INTERNATIONAL STANDARD

ISO 5367

Fourth edition
2000-06-01

Breathing tubes intended for use with anaesthetic apparatus and ventilators

Tuyaux de ventilation destinés à être utilisés avec des appareils d'anesthésie et des ventilateurs

Reference number
ISO 5367:2000(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 734 10 79
E-mail copyright@iso.ch
Web www.iso.ch

Printed in Switzerland

Contents

Page

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 5367 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Tracheal tubes and other equipment*.

This fourth edition cancels and replaces the third edition (ISO 5367:1991), which has been technically revised. This edition differs from the previous edition primarily in that all sizes of breathing tubes are included and that each tube is required to be marked with the rated flow that the manufacturer claims can be achieved without exceeding specified limits for resistance.

Annexes A, B, C, D, E and F form a normative part of this International Standard. Annex G is for information only.

Introduction

This International Standard is one of a series dealing with anaesthetic and respiratory equipment. It is primarily concerned with basic requirements for breathing tubes. Breathing tubes are characterized by the rated flow that a manufacturer claims can be achieved without exceeding specified limits for resistance. The requirements also include means of connection and several test methods, some of which have not been included in earlier editions of this International Standard.

This International Standard includes requirements for both single-use and re-usable breathing tubes. Re-usable breathing tubes are intended to comply with the requirements of this International Standard for the recommended product life.

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

Recommendations for materials and design are given in annex G.

Breathing tubes intended for use with anaesthetic apparatus and ventilators

1 Scope

This International Standard specifies basic requirements for antistatic and non-antistatic breathing tubes and breathing tubing supplied to be cut to length, intended for use with anaesthetic apparatus and ventilators, humidifiers and nebulizers. It also applies to breathing tubes and Y-pieces supplied already assembled and to those supplied as components and assembled in accordance with the manufacturers' instructions.

Provision is made for breathing tubes having ends incorporating adaptors with conical connectors (assembled ends) or with plain ends (either cylindrical or tapered).

Breathing tubes for special purposes, such as those used with ventilators having special compliance requirements and coaxial lumen tubes, are outside the scope of this International Standard.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 468, *Surface roughness — Parameters, their values and general rules for specifying requirements.*

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

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing.*

ISO 11607, *Packaging for terminally sterilized medical devices.*

IEC 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety.*

EN 556:1994, *Sterilization of medical devices — Requirements for medical devices to be labelled "STERILE".*

3 Terms and definitions

For the purposes of this International Standard, the following terms and definitions apply.

3.1
APL valve
adjustable pressure-limiting valve
pop-off valve
pressure-limiting valve which releases gas over an adjustable range of pressures

[ISO 4135]

3.2
breathing tube
non-rigid tube used to convey gases and/or vapours between components of a breathing system

[ISO 4135]

3.3
adaptor
specialized connector to establish functional continuity between otherwise disparate or incompatible components, one end of which is intended to be inserted into the end of a breathing tube, the other end having a conical connector complying with ISO 5356-1

3.4
assembled end
end of a breathing tube incorporating an adaptor

3.5
plain end
end of a breathing tube designed to fit directly over a male conical connector complying with ISO 5356-1

3.6
patient end
that end of the breathing tube which is intended to be connected to the Y-piece or other appropriate component near the patient

3.7
machine end
that end of the breathing tube which is intended to be connected to the anaesthetic workstation, ventilator or other breathing attachment furthest from the patient

3.8
anti-static
property of breathing tubes and any integrally attached components with electrical conductivity satisfying specified limits under the test conditions

3.9
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 an ambient atmospheric pressure

[ISO 4135]

3.10
patient connection port
that opening at the patient end of a breathing system intended for connection of a device such as a tracheal or tracheostomy tube connector, a face mask, a laryngeal mask airway or a cuffed oropharyngeal airway

[ISO 4135]

3.11
3-way breathing system connector
Y-piece
tubular connector with three ports, one of which is a patient connection port

[ISO 4135]

3.12
swivel 3-way breathing connector
swivel Y-piece
specialized three-way connector which allows variation in the position of its three ports relative to each other

[ISO 4135]

3.13
rated flow
flow that the manufacturer claims results in an increase in pressure of not more than that specified in 4.5.1 or 4.5.2, as appropriate

4 General requirements

4.1 Re-usable breathing tubes

Re-usable breathing tubes shall comply with the requirements of this International Standard throughout the recommended product life as specified in 8.2.

