BRITISH STANDARD

BS EN
12342:1998

Incorporating
Corrigendum No. 1

Breathing tubes intended for use with anaesthetic apparatus and ventilators

The European Standard EN 12342:1998 has the status of a British Standard

ICS 11.040.10

National foreword

This British Standard is the English language version of EN 12342:1998. It supersedes BS 6151:1992 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/45, Tracheal tubes and related equipment, which has the responsibility to:

— aid enquirers to understand the text;

— present to the responsible European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;

— monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this committee can be obtained on request to its secretary.

Cross-references

The British Standards which implement international or European publications referred to in this document may be found in the BSI Standards Catalogue under the section entitled "International Standards Correspondence Index", or by using the "Find" facility of the BSI Standards Electronic Catalogue.

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This British Standard, having been prepared under the direction of the Health and Environment Sector Board, was published under the authority of the Standards Board and comes into effect on 15 November 1998

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Amendments issued since publication

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10395 Corrigendum	December 1998	Annex I, renumbered as Annex ZA

Summary of pages

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 12342

June 1998

ICS 11.040.10

English version

Breathing tubes intended for use with anaesthetic apparatus and ventilators

Tubes (tuyaux) respiratoires destinés à être utilisés avec des appareils d'anesthésie et des ventilateurs

Atemschläuche zur Verwendung mit Anästhesie- und Beatmungsgeräten

This European Standard was approved by CEN on 30 May 1998.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart 36, B-1050 Brussels

Ref. No. EN 12342:1998 E

Foreword

This European Standard has been prepared by Technical Committee CEN/TC 215, Respiratory and anaesthetic equipment, the Secretariat of which is held by BSI.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative annex ZA, which is an integral part of this standard.
This European Standard is based on the reference standard ISO 5367, *Breathing tubes intended for use with anaesthetic apparatus and ventilators*. It differs from ISO 5367 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 are normative.
Annexes G, H and ZA are for information only.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by December 1998, and conflicting national standards shall be withdrawn at the latest by December 1998.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Contents

Introduction

This European Standard is one of a package dealing with anaesthetic and respiratory equipment. It is primarily concerned with basic requirements for breathing tubes, including those breathing tubes used with 8,5 mm connectors. 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 methods of test, some of which have not been included in previous International Standards.

Recommendations for materials and design are given in annex G.

1 Scope

This European Standard specifies the basic requirements for 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 European Standard.

Unless specified otherwise, the requirements of this European Standard apply equally to breathing tubes intended by the manufacturer for single use and those intended for re-use.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

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

EN 868-1, *Packaging materials and systems for medical devices which are to be sterilized — Part 1: General requirements and test methods.*

EN 980, *Graphical symbols for use in the labelling of medical devices.*

EN 1281-1, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets.*

EN 30993-1, *Biological evaluation of medical devices – Part 1: Guidance on selection of tests.*
(ISO 10993-1:1992 + Technical Corrigendum 1:1992)

EN 60601-1:1990, *Medical electrical equipment — Part 1: General requirements for safety.*
(IEC 601-1:1988)

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

3 Definitions

For the purposes of this European Standard, the following 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
[EN ISO 4135:1996]

3.2

breathing tube

non-rigid tube used to convey gases and/or vapours between an anaesthetic machine and/or some ventilators, and a patient
[EN ISO 4135:1996]

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 EN 1281-1

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 EN 1281-1

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

antistatic

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
[EN ISO 4135:1996]

3.10

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
[**5.2.2** of EN ISO 4135:1996]

3.11

3-way breathing system connector; T- or Y-piece

3-way tubular connector for use within a breathing system with a patient connection port and two ports for connection to the breathing system
[EN ISO 4135:1996]

3.12

swivel 3-way breathing connector; swivel Y-piece

Specialized 3-way connector which allows variation in the position of its three ports relative to each other
[EN ISO 4135:1996]

3.13

rated flow

flow that the manufacturer claims results in an increase in pressure of not more than that specified in **7.1** or **7.2**, as appropriate

4 Materials

Breathing tubes, in their ready-for-use state after any preparation recommended by the manufacturer, shall satisfy appropriate biological safety testing, as indicated in EN 30993-1.

5 Design

Breathing tubes, whether of corrugated construction or otherwise, shall have plain ends (cylindrical or tapered) and/or assembled ends incorporating 22 mm, 15 mm or 8,5 mm conical connectors complying with EN 1281-1.

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

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

NOTE 3 Recommendations for materials and design are given in annex G.

6 Length

6.1 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.

