INTERNATIONAL STANDARD

ISO 5367

Third edition
1991-08-01

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

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Reference number
ISO 5367:1991(E)

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.

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.

International Standard ISO 5367 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*.

This third edition cancels and replaces the second edition (ISO 5367:1985), of which it constitutes a minor revision.

Annex A forms an integral part of this International Standard. Annex B is for information only.

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Breathing tubes intended for use with anaesthetic apparatus and ventilators

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1 Scope

This International Standard specifies the basic requirements for breathing tubes intended for use with anaesthetic apparatus and most 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 manufacturer's instructions.

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

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

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 468:1982, *Surface roughness — Parameters, their values and general rules for specifying requirements.*

ISO 2882:1979, *Rubber, vulcanized — Antistatic and conductive products for hospital use — Electrical resistance limits.*

ISO 5356-1:1987, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets.*

3 Definitions

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

3.1 breathing tube: Non-rigid tube, usually corrugated, used to convey gases and/or vapours between the anaesthetic machine and/or humidifiers/nebulizers and/or some ventilators.

NOTE 1 A breathing tube is usually described as having two ends and a body.

3.2 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.

3.3 machine end: That end of the breathing tube which is intended to be connected to the anaesthetic machine or ventilator.

3.4 antistatic (conductive): Pertaining to breathing tubes and any integrally attached components with electrical conductivity satisfying specified limits under the test conditions.

3.5 non-conductive: Pertaining to breathing tubes and any integrally attached components with insufficient electrical conductivity to meet specified limits under the test conditions.

3.6 compliance: Volume added per unit pressure increase when gas is added to an enclosed space and that added volume is expressed at the temperature and humidity in that enclosed space and at an ambient atmospheric pressure.

3.7 patient connection port: That opening at the patient end of a breathing system intended for connection to a tracheal or tracheostomy tube connector or adaptor, a face mask or a face mask angle-piece.

3.8 3-way breathing system connector (T- or Y-piece): Tubular connector for use within a breathing

system with a patient connection port and two ports for connection to the breathing system.

4 Design

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

NOTES

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

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

4 Recommendations for materials are given in annex B.

5 Dimensions

5.1 Length

The length of breathing tubes shall be designated by their nominal overall length, expressed in metres, when measured in the unstretched condition. The actual length shall be within 10 % of the designated length.

5.2 Inside diameter

Except for smooth bore breathing tubes, the inside diameter of the body of the tube shall be not less than 18 mm. For smooth bore breathing tubes, the inside of the tube body shall be not less than 15 mm.

There should be a smooth transition of the inside surface between the body of the breathing tube and the ends to minimize gas turbulence.

6 Resistance to flow

When tested as described in A.2, the resistance to the flow of air through a breathing tube shall not exceed 100 Pa (1,0 cmH_2O) per metre length of tube at 60 l/min.

7 Means of connection

7.1 Plain ends

7.1.1 The inside diameter of plain ends of breathing tubes, excluding those specified in 7.1.2, shall be not less than 18 mm and the axial length shall be not less than 21 mm, when measured in the unstretched condition.

7.1.2 The inside diameter of plain ends of breathing tubes that incorporate an internal ridge, intended to engage with the recess at the base of a 22 mm male conical connector, as shown in figure 3 a) of ISO 5356-1:1987, shall be not less than 18 mm, excluding the ridge. The axial length shall be not less than 26,5 mm, when measured in the unstretched condition.

7.1.3 When tested as described in A.3, plain ends of breathing tubes shall not become detached from the 22 mm male conical connector.

7.2 Assembled ends

When tested as described in A.4, the conical connector shall not become detached from the tube.

7.3 Breathing tubes permanently attached to a Y-piece

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

7.4 Freedom from leakage

For single breathing tubes and for breathing tubes supplied in pairs permanently attached to a non-swivel Y-piece, when tested as described in A.5, there shall be no escape of air bubbles.

NOTE 5 Requirements for leakage from breathing tubes attached to swivel Y-pieces are under consideration. It is intended to include them in a future revision of this International Standard.

8 Occlusion

When tested as described in A.6, the increase in pressure at the point of application of the air flow shall not exceed 1 kPa.

9 Information to be supplied by manufacturer

9.1 The manufacturer shall, when requested, provide information to the user on the compliance of the breathing tube.

NOTE 6 A suitable method for measuring compliance is given in A.7.

The compliance of breathing tubes varies according to sterilization processes, usage and storage conditions. The compliance of a new tube at a pressure of 10 kPa (100 cmH_2O) should not exceed 8 ml/kPa (0,8 ml/cmH_2O) per metre length of tube.