4.2 Materials

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

NOTE Recommendations for materials are given in annex G.

4.3 Design

Breathing tubes, whether of corrugated construction or otherwise, shall have plain ends (cylindrical or tapered) and/or assembled ends incorporating 22 mm or 15 mm conical connectors complying with ISO 5356-1.

NOTE 1 A loop for suspending the tube may be provided near one of the ends.

NOTE 2 The ends of breathing tubes may be constructed to engage with the recess at the base of a 22 mm male conical connector.

NOTE 3 Recommendations for design are given in annex G.

4.4 Length

4.4.1 The length of breathing tubes shall be designated by their nominal overall length, expressed in metres, when measured in the resting condition (without being held under tension), lying on a horizontal surface. Breathing tubes intended to be extended when used shall be designated by both the unextended and extended lengths.

4.4.2 The designated length of breathing tubes provided integrally attached to a Y-piece shall include the length of the Y-piece and any assembled ends.

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

4.5 Resistance to flow

4.5.1 The manufacturer shall determine the rated flow to be marked.

4.5.2 When a breathing tube supplied ready for use (with assembled ends and Y-piece, if provided) is tested in accordance with annex A using the rated flow marked by the manufacturer [see 7.2 d) and 7.3 d)], the increase in pressure shall not exceed 0,2 kPa.

4.5.3 When breathing tubing supplied to be cut to length is tested in accordance with annex A using the rated flow marked by the manufacturer [see 7.2 e) and 7.3 e)], the increase in pressure shall not exceed 0,1 kPa per metre length of tubing.

4.6 Means of connection

4.6.1 Plain ends of tubes

4.6.1.1 The axial length (l_1) of plain ends of breathing tubes [see Figure 1 a)], excluding those specified in 4.6.1.2, 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.

4.6.1.2 The axial length (l_2) of 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.

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

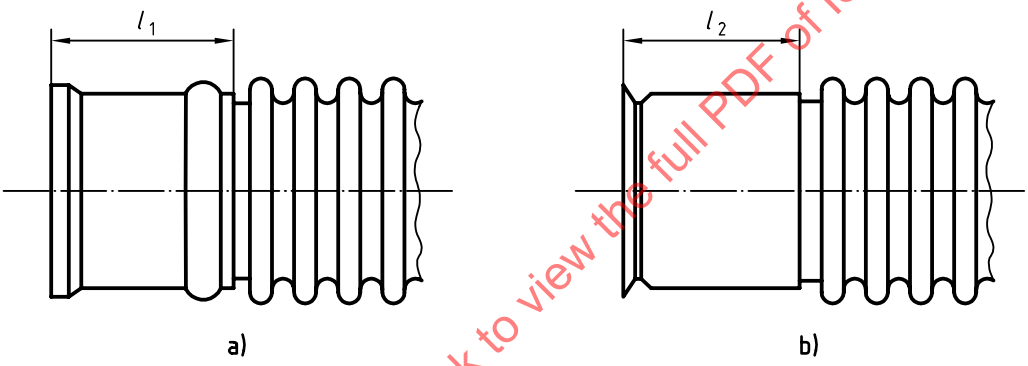


Figure 1 — Axial length of plain end of breathing tube

4.6.2 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.

4.6.3 Assembled end

When tested as described in annex C, the adaptor shall not become detached from the tube at a force of less than 45 N.

NOTE For the purpose of this requirement, a Y-piece provided integrally attached to a breathing tube is regarded as an adaptor.

