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# Anaesthetic and respiratory equipment — Tracheal tubes and connectors

*Matériel d'anesthésie et de réanimation respiratoire — Sondes trachéales et raccords*



Reference number
ISO 5361:1999(E)

## Contents







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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.

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.

International Standard ISO 5361 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Tracheal tubes and other equipment*.

This first edition cancels and replaces previous editions of ISO 5361-1:1988, ISO 5361-2:1993, ISO 5361-3:1984, ISO 5361-5:1984 and ISO 7228:1993, which have been technically revised. The requirements of ISO 5361-4:1987, *Tracheal tubes — Part 4: Cole type,* have not been included in this revision because Cole type tubes are specialized tubes, and as such, are excluded from the scope of this International Standard.

Annexes A, B and C form a normative part of this International Standard.

Annex D is for information only.

## Introduction

This International Standard specifies the dimensions, basic properties and method of size designation of the most commonly used types of tracheal tube made of plastics materials and/or rubber. Tubes with walls reinforced with metal or nylon, tubes with shoulders, tapering tubes and the many other types of tube devised for specialized applications are not specifically covered, although most may be classified by their inside diameter as required by this International Standard.

While the inside diameter has been specified for size reference, this International Standard requires that the outside diameter also be marked, since this information is of clinical importance.

Clinical considerations have also dictated the apparently excessive specified length of tubes because long tubes, sometimes of relatively narrow diameter, may be urgently required and therefore should be readily available. Provision has also been included for pre-cut tracheal tubes.

Cuffed tracheal tubes can be characterized by a combination of the tube inside and outside diameters and by the cuff resting diameter.

For tubes intended for re-use, information on the cuff resting diameter is required to be marked on the package or insert but not on the tube itself. This is because re-use may alter the elastic properties, and thereby the diameter, of the cuff.

The relationship between the cuff and tracheal diameters dictates the intracuff pressure required to provide a seal. Excessive pressure on the tracheal wall may obstruct capillary blood flow.

Tracheal tubes, when in position, are intended to conform as closely as possible to human anatomy.

A range of cuff designs is available to meet particular clinical requirements. This International Standard requires that the resting diameter of the cuff be marked on the unit package, as this information allows the clinician to match the product to the application.

Herniation in relation to cuffs is a term widely understood in clinical anaesthetic practice. It is used to describe a cuff which protrudes excessively at its patient end so that it partially or completely occludes the orifice at the bevel. Herniation may be due to a variety of causes, singly or in combination: these may include over-inflation of the cuff, traction of the tube when the cuff is inflated or deterioration of the material of the cuff.

It should be noted that although certain requirements for cuffs apply to tubes of sizes 2,0 to 4,5, cuffs are infrequently used on these smaller sizes of tube.

Flammability of tracheal tubes, for example if flammable anaesthetics, electrosurgical units or lasers are used, is a well-recognized hazard[1)] that is addressed by appropriate clinical management, outside the scope of this International Standard.

It is a requirement that tracheal tubes include length mark(s) in centimetres, measured from the patient end. It is recognized, however, that additional marks, easier to see during intubation, may assist the clinician in positioning the tracheal tube within the trachea. There is currently, however, no clear consensus on the optimum style and positioning of these marks and whether the positioning should differ with size of tube. Further clinical data is required in order to support inclusion of recommendations for these marks in a future revision of this International Standard.



1) See ISO/TR 11991.

# Anaesthetic and respiratory equipment — Tracheal tubes and connectors



## 1 Scope

This International Standard specifies requirements for the dimensions, basic properties and method of size designation of the most commonly used types of oro-tracheal and naso-tracheal tube made of plastics materials and/or rubber (plain and cuffed), and requirements for tracheal tube connectors.

Specialized tubes are excluded from 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 594-1, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General 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: Guidance on selection of tests.*

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

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**
**angle of bevel**
acute angle between the plane of the bevel and the longitudinal axis of the tracheal tube at the patient end

[ISO 4135:1995]

**3.2**
**bevel**
slanted portion at the patient end of the tracheal tube

[ISO 4135:1995]

**3.3**
**cuff**
inflatable balloon permanently attached around the tracheal tube near the patient end to provide an effective seal between the tube and the trachea

**3.4**
**inflating tube**
tube through which the cuff is inflated

[ISO 4135:1995]

**3.5**
**inflation lumen**
lumen within the wall of the tracheal tube for inflating the cuff

**3.6**
**machine end**
that end of a tracheal tube which is intended to project from a patient

[ISO 4135:1995]

**3.7**
**machine end**
that portion of the tracheal tube connector intended to mate with the breathing system of an anaesthetic machine or ventilator

**3.8**
**Murphy eye**
hole through the wall of a tracheal tube near the patient end and on the side opposite to the bevel

**3.9**
**naso-tracheal tube**
tracheal tube for insertion through the nose into the trachea

[ISO 4135:1995]

**3.10**
**oro-tracheal tube**
tracheal tube for insertion through the mouth into the trachea

[ISO 4135:1995]

**3.11**
**patient end**
that end of the tracheal tube which is intended to be inserted into the trachea

[ISO 4135:1995]

**3.12**
**patient end**
that end of the tracheal tube connector nearest to the patient, which is inserted into the tracheal tube.

**3.13**
**pilot balloon**
balloon fitted to the inflating tube to indicate inflation of the cuff

[ISO 4135:1995]

**3.14**
**tracheal tube**
tube designed for insertion through the larynx into the trachea to convey gases and vapours to and from the trachea

[ISO 4135:1995]

**3.15**
**tracheal tube connector**
tubular component that fits directly into a tracheal tube

[ISO 4135: 1995]

**3.16**
**tracheal tube of the 'Magill' type**
tracheal tube with a radius of curvature (as specified in 4.7)

## 4 General requirements for tracheal tubes and tracheal tube connectors

### 4.1 Size designation

The size of tracheal tubes and tracheal tube connectors shall be designated by the nominal inside diameter, expressed in millimetres, in accordance with Table 1 for tracheal tubes and Table 2 for tracheal tube connectors.

### 4.2 Dimensions

#### 4.2.1 Tracheal tubes

**4.2.1.1** The basic dimensions of tracheal tubes shall be in accordance with Table 1.

**4.2.1.2** The actual inside diameter shall be the marked inside diameter subject to a tolerance of ± 0,15 mm for sizes 6,0 and smaller, or subject to a tolerance of ± 0,20 mm for sizes 6,5 and larger.

