correct for excessive *VBS compliance*, resulting from damaged, leaky or corrupted *breathing tubes*.

l) Allergy, including allergy to natural rubber latex.

Annex C
(normative)

Test for security of attachment of *plain end* to conical connector

C.1 Principle

The security of attachment of a plain-ended *breathing tube* to a conical connector that is intended to be detachable by an operator is tested by applying a tensile load along the linear axis of the end and noting whether the end becomes detached from the connector at a specified force.

C.2 Test piece

The test is carried out on a *breathing tube* with a *plain end*.

C.3 Apparatus

C.3.1 Means of applying a tensile load of not less than 40 N, at a rate of (50 ± 5) mm/min along the linear axis of the tube at least 150 mm from the end of the tube.

C.3.2 Means of measuring the applied tensile load, with an accuracy of ±2 N.

C.3.3 A 22 mm or 15 mm or 11,5 mm conical test connector, as appropriate for the size of *breathing tube* to be tested, made of metal with a recess in the case of a 22 mm connector, dimensioned as specified in ISO 5356-1 and having a surface roughness of 0,8 µm (roughness number N6).

C.4 Procedure

C.4.1 Condition the *breathing tube* at (42 ± 3) °C and at not less than 80 % relative humidity for at least 1 h prior to testing. Conduct the test procedure at a temperature of (23 ± 3) °C within 5 min after the 1 h conditioning.

NOTE Conditioning at a high temperature is intended to replicate the temperature of the tubing and gas pathways after 1) exposure to the exothermic reactions within carbon dioxide absorbers, 2) the high temperatures of heated humidifiers or 3) the high ambient temperatures when placed in proximity to warming blankets.

C.4.2 Engage the *plain end* of the *breathing tube* over the test connector by wetting the end in distilled water and pushing it onto the test connector so that the entire axial length of the test connector is covered. Secure the test connector.

C.4.3 Apply a tensile load of not less than 40 N (25 N for 11,5 mm connectors) at a rate of (50 ± 5) mm/min at a point not less than 150 mm from the end of the *breathing tube*, along the linear axis of the *breathing tube*.

C.5 Expression of results

Verify that the breathing tube does not become detached from the test connector at a force less than 40 N (25 N for 11,5 mm connectors).

Annex D
(normative)

Test for security of attachment of *assembled ends* and axial strength of *breathing tubes*

D.1 Principle

The security of attachment of *assembled ends* and the axial strength of a *breathing tube* are tested by applying a tensile load along the linear axis of the *breathing tube* and its *assembled end* and noting whether the *patient end adaptor* becomes detached from the *breathing tube* or the integrity of the tube is compromised in any way.

D.2 Test piece

The test is carried out on a *breathing tube* with an *assembled end*.

D.3 Apparatus

D.3.1 Means of securing the *assembled end* of the *breathing tube*, so that the *adaptor* is not distorted and can withstand a tensile load of > 45 N applied for 1 min along the linear axis of the test piece at least 150 mm from the end of the test piece.

D.3.2 Means of measuring the applied tensile load, with an accuracy of ±2 N.

D.3.3 Means of applying a tensile load of not less than 45 N at a rate of (50 ± 5) mm/min along the linear axis of the test piece.

D.4 Procedure

D.4.1 Condition the test piece at (42 ± 3) °C and at not less than 80 % relative humidity for at least 1 h prior to testing. Conduct the test procedure at a temperature of (23 ± 3) °C within 5 min after the 1 h conditioning.

NOTE Conditioning with high temperature is intended to replicate the temperature of the tubing and gas pathways after 1) exposure to the exothermic reactions within carbon dioxide absorbers, or 2) the high temperatures of heated humidifiers, or 3) the high ambient temperatures when placed in proximity to warming blankets.

D.4.2 Secure the *adaptor* so that the part incorporated into the *breathing tube* is not distorted.

D.4.3 Apply a tensile load of 45 N (30 N for 11,5 mm connectors) at a rate of (50 ± 5) mm/min at a point not less than 150 mm from the secured assembled end of the *breathing tube* along its linear axis.

D.4.4 Verify that the assembled end and the breathing tube meet the requirements for leakage according to 6.4 and compliance according to 6.6

D.5 Expression of results

Verify that the integrity of the *assembled end* and the *breathing tube* have not been compromised.

Annex E
(normative)

Test for leakage

E.1 Principle

Leakage is tested by applying and maintaining an internal gas pressure by introducing air into a *breathing tube* or *breathing set* and recording the flow of air required to maintain that internal pressure. This will test leakage from the body of the *breathing tube*; in the case of a *breathing tube* or *breathing set* with *assembled ends*, from the tube, the adaptor and their connection; and in the case of *breathing tubes* with *plain ends*, from the connection of the *breathing tube* to an appropriately sized conical connector.

E.2 Test piece

The test is carried out on a *breathing tube* or *breathing set* as supplied in its ready for use condition. *Breathing tubes* supplied uncut are cut to a length suitable for testing.

E.3 Apparatus

E.3.1 Means of applying and maintaining an internal gas pressure of (60 ± 3) hPa [(60 ± 3) cmH_2O].

E.3.2 Means of conditioning the *breathing tube* and carrying out the test procedure at a temperature of (23 ± 3) °C.

E.3.3 Means of recording air flow rate up to 100 ml/min, accurate to within 5 % at 50 hPa (50 cmH_2O).

E.3.4 An appropriately sized cone conical test connector, as in C.3.3.

