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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

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).

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).

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.

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 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.

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.

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*.

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 male 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*

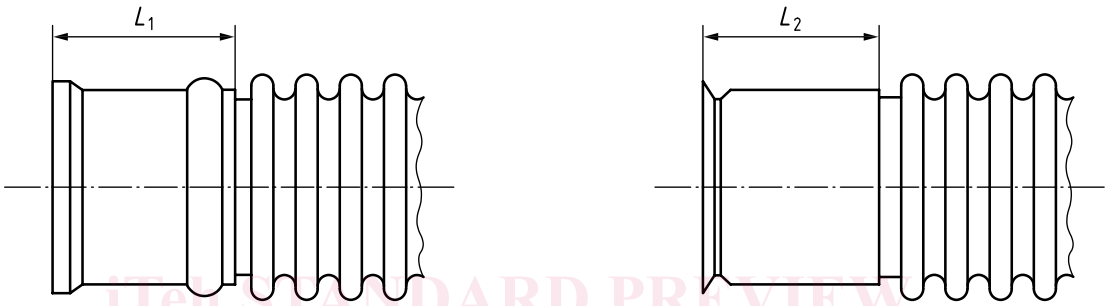
Check conformance by inspection.

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*

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 female cone 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.

Table 1 — Breathing tube end specifications

Cone size (mm)	Axial lengths		Axial force (N)
	l1 (mm)	l2 (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			

6.4 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 clause 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
NOTE See Annex H.			

Table 5 *(continued)*

Patient category	Intended delivered volume	Compliance limit ml/hPa/m (ml/ cmH_2O /m)	At pressure hPa (cmH_2O)
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.