**4.2.1.3** The actual outside diameter (OD) shall be the marked outside diameter (OD) subject to a tolerance of ± 0,15 mm for sizes 6,0 and smaller, or subject to a tolerance of ± 0,20 mm for sizes 6,5 and larger [see 7.2.1.1 b)].

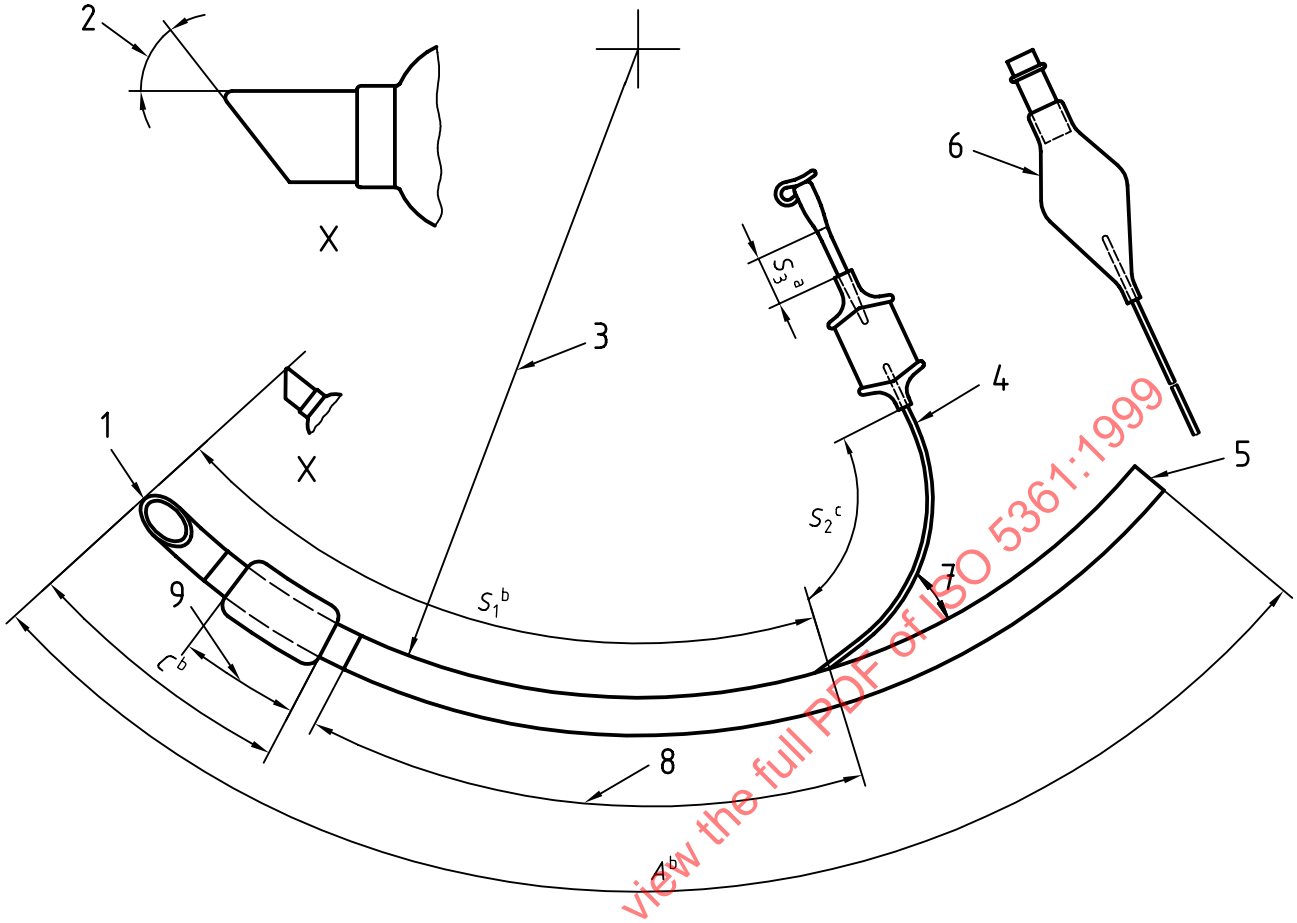
**Table 1 — Basic dimensions of tracheal tubes**

Dimensions in millimetres

| **Designated size** (nominal inside diameter) | **Minimum length of tube** [see Figure 1 a) and b), dimension $A$] | | **Maximum distance** $C$ from the patient end of the tube to the machine end of the inflatable length of the cuff[b] [see Figure 1 a) and b)] | **Minimum distance** of point of separation of the inflating tube from the patient end of the tube [see Figure 1 a) and b), dimension $S_1$[a, b]] |
|---|---|---|---|---|
| | **Nasal or oral/nasal** | **Oral** [a] | | |
| 2,0 | 130 | 110 | — | — |
| 2,5 | 140 | 110 | — | — |
| 3,0 | 160 | 120 | — | — |
| 3,5 | 180 | 130 | — | — |
| 4,0 | 200 | 140 | — | — |
| 4,5 | 220 | 150 | — | — |
| 5,0 | 240 | 160 | 56 | 110 |
| 5,5 | 270 | 170 | 56 | 120 |
| 6,0 | 280 | 190 | 58 | 125 |
| 6,5 | 290 | 210 | 62 | 135 |
| 7,0 | 300 | 230 | 66 | 140 |
| 7,5 | 310 | 240 | 69 | 145 |
| 8,0 | 320 | 250 | 72 | 150 |
| 8,5 | 320 | 260 | 75 | 155 |
| 9,0 | 320 | 270 | 78 | 160 |
| 9,5 | 320 | 280 | 81 | 165 |
| 10,0 | 320 | 280 | 85 | 170 |
| 10,5 | 320 | 280 | 85 | 170 |
| 11,0 | 320 | 280 | 85 | 170 |

[a] Manufacturers desiring to market packaged sterile oral pre-cut tubes with connectors inserted may be guided by the tube lengths shown in the table. However, the user is cautioned that anatomical variations, conditions of use, length of tube inserted or other factors may well result in the use of a tracheal tube either too long or too short for a given patient. The necessity remains for expert clinical judgement in selecting the size and length of tracheal tubes.