E.4 Procedure

E.4.1 Test conditions

Condition the test piece at a temperature of (23 ± 3) °C for at least 1 h prior to testing. Maintain this temperature during testing.

E.4.2 Engaging the test piece to the test apparatus

E.4.2.1 Care should be taken when performing the test to exclude the possibility of leaking between the tubing and the apparatus.

E.4.2.2 For a *breathing tube* supplied to be cut to length, cut a suitable length of not less than 1 m as the test piece.

E.4.2.3 For a *breathing tube* intended to be extended when used, condition and test in the extended state.

E.4.2.4 Engage the test piece over the test connector as described in C.4.2 and close off one end.

E.4.2.5 For complete *breathing sets* or *breathing tubes* supplied in pairs with *assembled ends* and *Y-piece* or *patient end adaptor*, and all provided components, engage the end of one opening of the *breathing tube* over the test connector as in C.4.2, occluding any openings.

E.4.3 Application of internal gas pressure

Apply an internal gas pressure of (60 ± 3) hPa [(60 ± 3) cmH_2O] by introducing air into the *breathing tube* or *breathing set* and allowing the pressure to stabilize. Record the flow rate of air required to maintain that internal gas pressure.

E.5 Expression of results

E.5.1 Express the flow rate of air required to maintain the specified internal gas pressure in millilitres per minute.

E.5.2 Verify that the leakage is less than that specified in 6.4 as appropriate.

Annex F
(normative)

Measurement of resistance to flow

F.1 Principle

The resistance to flow is tested by measuring the pressure increase through the *breathing set* or *breathing tube*

F.2 Test piece

F.2.1 The test is carried out on a *breathing set*, *breathing tube* supplied ready for use, or a 1 m length of *breathing tube* supplied to be cut to length.

F.2.2 If other components (e.g. water traps, water chambers for humidifying systems) are attached to the *breathing set* an additional test is carried out including these attached components. See 9.2 c).

Components (e.g. HMEs, Filters) that have their own standard shall be tested according to the specific product standard.

F.3 Apparatus

F.3.1 Flow-controlling device, capable of controlling the flow of air and having an accuracy of ±2,5 %.

F.3.2 Pressure-measuring device, having an accuracy of ±0,10 hPa (±0,10 cmH_2O).

F.3.3 Buffer reservoir, comprising a sealed jar of 5 l capacity with a gas inlet placed near the bottom of the jar and a gas outlet placed at the top of the jar (see Figure F.1). The outlet shall be funnel-shaped with an inside diameter greater than that of the *breathing tube* under test. A connection to the pressure-measuring device (F.3.2) shall be placed in the jar halfway between the gas inlet and gas outlet. Any transition in inside diameter between the outlet and the connector, if provided, and the *breathing tube* should be smooth to minimize turbulent flow.

F.3.4 Compressed non-condensing air.

F.4 Procedure

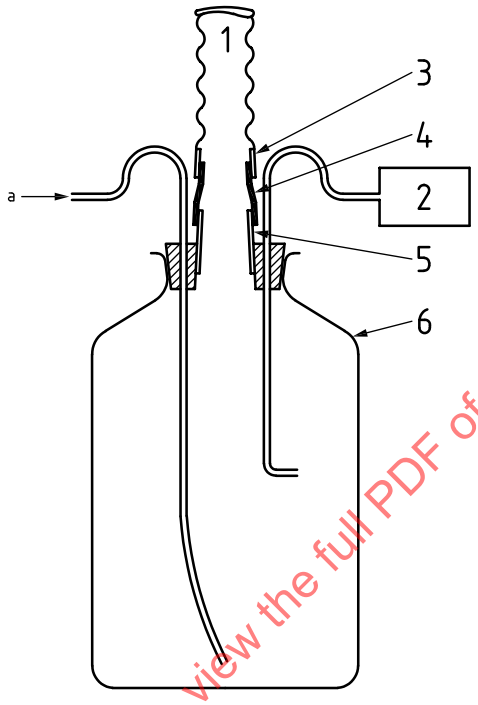
F.4.1 Condition the test piece at a temperature of (23 ± 3) °C for at least 1 h prior to testing. Maintain this temperature during testing.

F.4.2 Set up the apparatus as shown in Figure F.1, but without the *breathing set* or *breathing tube* attached. Adjust the air flow rate to the flow stated in Table F.1 and maintain for 30 s. Record the reading (p_1) on the pressure-measuring device.

F.4.3 Fit the *breathing set* or *breathing tube*, including integral connectors if present, over the outlet of the buffer reservoir using an appropriate connector.

F.4.4 For *breathing tubes* intended to be extended when used, condition and test in the extended state.

F.4.5 For *breathing sets* and *breathing tubes* supplied in pairs securely attached to a *patient end adaptor*, occlude one opening of the tube at its *machine end*. Secure the free end of the tube being tested, so that it is held straight and not constricted.



Key

1 *breathing tube*
2 pressure-measuring device
3 adaptor with conical connector, if provided
4 conical connector
5 outlet
6 buffer reservoir
[a] Air from flow-controlling device.

Figure F.1 — Typical apparatus for measuring resistance to air flow

F.4.6 Test the *breathing set* or *breathing tube* according to its intended use.

Table F.1 — Test Flow Rates

Patient category	Intended delivered volume ml	Test flow l/min
Adult	≥ 300 ml	30
Paediatric	50 ml < 300 ml	15
Neonatal	≤ 50 ml	2,5

F.4.7 Adjust the air flow to that stated in Table F.1 and maintain it for 30 s. Record the reading (p_2) on the pressure-measuring device.