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9.2 For breathing tubes intended for re-use, the manufacturer shall, when requested, provide information to the user on the resistance to flow of the breathing tube per metre length of tube at a flow of 60 l/min and the resistance to flow of the tube supplied at a flow of 60 l/min.

NOTE 7 For breathing tubes intended for single use, see 11.2 d).

9.3 Unless the breathing tube is intended and labelled as being for single use, the manufacturer shall recommend methods of cleaning and disinfection or sterilization.

10 Electrical conductivity

The electrical conductivity of breathing tubes and any integrally attached components made of conductive material that are intended for use with flammable anaesthetics shall comply either with ISO 2882 or with the requirements of the appropriate national authorities.

11 Marking

11.1 Marking of breathing tubes

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

a) The name and/or trademark of the manufacturer.

b) An identification reference to the batch or date of manufacture.

c) For breathing tubes and integrally attached non-metallic components made of antistatic (conductive) materials, the word "ANTISTATIC".

NOTE 8 They may also bear a continuous indelible yellow-coloured line throughout their length.

d) For black breathing tubes and black components made of non-conductive materials, the word "NON-CONDUCTIVE".

The marking should be resistant to the methods of cleaning and disinfection or sterilization recommended by the manufacturer (see 9.3).

11.2 Marking of packages

Packages containing breathing tubes intended for single use shall be marked with the information given in 11.1 and shall additionally be clearly marked with the following:

a) The words "STERILE" or "NON-STERILE", as appropriate.

b) Words indicating "for single use" or marking in accordance with the requirements of the relevant national regulatory authority.

NOTE 9 Symbol No. 1051 given in ISO 7000:1989, *Graphical symbols for use on equipment — Index and synopsis* may additionally be used.

c) The designated length, in accordance with 5.1.

d) The resistance to flow per metre length of tube at a flow of 60 l/min and the resistance to flow of the tube supplied at a flow of 60 l/min.

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Annex A
(normative)

Test methods

A.1 General conditions for test

Tests shall be conducted at 35 °C ± 2 °C after the breathing tubes have been conditioned at this temperature for at least 1 h.

A.2 Resistance to air flow

A.2.1 Apparatus

A.2.1.1 Flow-measuring device, capable of measuring flows of up to 70 l/min and having an accuracy of ± 5 %.

A.2.1.2 Pressure-measuring device, having an accuracy of ± 10 Pa (± 0,1 cmH_2O).

A.2.1.3 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 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.2.1.2) shall be placed in the jar half-way between the gas inlet and gas outlet.

A.2.2 Procedure

A.2.2.1 Set up the apparatus as shown in figure A.1, but without the breathing tube attached. Adjust the air flow to 60 l/min and hold for 30 s. Record the reading on the pressure-measuring device and determine the resistance to flow of the test apparatus.

A.2.2.2 For single breathing tubes, measure the length of the breathing tube in the unstretched condition. For breathing tubes supplied in pairs permanently attached to a Y-piece, measure the length of one tube in the unstretched condition and occlude the other tube. Fit the breathing tube, including integral connectors if present, over the 22 mm male conical connector. Secure the free end of the breathing tube ensuring that it is not constricted.

A.2.2.3 Adjust the air flow to 60 l/min and hold it for 30 s. Record the reading on the pressure-measuring device.

A.2.2.4 Subtract from the pressure reading the resistance of the test apparatus obtained in A.2.2.1 and determine the resistance to flow per metre length of tube by dividing the resistance obtained by the length of the breathing tube expressed in metres.