[b] These values are not specified for cuffed tracheal tubes of sizes 4,5 or smaller because cuffed tubes of these sizes are infrequently used.



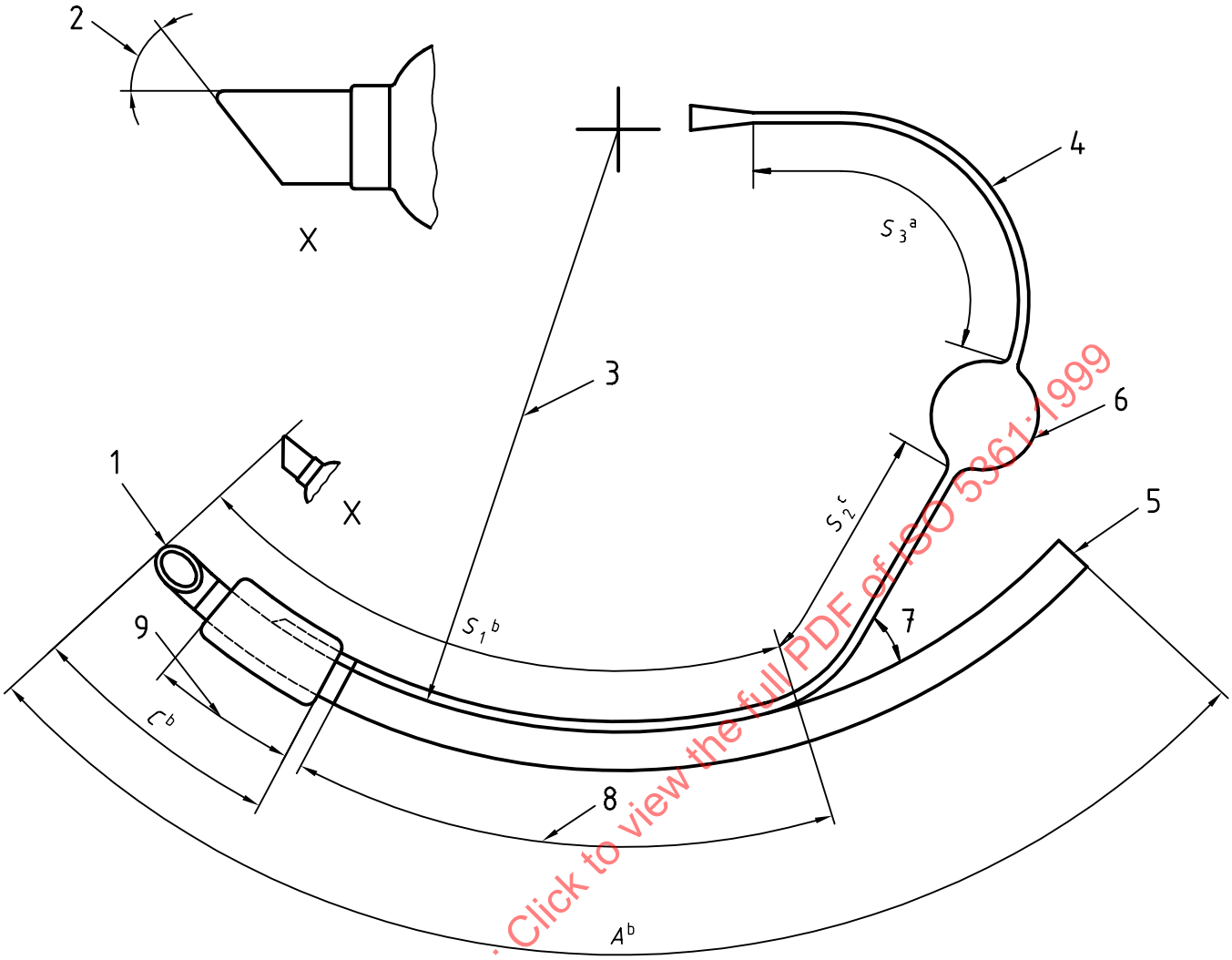

**Key**

1 Patient end
2 Angle of bevel (see 4.4)
3 Radius of curvature (see 4.7)
4 Inflating tube
5 Machine end
6 Alternative integral pilot balloon/valve assembly
7 Separating angle (see 4.6.2)
8 Region for marking size [see 7.2.1.1 f)]
9 Inflatable length of cuff

a See 4.6.6.
b See Table 1.
c Minimum value for $S_2 = A - S_1$.

**a) Typical cuffed tracheal tube ('Magill' type)**

**Figure 1 — Cuffed tracheal tubes**




**Key**

1 Patient end
2 Angle of bevel (see 4.4)
3 Radius of curvature (see 4.7)
4 Inflating tube
5 Machine end
6 Pilot balloon
7 Separating angle (see 4.6.2)
8 Region for marking size [see 7.2.1.1 f)]
9 Inflatable length of cuff

a See 4.6.6.
b See Table 1.
c Minimum value for $S_2 = A - S_1$.

**b) Typical cuffed tracheal tube (“Magill” type), showing alternative design features**

**Figure 1 — Cuffed tracheal tubes**



### 4.2.2 Tracheal tube connectors

**4.2.2.1** The basic dimensions of tracheal tube connectors shall be in accordance with Table 2.

**4.2.2.2** When a tracheal tube is supplied with a tracheal tube connector, the designated size of the connector shall be not less than that of the tracheal tube with which it is provided.

**4.2.2.3** The minimum inside diameter of a curved or angled connector shall be not less than 80 % of the designated size, and the corresponding cross-sectional area shall not be reduced by more than 10 %.

**4.2.2.4** A suction port, if provided, shall be designed so that its closure does not obstruct or narrow the lumen of the connector.

NOTE The connector may be straight, curved or angled. If curved or angled, the connector may incorporate a suction port.

**4.2.2.5** The machine end of a tracheal tube connector shall be a male 15 mm conical connector complying with ISO 5356-1. The inside diameter of the (conical) machine end shall be not less than that allowed by Table 2 for the patient end. Any transition in the inside diameter shall be tapered to permit an adequate lead-in for smooth passage of a suction catheter.

**4.2.2.6** The basic dimensions of the patient end (see Figures 2 and 3) of the connector shall be in accordance with Table 2.