4.6.4 Breathing tubes integrally attached to a Y-piece

If breathing tubes are supplied in pairs integrally attached to a Y-piece, the patient connection port of that Y-piece shall be a 22 mm male/15 mm female coaxial or 15 mm female conical connector complying with ISO 5356-1.

4.7 Leakage

4.7.1 When tested in accordance with annex D, breathing tubing supplied to be cut to length shall not leak at a rate of more than 10 ml·min^{-1} per metre length of tubing.

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

4.7.2 When tested in accordance with annex D, single breathing tubes shall not leak at a rate of more than 25 ml·min^{-1}.

4.7.3 When tested in accordance with annex D, breathing tubes supplied in pairs integrally attached to a non-swivel Y-piece, shall not leak at a rate of more than 50 ml·min^{-1}.

4.7.4 Breathing tubes with integrally attached specialized adaptors, e.g. a swivel Y-piece, shall either:

a) not leak at a rate of more than 50 ml·min^{-1} when tested in accordance with annex D, or

b) be marked with the leakage rate determined in accordance with annex D [see 7.2 f) and 7.3 f)].

4.7.5 Breathing tubes marked in accordance with 4.7.4 b) shall have a marked leakage rate of not more than 150 ml·min^{-1}.

4.7.6 The actual leakage rate of breathing tubes marked in accordance with 4.7.4 b) shall not be more than 10 % greater than the marked leakage rate.

4.8 Increase in flow resistance with bending

When tested in accordance with annex E, the pressure at the rated flow when the breathing tube is suspended over the metal cylinder shall not exceed 150 % of the value obtained with the tube straight.

4.9 Compliance

The compliance of breathing tubes at a pressure of 6 kPa shall not exceed 10 ml·kPa^{-1} per metre length of tube when tested in accordance with annex F.

5 Prevention of electrostatic charges

5.1 Antistatic breathing tubes and any integrally attached components [see 7.2 c)] shall comply with the requirements for prevention of electrostatic charges specified in subclause 39.3 b) of IEC 60601-1:1988.

5.2 Breathing tubes coloured black shall be antistatic and comply with 5.1.

6 Requirements for breathing tubes supplied sterile

6.1 Sterility assurance

Breathing tubes supplied and marked “STERILE” shall satisfy the requirements of 4.1 of EN 556:1994.

6.2 Packaging of breathing tubes supplied sterile

6.2.1 Breathing tubes supplied and marked “STERILE” shall be contained in an individual pack.

6.2.2 The pack shall serve as an effective barrier to the penetration of microorganisms and particulate matter in accordance with ISO 11607.

6.2.3 The pack shall not permit reclosure without clearly revealing that it has been opened.

7 Marking

7.1 General

Marking of breathing tubes, unit packs and shelf or multi-unit packs, and information to be supplied by the manufacturer should comply with EN 1041.

The requirements of 7.2 and 7.3 may be met by use of the appropriate symbols as given in ISO 7000 and EN 980.

7.2 Marking of breathing tubes intended for re-use

Breathing tubes intended for re-use shall be legibly and durably marked with the following information:

a) the name and/or trademark of the manufacturer and/or supplier;

b) the batch number;

c) for breathing tubes and integrally attached non-metallic components made of antistatic materials, the word “ANTISTATIC”;

NOTE They may also bear a continuous indelible yellow-coloured marking throughout their length.

d) for breathing tubes supplied ready for use, the rated flow, expressed in accordance with 7.4 and marked in accordance with the following example:

   30 l·min^{-1}, $\leqslant$ 0,2 kPa

e) for breathing tubing supplied to be cut to length, the rated flow per metre length of tube, expressed in accordance with 7.4 and marked in accordance with the following example:

   30 l·min^{-1}, $\leqslant$ 0,1 kPa·m^{-1}.

f) for breathing tubes to be marked in accordance with 4.7.4 b), the leakage rate, expressed as millilitres per minute.