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

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

7 Resistance to flow

7.1 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 [see **15.2**d) and **15.3**d)], the increase in pressure shall not exceed 0,2 kPa (2,0 cmH_2O).

7.2 When breathing tubing supplied to be cut to length is tested in accordance with annex A using the rated flow [see **15.2**e) and **15.3**e)], the increase in pressure shall not exceed 0,1 kPa (1,0 cmH_2O) per metre length of tubing.

8 Means of connection

8.1 Plain ends of tubes

8.1.1 The axial length of plain ends of breathing tubes, excluding those specified in **8.1.2**, when measured in the resting condition, shall be not less than 21 mm for breathing tubes intended to engage with 22 mm conical connectors, not less than 14 mm for breathing tubes intended to engage with 15 mm conical connectors, or not less than 8 mm for breathing tubes intended to engage with 8,5 mm conical connectors.

8.1.2 The axial length 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 specified in EN 1281-1, shall be not less than 26,5 mm when measured in the resting condition.

8.1.3 When tested as described in annex B, plain ends of breathing tubes shall not become detached from the appropriate male conical connector.

8.2 Adaptor

The end of the adaptor which is not intended for attachment to the breathing tube shall have a 22 mm, 15 mm or 8,5 mm conical connector conforming to EN 1281-1.

8.3 Assembled end

When tested as described in annex C, the adaptor shall not become detached from the tube.

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

8.4 Breathing tubes permanently attached to a Y-piece

If breathing tubes 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 or 15 mm/8,5 mm male/female coaxial conical connector conforming to EN 1281-1.

9 Leakage

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

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

9.3 When tested in accordance with annex D, breathing tubes supplied in pairs permanently attached to a swivel Y-piece shall not leak at a rate of more than 75 $ml \cdot min^{-1}$.

NOTE Requirements for leakage from complete breathing systems including those systems incorporating breathing tubes with swivel Y-pieces are specified in EN 740.

10 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.

11 Compliance of breathing tubes

The compliance of breathing tubes at a pressure of 6 kPa (60 cmH_2O) shall not exceed 10 $ml \cdot kPa^{-1}$ (1 $ml \cdot cmH_2O^{-1}$) per metre length of tube when tested in accordance with annex F.

12 Information to be supplied by the manufacturer

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

12.2 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.

13 Electrical resistance

The electrical resistance of breathing tubes and any integrally attached components made of conductive material that are intended for use with flammable anaesthetics shall conform to the requirements for prevention of electrostatic charges specified in subclause **3.9.3**b) of EN 60601-1:1990.

14 Requirements for breathing tubes supplied sterile

14.1 Sterility assurance

Breathing tubes supplied and marked as "STERILE" shall satisfy the requirements of **4.1** of EN 556:1994 for the assurance of sterility needed to make the claim of being sterile.

14.2 Packaging of breathing tubes supplied sterile

14.2.1 Breathing tubes supplied and marked "STERILE" shall be contained in an individual pack.

14.2.2 The pack shall serve as an effective barrier to the penetration of micro-organisms and particulate matter in accordance with EN 868-1.

14.2.3 The pack shall permit the aseptic extraction of the contents and shall not permit reclosure without showing that it has been opened.

15 Marking

NOTE 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.

15.1 Use of symbols

The requirements of **15.2** and **15.3** shall be met either by the use of words or, if an appropriate symbol exists in EN 980, by the use of that symbol.

15.2 Marking of breathing tubes intended for re-use

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) the batch number;

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

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

d) for breathing tubes supplied ready for use, the rated flow, expressed in accordance with **15.4** and marked in accordance with the following example:

$30\ l \cdot min^{-1}, \leq 0{,}2$ kPa;

e) for breathing tubing supplied to be cut to length, the rated flow per metre length of tube, expressed in accordance with **15.4** and marked in accordance with the following example:

$30\ l \cdot min^{-1}, \leq 0{,}1\ kPa \cdot m^{-1}$.

15.3 Marking of packages containing breathing tubes intended for single use

Packages containing breathing tubes intended for single use shall be marked with the information given in **15.2**.

NOTE The "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;

c) the designated length, in accordance with clause **6**;

d) for breathing tubes supplied ready for use, the rated flow, expressed in accordance with **15.4** and marked in accordance with the following example:

$30\ l \cdot min^{-1}, \leq 0{,}2\ kPa$;

e) for breathing tubing supplied to be cut to length, the rated flow per metre length of tube, expressed in accordance with **15.4** and marked in accordance with the following example:

$30\ l \cdot min^{-1}, \leq 0{,}1\ kPa \cdot m^{-1}$.