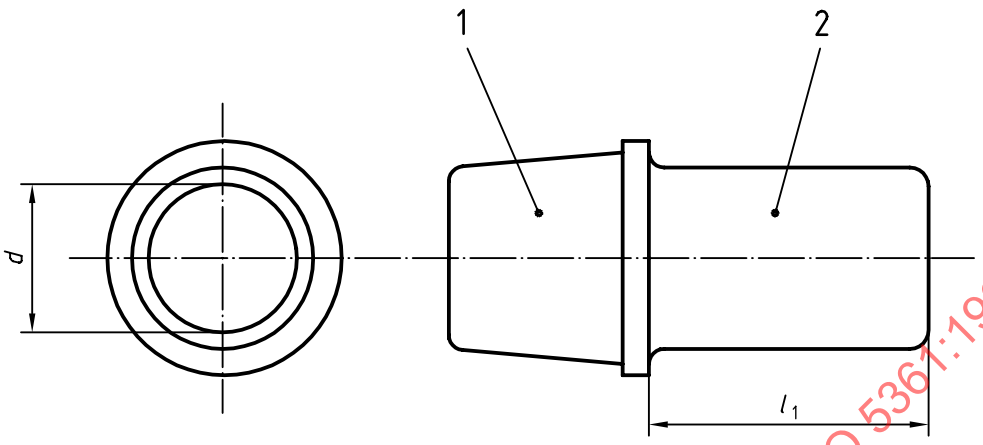
**4.2.2.7** The opening at the patient end shall have a plane at (90 ± 5)° to the long axis of the patient end of the connector.

**Table 2 — Tracheal tube connectors — Size range and basic dimensions of patient end**

Dimensions in millimetres

| **Designated size** (nominal inside diameter) | **Inside diameter** $d$ (± 0,15) | **Straight connectors — minimum dimension** $l_1$ (effective length)[a] (Figure 2) | **Curved connectors — minimum dimension** $l_2$ (effective length)[a] (Figure 3) |
|---|---|---|---|
| 2,0 | 2,0 | 9 | — |
| 2,5 | 2,5 | 9 | — |
| 3,0 | 3,0 | 9 | — |
| 3,5 | 3,5 | 11 | — |
| 4,0 | 4,0 | 11 | — |
| 4,5 | 4,5 | 12 | — |
| 5,0 | 5,0 | 12 | — |
| 5,5 | 5,5 | 13 | 10 |
| 6,0 | 6,0 | 13 | 10 |
| 6,5 | 6,5 | 16 | 10 |
| 7,0 | 7,0 | 16 | 10 |
| 7,5 | 7,5 | 16 | 10 |
| 8,0 | 8,0 | 16 | 10 |
| 8,5 | 8,5 | 16 | 10 |
| 9,0 | 9,0 | 16 | 10 |
| 9,5 | 9,5 | 16 | 10 |
| 10,0 | 10,0 | 16 | 10 |
| 10,5 | 10,5 | 16 | 10 |
| 11,0 | 11,0 | 16 | 10 |

[a] The effective length of the patient end of a tracheal tube connector is that length available for insertion into the tracheal tube.



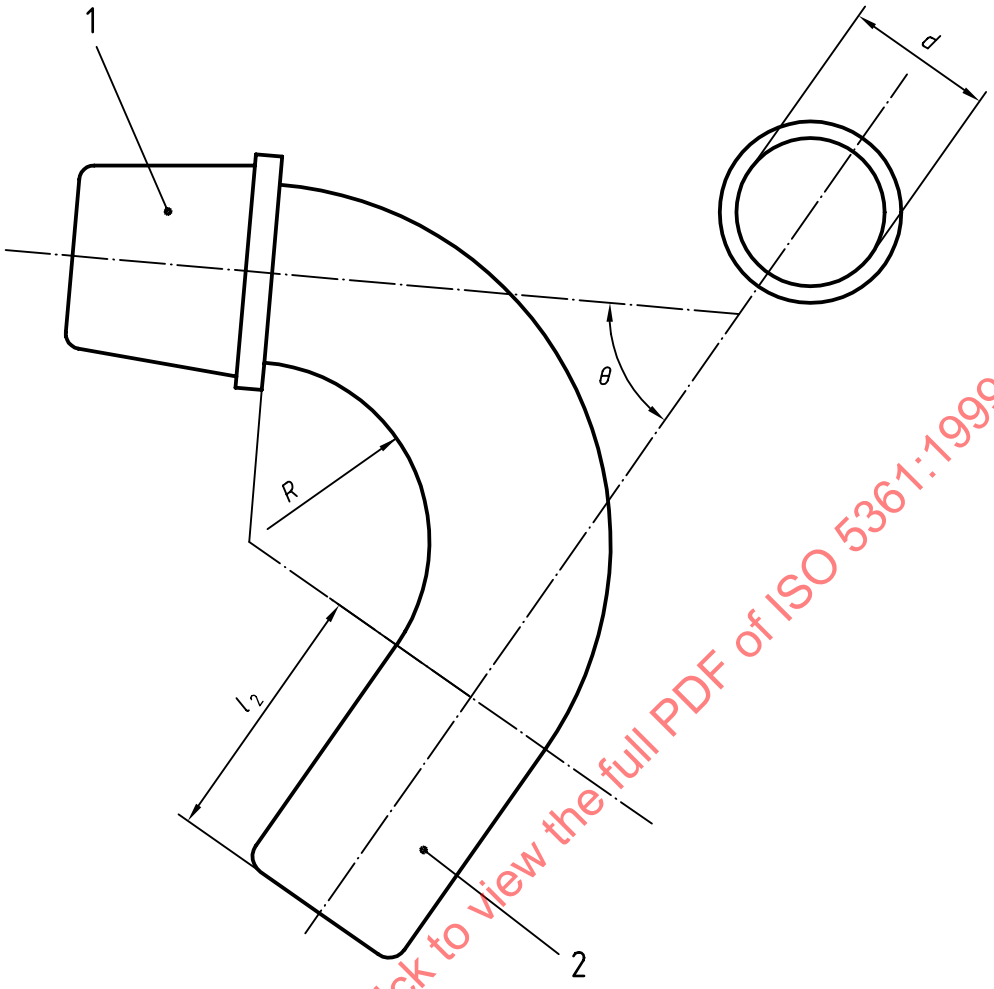

**Key**

1 Machine end (see 4.2.2.5)

2 Patient end

NOTE This figure illustrates a tracheal tube connector for the purpose of defining basic dimensions, and is intended as an example only.