7.3 Marking of packages

Packages containing breathing tubes intended for single use shall be marked with the information given in 7.2. If appropriate, a ‘use-by’ date should be given.

Packages shall additionally be clearly marked with the following:

a) the word “STERILE” if appropriate;

b) the words “single use” or equivalent, if appropriate;

c) the designated length, in accordance with 4.4;

d) for breathing tubes supplied ready for use, the rated flow, expressed in accordance with 7.4 and marked in accordance with the following example:

30 l·min^{-1}, $\leqslant$ 0,2 kPa

e) for breathing tubing supplied to be cut to length, the rated flow per metre length of tube, expressed in accordance with 7.4 and marked in accordance with the following example:

30 l·min^{-1}, $\leqslant$ 0,1 kPa·m^{-1}.

f) for breathing tubes to be marked in accordance with 4.7.4 b), the leakage rate expressed as millilitres per minute.

7.4 Expression of rated flow

Rated flows of less than 10 l·min^{-1} shall be expressed to the nearest 0,5 l·min^{-1}.

Rated flows of 10 l·min^{-1} to 30 l·min^{-1} shall be expressed to the nearest 1 l·min^{-1} .

Rated flows of greater than 30 l·min^{-1} shall be expressed to the nearest 5 l·min^{-1}.

8 Information to be supplied by the manufacturer

8.1 The manufacturer shall, when requested, provide information on the recommended maximum working temperature of the breathing tube when attached to a heated humidifier.

8.2 Unless the breathing tube is 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 re-uses.

Annex A
(normative)

Measurement of resistance to air flow

A.1 Principle

The resistance to air flow is tested by measuring the pressure increase at the rated flow through the breathing tube.

A.2 Test piece

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

A.3 Apparatus

A.3.1 Flow-measuring device, capable of measuring the rated flow of the breathing tube or the breathing tubing, and having an accuracy of ± 2,5 %.

A.3.2 Pressure-measuring device, having an accuracy of ± 0,01 kPa.

A.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 top of the jar (see Figure A.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 (A.3.2) shall be placed in the jar halfway between the gas inlet and gas outlet.

NOTE Any transition in inside diameter between the outlet and the connector, if provided, and the breathing tube should be smooth to minimize turbulence of flow.

A.4 Procedure

A.4.1 Breathing tubes intended to be extended when used shall be tested in the extended state.

A.4.2 Carry out the test procedure at a temperature of (23 ± 2) °C after conditioning the breathing tube, or 1 m length of breathing tubing, at this temperature for at least 1 h.

A.4.3 Set up the apparatus (A.3.3) as shown in Figure A.1, but without the breathing tube attached. Adjust the air flowrate to the rated flow stated by the manufacturer and maintain for 30 s (A.3.1). Record the reading (p_1) on the pressure-measuring device (A.3.2).

A.4.4 Fit the breathing tube, including integral connectors if present, over the outlet of the buffer reservoir (A.3.3) using an appropriate connector. For breathing tubes supplied in pairs integrally attached to a Y-piece, occlude one limb at its machine end. Secure the free end of the tube being tested, so that it is held straight and not constricted.

A.4.5 Adjust the air flowrate to the rated flow stated by the manufacturer and maintain it for 30 s. Record the reading (p_2) on the pressure-measuring device (A.3.2).