15.4 Expression of rated flow

Rated flows of less than $10\ l \cdot min^{-1}$ shall be expressed to the nearest $0{,}5\ l \cdot min^{-1}$. Rated flows of $10\ l \cdot min^{-1}$ to $30\ l \cdot min^{-1}$ shall be expressed to the nearest $1\ l \cdot min^{-1}$. Rated flows of greater than $30\ l \cdot min^{-1}$ shall be expressed to the nearest $5\ l \cdot min^{-1}$.

Annex A (normative)
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

Breathing tube supplied ready for use, or 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 (±0,1 cmH_2O).

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 (see **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 the breathing tube or 1 m length of breathing tubing has been conditioned at this temperature for at least 1 h.

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

A.4.4 Fit the breathing tube, including integral connectors if present, over the outlet of the buffer reservoir (which may be fitted with an appropriate connector). For breathing tubes supplied in pairs permanently 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.

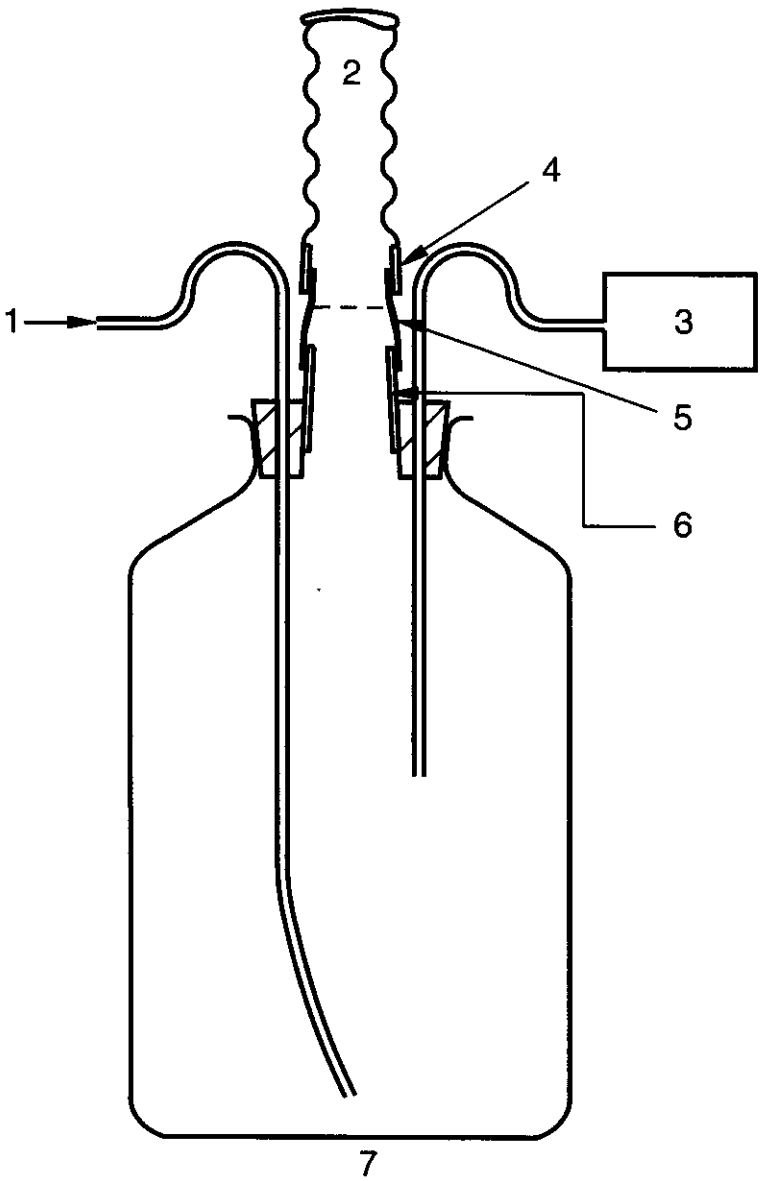
A.4.5 Adjust the air flow to the rated flow stated by the manufacturer and maintain it for 30 s. Record the reading on the pressure-measuring device (p_2).

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

A.4.7 For breathing tubes supplied in pairs permanently 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

Express the increase in pressure ($p_2 - p_1$) due to breathing tubes supplied ready for use in kPa. Express the increase in pressure ($p_2 - p_1$) due to breathing tubing supplied to be cut to length in kPa per metre length of tubing.