**Figure 2 — Straight tracheal tube connector**




**Key**

1 Machine end (see 4.2.2.5)

2 Straight patient end

NOTE 1 Angle $\theta$ may be any angle greater than 45°.

NOTE 2 This figure illustrates a tracheal tube connector for the purpose of defining basic dimensions, and is intended as an example only.

**Figure 3 — Example of a curved tracheal tube connector**



## 4.3 Materials

Tracheal tubes, including cuffs, and tracheal tube connectors in their ready-for-use state after any preparation for use recommended by the manufacturer, shall satisfy appropriate biological safety testing, as indicated in ISO 10993-1.

NOTE See annex D for guidance on materials and design.

## 4.4 Bevel

All tubes shall have an angle of bevel of (38 ± 10)°.

NOTE The bevel of the tube should have the opening facing to the left when the tube is viewed towards the concave aspect from the machine end [see Figure 1 a) and b)].

## 4.5 Cuff

**4.5.1** A cuff, if provided, shall be integrally attached to the tube.

**4.5.2** The maximum distance from the patient end of tube to the machine end of the inflatable length of the cuff [dimension $C$ in Figure 1 a) and b)] shall be as given in Table 1.

**4.5.3** The cuff resting diameter shall be within ± 15 % of the marked value [see 7.2.2.1 k)], when determined in accordance with annex A.

**4.5.4** When tested for tube collapse according to the method described in annex B, the steel ball shall pass freely through the tube.

**4.5.5** When tested for cuff herniation according to the method described in annex C, no part of the inflated cuff shall reach beyond the nearest edge of the bevel (see Figure C.1).

## 4.6 Inflating tubes for cuffs

**4.6.1** The inflating tube, if provided, shall have an outside diameter of not more than 3,0 mm and the point of separation shall be situated on the concave aspect of the tracheal tube. The wall around the inflation lumen shall not encroach on the lumen of the tracheal tube by more than 10 % of the inside diameter of the tracheal tube. The dimensions of the inflating tube shall be in accordance with Table 1 and Figure 1 a) and b).

**4.6.2** The angle between the inflating tube and the tracheal tube at the point of separation [see Figure 1 a) and b)] shall not exceed 45°.

**4.6.3** The inflating tube shall have a pilot balloon and/or other device to indicate inflation/deflation of the cuff.

NOTE This (these) device(s) may also serve as a pressure-indicating or -limiting device.

**4.6.4** The intentional deflation of the cuff shall not be prevented by the inflating tube, inflating valve or any closure device acting as a non-return valve.

**4.6.5** The free end of the inflating tube shall be either open or sealed with a closure device or inflation valve, but in all instances it shall be capable of accepting a male conical fitting with a 6% (Luer) taper, complying with ISO 594-1.

**4.6.6** Dimension $S_3$ of the inflating tube [see $S_3$ in Figure 1 a) and b)] shall be at least 40 mm unless an inflation valve or closure device is provided. If such a closure device is provided, except if the pilot balloon and valve are integral, dimension $S_3$ shall be not less than 10 mm.

NOTE This is to facilitate clamping of the inflating tube.

**4.6.7** If the distance of the point of separation of the inflating tube and the tracheal tube from the patient end is marked [see 7.2.2.1 a)], the actual distance shall be the marked value ± 10 mm.

## 4.7 Curvature of tube

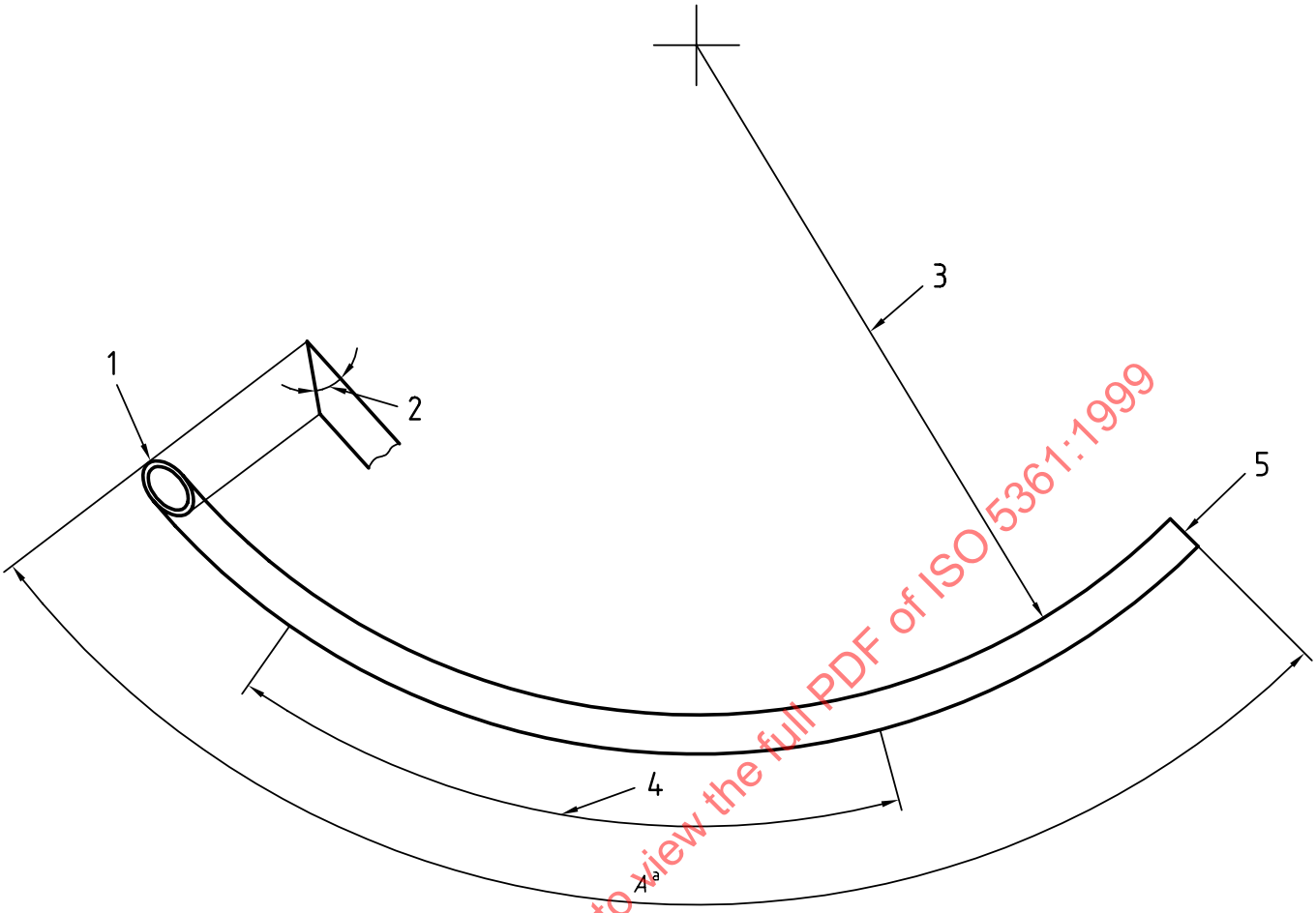
**4.7.1** Tracheal tubes may be straight or curved.