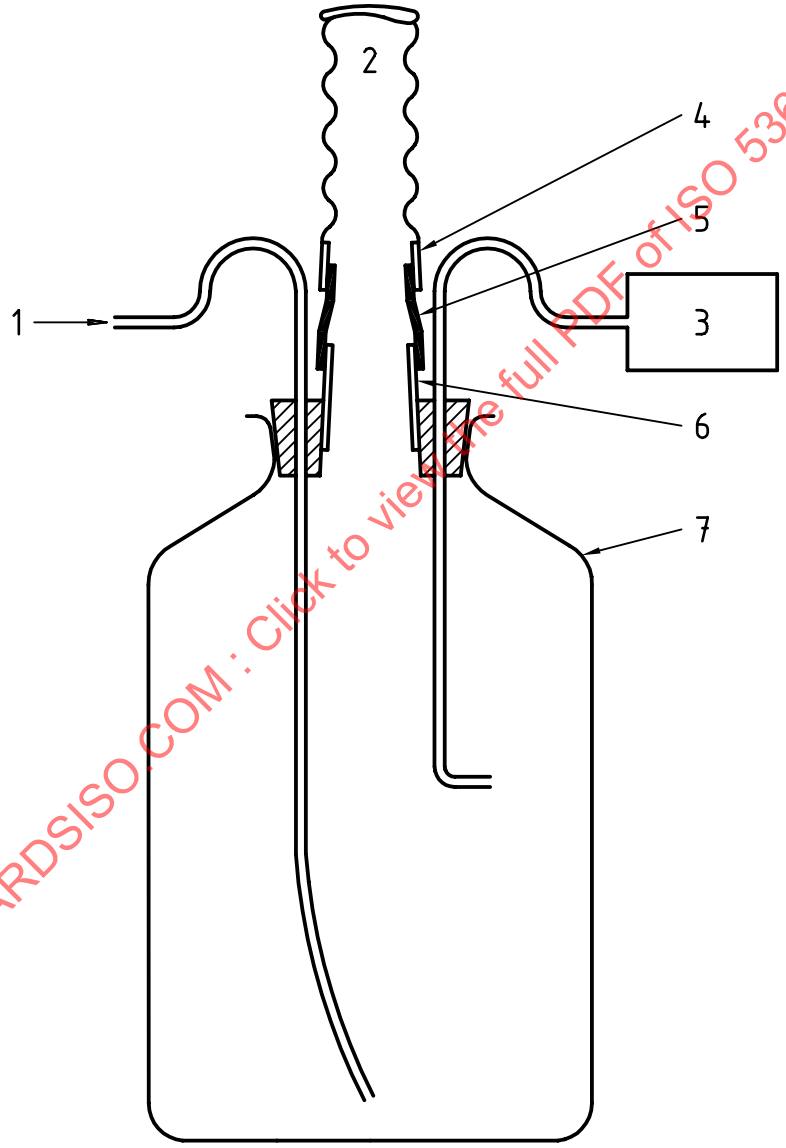
A.4.6 Calculate the increase in pressure due to the breathing tube ($p_2 - p_1$), expressed in kilopascals, and record the value.

A.4.7 For breathing tubes supplied in pairs integrally attached to a Y-piece, repeat the procedure given in A.4.4 to A.4.6 using the second limb with the first limb occluded at its machine end. Record the higher of the values for the two limbs tested.

A.5 Expression of results

For breathing tubes supplied ready for use, express the increase in pressure ($p_2 - p_1$) in kilopascals.

For breathing tubing supplied to be cut to length, express the increase in pressure ($p_2 - p_1$) in kilopascals per metre length of tubing.



Key

1 Air from flow-measuring device
2 Breathing tube
3 Pressure-measuring device
4 Adaptor with conical connector, if provided
5 Conical connector
6 Outlet
7 Buffer reservoir

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

Annex B
(normative)

Test for security of attachment of plain end to appropriately-sized male conical connector

B.1 Principle

The security of attachment of a plain-ended breathing tube to an appropriately-sized male conical connector 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.

B.2 Test piece

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

B.3 Apparatus

B.3.1 **Means of applying a tensile load**, of not less than 40 N, at a rate of (50 ± 5) mm·min^{-1} along the linear axis of the tube at least 150 mm from the end of the tube.

B.3.2 **Means of measuring the applied tensile load** (B.3.1), with an accuracy of ± 2 N.

B.3.3 **A 22 mm or 15 mm male conical test connector**, as appropriate, made of metal with 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) when determined in accordance with the requirements specified in ISO 468.