1 Air from flow measuring device
2 Breathing tube
3 Pressure measuring device
4 Adaptor with female conical connector, if provided
5 Male conical connector, if required
6 Outlet (tube)
7 Buffer reservoir

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

Annex B (normative)

Method of testing 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.

B.2 Test piece

Breathing tube with a plain end.

B.3 Apparatus

B.3.1 *Means of applying a tensile load,* of (40 ± 2) N at a rate of (50 ± 5) mm·min^{-1} and maintaining this load for 1 min along the linear axis of the tube at least 150 mm from the end of the tube.

B.3.2 *A 22 mm, 15 mm or 8,5 mm male conical connector as appropriate,* made of metal with recess in the case of a 22 mm connector, dimensioned as specified in EN 1281-1 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 at a temperature of (42 ± 3) °C after the breathing tube has been conditioned 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 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 connector.

B.4.3 Apply a tensile load of (40 ± 2) N at a rate of (50 ± 5) mm·min^{-1} and maintain this load for 1 min 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 connector.

Annex C (normative)

Method of testing 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.

C.2 Test piece

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 applying a tensile load,* of (45 ± 2) N at a rate of (50 ± 5) mm·min^{-1}, and maintaining that load for 1 min along the linear axis of the assembled end of the tube.

C.4 Procedure

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

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

C.4.3 Apply a tensile load of (45 ± 2) N at a rate of (50 ± 5) mm·min^{-1} and maintain that load for 1 min 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.

Annex D (normative)

Method of testing 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

Breathing tube.

D.3 Apparatus

D.3.1 *Means of applying and maintaining for 5 min an internal gas pressure*, of $(6 \pm 0{,}3)$ kPa $[(60 \pm 3)\ cmH_2O]$.

D.3.2 *Means of conditioning the breathing tube*, and carrying out the test procedure at a temperature of (42 ± 3) °C.

D.3.3 *Means of recording the flow of air*, required to maintain the specified internal gas pressure in the tube being tested, accurate to within ±5 % of the flows indicated in clause **9**.

D.3.4 *An appropriately sized male conical connector*, as in **B.3.2**.

D.4 Procedure

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

D.4.2 Carry out the test procedure at a temperature of (42 ± 3) °C after the breathing tube has been conditioned at this temperature for at least 1 h.

D.4.3 Engage the end of the single breathing tube over the test connector as in **B.4.2**, closing off one end.

D.4.4 If testing breathing tubes supplied in pairs permanently 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.4.5 Apply an internal gas pressure of $(6 \pm 0{,}3)$ kPa $[(60 \pm 3)\ cmH_2O]$ by introducing air into the breathing tube. Record the flow of air required to maintain that internal gas pressure.

D.5 Expression of results

The flow of air required to maintain the specified internal gas pressure shall be expressed in $ml \cdot min^{-1}$.

Annex E (normative)

Method of testing increase in flow resistance with bending

E.1 Principle

The resistance to air flow with the tube straight is determined as in annex A. The increase in flow resistance of a tube with bending is tested by suspending the tube over a metal cylinder of small diameter and attaching masses to the ends of the tube in order to maintain the breathing tube in contact with half the circumference of the cylinder. The rated flow stated by the manufacturer is introduced into the tube and the increase in pressure is noted.

E.2 Test piece

Breathing tube.

E.3 Apparatus

E.3.1 *Metal cylinder*, having a diameter of 2,5 cm.

E.3.2 *Pair of masses*, just sufficient to maintain the breathing tube in continuous contact over half the circumference of the metal cylinder (see **E.3.1**).

E.3.3 *Flow measuring device, pressure measuring device and buffer reservoir*, as specified in **A.3**.

E.3.4 *Means of introducing the rated air flow stated by the manufacturer*, at a temperature of (42 ± 3) °C and at not less than 80 % relative humidity into the end of the breathing tube.

E.4 Procedure

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

E.4.2 Carry out the test procedure at a temperature of (42 ± 3) °C after the breathing tube has been conditioned at this temperature and at not less than 80 % relative humidity for at least 1 h.

E.4.3 Connect the pressure measuring device to one end of the breathing tube.

E.4.4 With the tube held straight and not constricted, introduce the rated flow stated by the manufacturer at a temperature of (42 ± 3) °C and at not less than 80 % relative humidity into the tube at the end at which the pressure measuring device is connected. Record the pressure (p_1) after 30 s.

E.4.5 Suspend the breathing tube over the metal cylinder and attach masses from each end of the tube just sufficient to maintain the tube in continuous contact over half of the circumference of the metal cylinder.