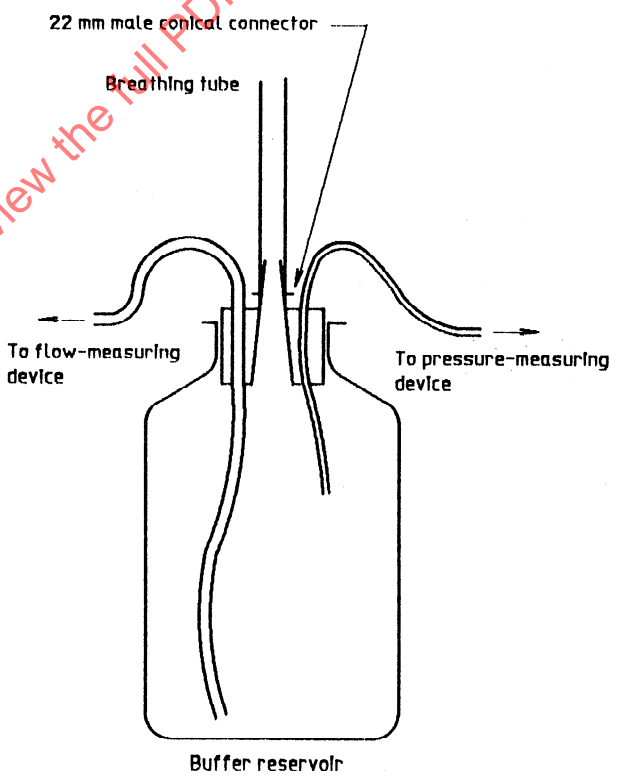

Figure A.1 — Apparatus for measuring resistance to air flow

A.2.2.5 For breathing tubes supplied in pairs permanently attached to a Y-piece, repeat the procedure given in A.2.2.2 to A.2.2.4 using the second breathing tube with the first breathing tube occluded.

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A.3 Disengagement of plain ends

A.3.1 Wet the end with distilled water and engage it with a 22 mm male conical connector made of metal, dimensioned as specified in ISO 5356-1 and having a surface roughness of 0,8 µm (roughness number N6) when determined as specified in ISO 468. Engagement shall be beyond the major diameter of the conical connector.

NOTE 10 Strictly, it should also be necessary to specify the engagement force. For the purpose of this test, however, such a requirement was not considered to be readily practicable and engagement with the conical connector should be by hand, as in normal clinical practice.

A.3.2 Apply a tensile load of 40 N for 1 min along the linear axis of the tube at least 250 mm from the end of the tube and note whether the tube becomes disengaged from the conical connector.

A.4 Security of assembled ends

A.4.1 Secure the assembled end of the breathing tube such that the connector is not distorted.

A.4.2 Apply a tensile load of 100 N for 1 min along the linear axis of the tube at least 250 mm from the end of the tube and note whether the connector becomes detached from the tube.

A.5 Leakage

A.5.1 Wet the end with distilled water and engage it with a 22 mm male conical connector as described in A.3.1.

A.5.2 If testing breathing tubes supplied in pairs permanently attached to a non-swivel Y-piece, occlude the tube that is not under test.

A.5.3 Immerse the connection in water to a depth of 50 mm and apply an internal gas pressure of 10 kPa ± 0,5 kPa (100 cmH_2O ± 5 cmH_2O). Hold this pressure for 5 min and observe whether any bubbles escape from the connection.

A.5.4 For breathing tubes supplied in pairs permanently attached to a Y-piece, repeat the procedure given in A.5.1 to A.5.3 using the second breathing tube with the first breathing tube occluded.

A.6 Occlusion

A.6.1 Apparatus

A.6.1.1 Metal cylinder, having a diameter of 2,5 cm.

A.6.1.2 Pressure-measuring device, as specified in A.2.1.2.

A.6.2 Procedure

A.6.2.1 Connect the pressure-measuring device to one end of the breathing tube. Suspend at least 1 m of the tube over the metal cylinder and suspend masses from each end of the tube just sufficient to maintain the tube in continuous contact with the cylinder.

A.6.2.2 Introduce an air flow of 60 l/min into the tube at the end at which the pressure-measuring device is connected and record the resulting increase in pressure.

A.7 Compliance

A.7.1 Block one end of the breathing tube and provide a means of injecting a known volume of air at the other end.

A.7.2 Mount the tube in such a manner so as not to impede movement, for example by floating it on water.

A.7.3 Inflate the tube with a known volume of air to a gauge pressure of 10 kPa ± 0,5 kPa (100 cmH_2O ± 5 cmH_2O).

A.7.4 Record the volume of air required to achieve a stable internal pressure.

A.7.5 Measure the overall length of the tube at the ambient pressure.

A.7.6 Determine the compliance of the tube expressed as millilitres per kilopascal (or millilitres per centimetre of water) per metre length.

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Annex B
(informative)

Recommendations for materials

B.1 Breathing tubes should be made of materials which are reasonably resistant to anaesthetic agents.

B.2 Unless designated and marked as being for single use, breathing tubes should be resistant to ordinary methods of cleaning, disinfection and sterilization, as recommended by the manufacturer or supplier. It is desirable that breathing tubes not intended for single use should withstand accepted methods of steam sterilization.

NOTE 11 Attention is drawn to the absorption of volatile anaesthetic agents and other substances by breathing tubes. These agents and substances may be subsequently liberated and may pose a hazard. Also, for breathing tubes of a laminated construction, there is a risk of internal delamination and bubble formation when they are exposed to volatile anaesthetic agents.

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