B.4 Procedure

B.4.1 Carry out the test procedure at a temperature of (42 ± 3)°C after conditioning the breathing tube at this temperature and at not less than 80 % relative humidity for at least 1 h.

B.4.2 Engage the end of the breathing tube over the test connector (B.3.3) by wetting the end in distilled water and fitting it over the test connector so that the entire axial length of the connector is covered. Secure the conical test connector.

B.4.3 Apply a tensile load (B.3.1) at a rate of (50 ± 5) mm·min^{-1} at a point not less than 150 mm from the end of the tube, along the linear axis of the tube, and note whether the tube becomes detached from the male conical test connector at a force of less than 40 N.

Annex C
(normative)

Test for security of attachment of adaptor to breathing tube

C.1 Principle

The security of attachment of an adaptor to a breathing tube is tested by applying a tensile load along the linear axis of the assembled end and noting whether the adaptor becomes detached from the body of the breathing tube at a specified force.

C.2 Test piece

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

C.3 Apparatus

C.3.1 Means of securing the adaptor of the assembled end of the breathing tube, so that the adaptor is not distorted and withstands a tensile load of > 45 N applied for 1 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 (C.3.3), with an accuracy of ± 2 N.

C.3.3 Means of applying a tensile load, of not less than 45 N at a rate of (50 ± 5) mm·min^{-1} along the linear axis of the assembled end of the tube.

C.4 Procedure

C.4.1 Carry out the test procedure at a temperature of (42 ± 3) °C after conditioning the breathing tube at this temperature and at not less than 80 % relative humidity for at least 1 h.

C.4.2 Secure the adaptor (C.3.1) so that the part incorporated into the breathing tube is not distorted.

C.4.3 Apply a tensile load (C.3.3) at a rate of (50 ± 5) mm·min^{-1} at a point not less than 150 mm from the end of the tube along the linear axis of the tube, and note whether the tube becomes detached from the adaptor at a force of less than 45 N.

Annex D
(normative)

Test for leakage

D.1 Principle

Leakage is tested by applying and maintaining an internal gas pressure by introducing air into a tube, 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 breathing tubes 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 male conical connector.

D.2 Test piece

The test is carried out on a breathing tube.

D.3 Apparatus

D.3.1 **Means of applying and maintaining an internal gas pressure** of (6 ± 0,3) kPa.

D.3.2 **Means of conditioning the breathing tube** and carrying out the test procedure at a temperature of (23 ± 2) °C.

D.3.3 **Means of recording the flowrate of air** required to maintain the specified internal gas pressure in the tube being tested, accurate to within ± 5 % of the flowrates indicated in 4.7.

D.3.4 **An appropriately-sized male conical test connector**, as in B.3.3.

D.4 Procedure

D.4.1 Breathing tubes intended to be extended when used shall be tested in the extended state.

D.4.2 For breathing tubing supplied to be cut to length, cut a suitable length of not less than 1 m as the test piece.

D.4.3 Carry out the test procedure at a temperature of (23 ± 2) °C after conditioning the breathing tube at this temperature for at least 1 h.

D.4.4 Engage the end of the single breathing tube, or length of breathing tubing, over the test connector as in B.4.2, closing off one end.

D.4.5 If testing breathing tubes supplied in pairs integrally attached to a Y-piece, engage the end of one limb of the breathing tube over the test connector as in B.4.2, occluding the other two openings and APL valve, if fitted.

D.4.6 Apply an internal gas pressure (D.3.1) of (6 ± 0,3) kPa by introducing air into the breathing tube and allow the pressure to stabilize. Record the flowrate of air (D.3.3) required to maintain that internal gas pressure.

D.5 Expression of results

D.5.1 Express the flowrate of air required to maintain the specified internal gas pressure in millilitres per minute.

D.5.2 For breathing tubing supplied to be cut to length, express the result in millilitres per minute per metre length of tubing.