**4.7.2** If tracheal tubes are described as being of the 'Magill' type, the radius of curvature shall be (140 ± 20) mm for tubes of sizes 6,5 and larger [see Figure 1 a) and b) and Figure 4], except that:

a) this curvature may be omitted from the tip of the bevel to not more than 30 mm beyond the machine end of the cuff (see Figure 5). If this curvature is so omitted, the straight portion shall be tangential to the curve of the tube.

b) this curvature may be omitted from uncuffed tubes of sizes 6,5 and larger over the same equivalent distance as for cuffed tubes in a).

**4.7.3** Tracheal tubes of the 'Magill' type of sizes 6,0 and smaller may have a radius of curvature other than (140 ± 20) mm.



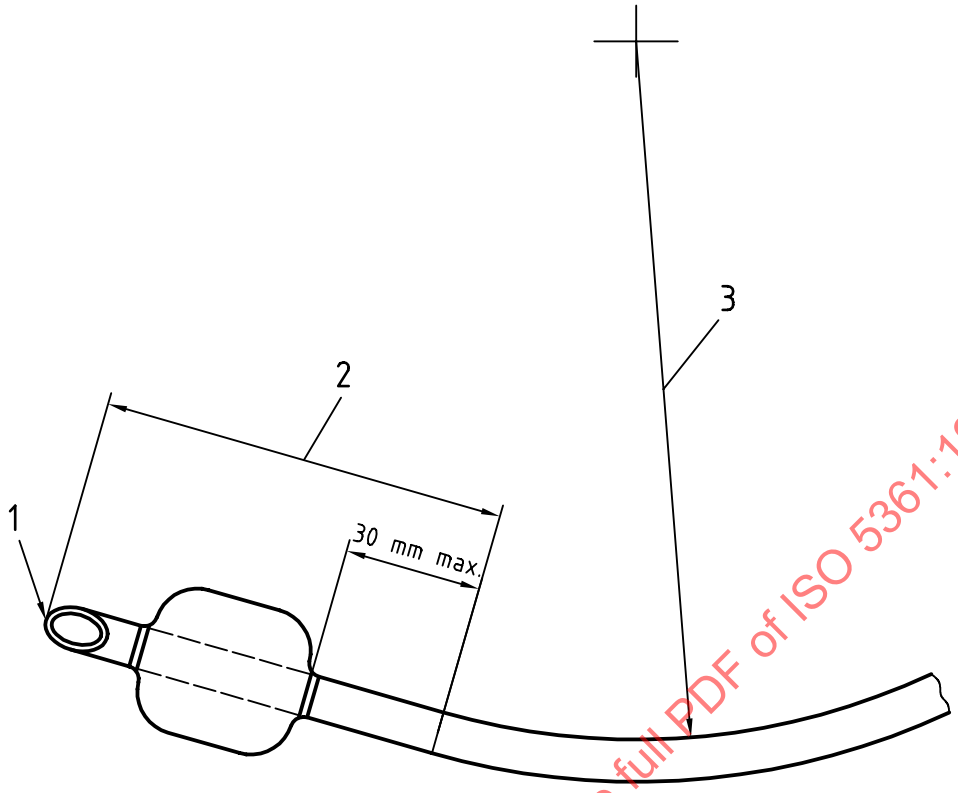

**Key**

1 Patient end
2 Angle of bevel (see 4.4)
3 Radius of curvature (see 4.7)
4 Region for marking size [see 7.2.1.1 f)]
5 Machine end

a Minimum length *A* (see Table 1).