E.4.6 Introduce the rated flow into the tube at the end at which the pressure measuring device is connected. Record the pressure (p_2) after 5 min.

E.5 Expression of results

Express p_2 as a percentage of p_1.

Annex F (normative)
Method of testing compliance

F.1 Principle

The compliance of the breathing tube is determined by inflating the tube to achieve a specified pressure and recording the volume of air required, after adjusting for any leakage as previously determined in annex D.

F.2 Test piece

Breathing tube.

F.3 Apparatus

F.3.1 *Means of inflating the tube with air,* to a gauge pressure of $(6 \pm 0{,}3)$ kPa [(60 ± 3) cmH_2O] and recording the volume of air required.

F.3.2 *Pressure measuring device,* as specified in **A.3.2.**

F.3.3 *Means of ensuring free movement along the length of tube* (e.g. a water bath in which to float the tube).

F.4 Procedure

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

F.4.2 Carry out the test procedure at a temperature of (23 ± 2) °C after the breathing tube has been conditioned at this temperature and at not less than 80 % relative humidity for at least 1 h.

F.4.3 Measure the overall length of the tube at the ambient pressure.

F.4.4 Block one end of the breathing tube and mount the tube in such a manner so as not to impede movement, for example by floating it on water.

F.4.5 Connect the pressure measuring device to the open end of the tube.

F.4.6 Inflate the tube with sufficient air to achieve a stable gauge pressure of $(6 \pm 0{,}3)$ kPa [(60 ± 3) cmH_2O] and record the volume of air required, taking into account the leakage (if any) previously determined in annex D.

F.5 Expression of results

Express the compliance of the tube in millilitres per kPa per metre length of tube.

Annex G (informative)
Recommendations for materials and design

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

NOTE Attention is drawn to the absorption of volatile anaesthetic agents and other substances by breathing tubes. These agents and substances can be subsequently liberated and can 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.

G.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. It is desirable that breathing tubes not intended for single use should withstand accepted methods of steam sterilization.

G.3 There should be a smooth transition of the inside surface between the body of the breathing tube and the ends to minimize gas turbulence.

Annex H (informative)
Bibliography

EN ISO 4135:1996, *Anaesthesiology — Vocabulary.* (ISO 4135:1995)

EN 740, *Anaesthetic workstations and their modules — Particular requirements.*

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

Annex ZA (informative)

Clauses of this European Standard addressing essential requirements or other provisions of EU Directives

This European Standard has been prepared under a mandate given to CEN/CENELEC by the European Commission and the European Free Trade Association and supports essential requirements of EU Directive 93/42/EEC.

WARNING: Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

The following clauses of this standard are likely to support requirements of Directive 93/94/EEC. Compliance with these clauses of this standard provides one means of conforming with the specific essential requirements of the Directive concerned and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and EU Directives

Clause/subclause of this European Standard	Corresponding essential requirement of Directive 93/42/EEC	Comments
4	1, 2, 3, 7.1, 7.2	
5	1, 2, 3, 4	
6	1, 2, 3, 13.3b)	
7	1, 2, 3, 4, 9.2	
8	1, 2, 3, 4, 7.5, 9.1	
9	1, 2, 3, 4, 7.5, 9.1, 9.2	
10	1, 2, 3, 4, 9.2	
11	1, 2, 3, 4, 9.2	
12	1, 2, 3, 13.1	
12.1	13.3j)	
12.2	8.1, 13.6h)	
13	1, 2, 3, 7.1, 7.3, 9.2, 9.3	
14	1, 2, 3, 8.1, 8.3	
14.1	8.4	
14.2	5, 7.2	
14.2.1	8.7	
15	1, 2, 3, 13.1, 13.3b)	
15.1	13.2, 13.3c), d), e), f), 13.4, 13.5	
15.2a)	13.3a)	
15.2b)	13.3d), 13.5	
15.2c)	13.4, 13.6b)	
15.2d)	13.4, 13.6b)	
15.2e)	13.4, 13.6b)	
15.3	13.3a), d), 13.5	
15.3a)	8.1, 8.3, 8.7, 13.3c)	
15.3b)	13.3f), 13.4	
15.3d)	13.4, 13.6b)	
15.3e)	13.4, 13.6b)	
Annex A	1, 2, 3, 4, 9.2	
Annex B	1, 2, 3, 4, 7.5, 9.1	
Annex C	1, 2, 3, 4, 7.5, 9.1	
Annex D	1, 2, 3, 4, 9.1, 9.2	
Annex E	1, 2, 3, 4, 9.2	
Annex F	1, 2, 3, 4, 9.2	

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