**Figure 4 — Typical plain tracheal tube ('Magill' type)**




**Key**
1 Patient end
2 Straight portion
3 Radius of curvature (see 4.7)

**Figure 5 — Typical straight patient end**



## 5 Additional requirements for tracheal tubes with a Murphy eye

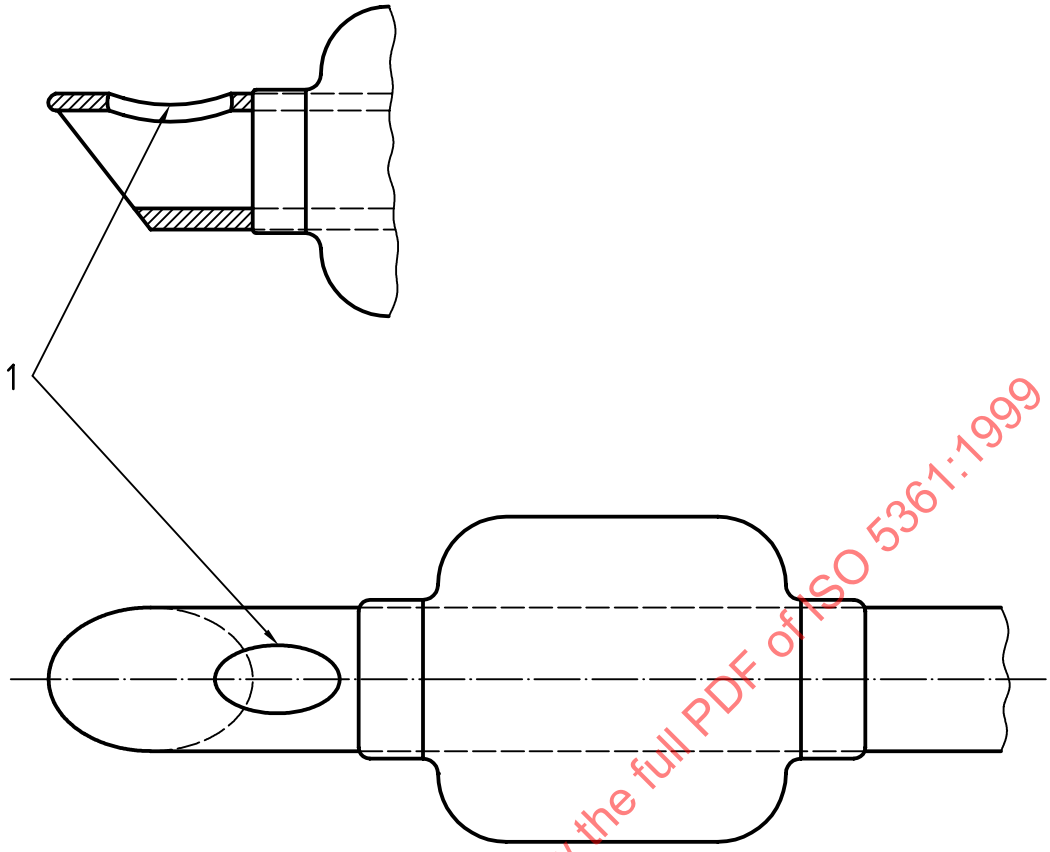
### 5.1 Size of the Murphy eye

The area of the Murphy eye shall be not less than 80 % of the cross-sectional area derived from the minimum inside diameter allowed by Table 1 for that size of tube.

### 5.2 Location of the Murphy eye

The location of the eye shall be on the side of the tube opposite the bevel (see Figure 6).

NOTE The size, shape and location of the eye should be such that the patient end of the tube is not unduly prone to kinking/collapse.




**Key**
1 Murphy eye

**Figure 6 — Patient end of tracheal tube showing Murphy eye**



## 6 Requirements for tracheal tubes with tracheal tube connector supplied sterile

### 6.1 Sterility assurance

Tracheal tubes with connectors supplied and marked as "STERILE" shall satisfy the requirements of 4.1 of EN 556:1994.

### 6.2 Packaging for tracheal tubes and tracheal tube connectors supplied sterile

Each tracheal tube with tracheal tube connector supplied and marked as "STERILE" shall be contained in an individual pack. The pack shall serve as an effective barrier to the penetration of microorganisms and particulate material, in accordance with ISO 11607. The pack shall permit the aseptic extraction of the contents and shall not be capable of re-closure without clearly revealing that it has been opened.

## 7 Marking

### 7.1 Use of symbols

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

Marking of tracheal tubes, connectors, packages, inserts and information to be supplied by the manufacturer should comply with EN 1041.

## 7.2 Tracheal tubes

### 7.2.1 Marking of the tracheal tube

**7.2.1.1** Marking of the tracheal tube shall include the following:

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

b) the designated size (nominal inside diameter) in accordance with 4.1 and the outside diameter, expressed in millimetres, marked in accordance with one of the following formats:

ID **4,0** 5,7 **OD**

**4,0** 5,7

The figure denoting the inside diameter shall be larger and in bold type.

c) for tracheal tubes not intended for re-use, the words "single use" or equivalent;

d) length mark(s) in centimetres measured from the patient end;

e) the word "Oral", "Nasal" or "Oral/Nasal", as appropriate;

f) marking of the size of tracheal tubes situated as shown in Figure 1 a) and b) and Figure 4, as appropriate, on the side of the tube reading from the patient end to the machine end. Plain tubes shall have the size marked in a region equivalent to cuffed tubes of similar size.

**7.2.1.2** Additional marks may be provided to assist in positioning the tracheal tube within the trachea.

**7.2.1.3** Marking materials shall be of a colour that contrasts with the colour of the tube.

### 7.2.2 Marking on the tracheal tube individual pack and any insert

**7.2.2.1** The following shall be marked on, or visible through, the tracheal tube individual pack and may additionally be given on an insert:

a) if the unit package of a cuffed tube is not transparent, the distance of the point of separation of the inflating tube and tracheal tube from the patient end;

b) a description of contents;

c) the word "Oral", "Nasal" or "Oral/Nasal" as appropriate;

d) the designated size (nominal inside diameter) in accordance with 4.1;

NOTE The figure denoting the inside diameter should be in larger and bolder type than that denoting the outside diameter.

e) the outside diameter expressed in millimetres;

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

g) the batch number;

NOTE It is strongly recommended that the 'use by' date be given.

h) the word "STERILE" if appropriate;

NOTE It is recommended that the method of sterilization be given.

i) for tubes not intended for re-use, the words "single use" or equivalent;

j) if the straight portion of the tube extends beyond the machine end of the cuff (see 4.7.2), this shall be stated, for example by the words "straight patient end";

k) for cuffed tubes, the resting diameter of the cuff, determined in accordance with annex A and expressed in millimetres to two significant figures.

**7.2.2.2** Unless the tracheal tube is intended and marked as being for single use, instructions for cleaning and disinfection or sterilization, and the maximum number or period of re-uses shall be marked on the tracheal tube package or on an insert.

## 7.3 Tracheal tube connectors

The tracheal tube connector shall be clearly marked with the designated size (nominal inside diameter) in accordance with 4.1.

# Annex A
(normative)

# Determination of cuff resting diameter

## A.1 Principle

The resting diameter of the cuff is measured when the cuff is inflated with a pressure which is intended to remove creases but minimize stretching of its walls.

## A.2 Apparatus

**A.2.1 Means to inflate the cuff** with sufficient air to create an internal overpressure of 2,0 kPa ± 5 %.

## A.3 Procedure

**A.3.1** Inflate the cuff with sufficient air (A.2.1) to create an internal overpressure of (2,0 ± 0,1) kPa and allow to stabilize for 5 min at (23 ± 2) °C, maintaining that overpressure.

**A.3.2** Locate the plane of maximum cuff diameter perpendicular to the axis of the tube. Measure four cuff diameters at intervals of 45° in the located plane.

## A.4 Expression of results

Calculate the arithmetic mean of the measurements obtained in A.3.2 and express the result in millimetres.

# Annex B
(normative)

# Test method for tube collapse

## B.1 Principle

The resistance to tube collapse due to inward cuff pressure is tested by passing a steel ball through the tracheal tube lumen with the cuff inflated within a transparent tube.

## B.2 Apparatus

**B.2.1 Transparent tube** made of glass or rigid plastics material, having a length of about twice the effective length of the cuff and an inside diameter of within 5 % of twice the marked outside diameter of the tracheal tube under test (see Figure B.1).

**B.2.2 Water bath**, thermostatically controlled at (40 ± 1) °C.

**B.2.3 Air supply**, capable of providing an air supply at the pressures given in Table B.1.

**B.2.4 Air pressure indicating device**, capable of indicating air pressure given in Table B.1 with an accuracy of ± 5 %.

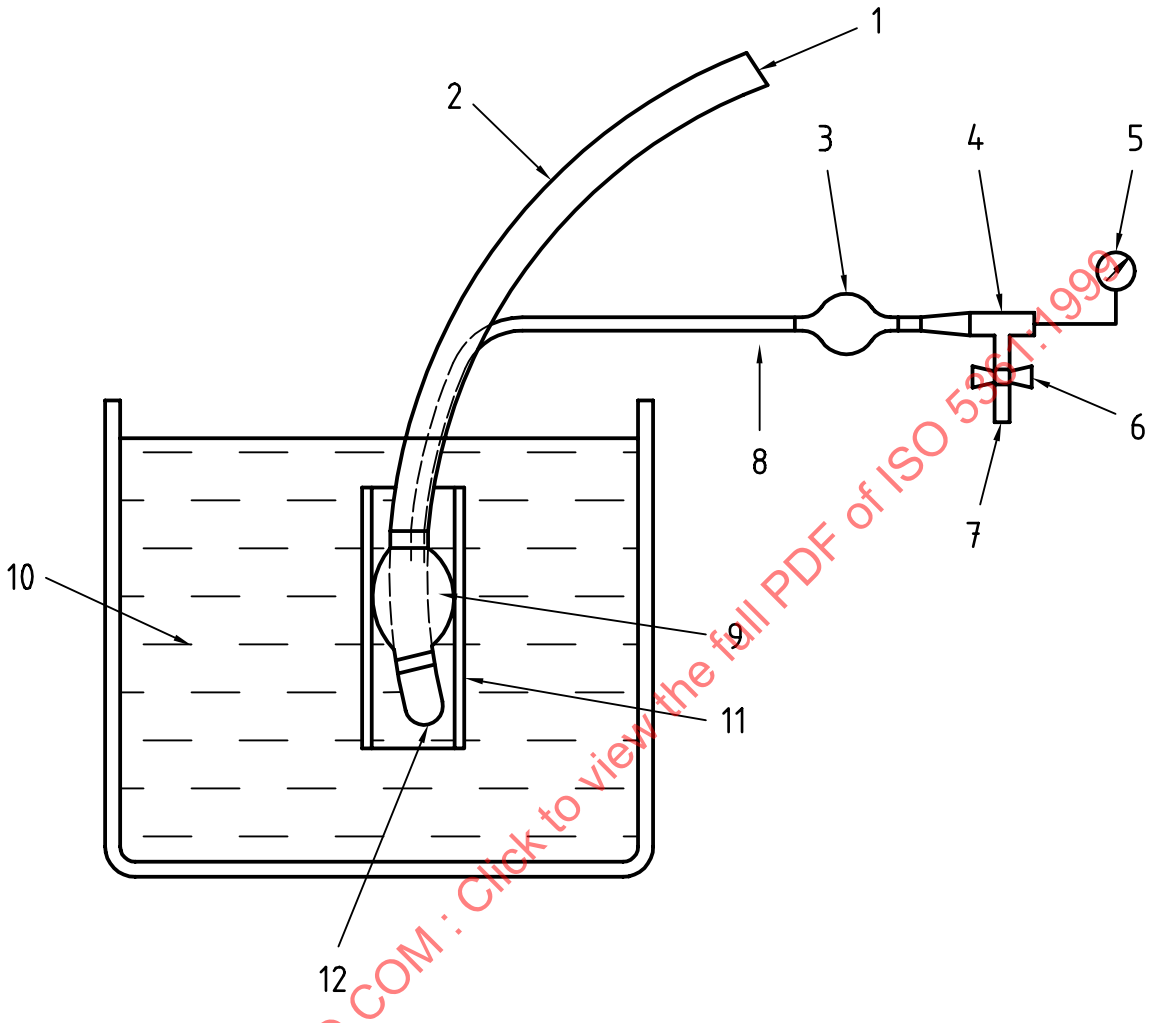
**B.2.5 Steel ball**, of diameter 75 % of the designated size (nominal inside diameter) of the tracheal tube undergoing test.

**Table B.1 — Selection of test inflation pressures**

| Reference inflation pressure | Test inflation pressure |
|---|---|
| ⩽ 16,6 kPa | Twice the reference inflation pressure or 2,7 kPa, whichever is greater |
| > 16,6 kPa and ⩽ 33,3 kPa | 33,3 kPa |
| > 33,3 kPa | Reference inflation pressure |

## B.3 Procedure

**B.3.1** Set up the apparatus as illustrated in Figure B.1.




**Key**

| | | | |
|---|---|---|---|
| 1 | Machine end | 7 | Air supply |
| 2 | Tracheal tube | 8 | Inflating tube |
| 3 | Pilot balloon | 9 | Cuff |
| 4 | T-piece with connector to fit inflating tube | 10 | Water bath at (40 ± 1) °C |
| 5 | Pressure-indicating device | 11 | Transparent tube |
| 6 | Stopcock | 12 | Patient end |

**Figure B.1 — Apparatus for tube collapse test**



**B.3.2** Place the patient end of the tracheal tube into the transparent tube (B.2.1) so that the cuff is centrally located.

**B.3.3** Attach the inflating tube to the air supply (B.2.3).

**B.3.4** Inflate the cuff with air until it just makes circumferential contact with the internal surface of the transparent tube.

NOTE For transparent cuffs, the addition of a small quantity of colouring, for example ink, may assist in determining the point of circumferential contact.

**B.3.5** Immerse the tracheal tube and the transparent tube in the water bath (B.2.2) at (40 ± 1) °C.