INTERNATIONAL STANDARD

ISO 5366-3

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Anaesthetic and respiratory equipment — Tracheostomy tubes —

Part 3: Paediatric tracheostomy tubes

Matériel respiratoire et d'anesthésie — Tubes de trachéostomie —

Partie 3: Tubes de trachéostomie pédiatriques

Reference number
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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.

Attention is drawn to the possibility that some of the elements of this part of ISO 5366 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 5366-3 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Tracheal tubes and other equipment*.

This second edition cancels and replaces the first edition (ISO 5366-3:1994), which has been technically revised.

ISO 5366 consists of the following parts, under the general title *Anaesthetic and respiratory equipment — Tracheostomy tubes*:

— *Part 1: Tubes and connectors for use in adults*

— *Part 3: Paediatric tracheostomy tubes*

Annexes A and B form a normative part of this part of ISO 5366. Annex C is for information only.

Introduction

ISO 5366 is concerned with the basic requirements and method of size designation of tracheostomy tubes made of plastics materials and/or rubber.

ISO 5366-1 gives requirements for adult tracheostomy tubes made of plastics materials and/or rubber.

This part of ISO 5366 gives requirements for paediatric tracheostomy tubes with an inside diameter from 2,0 mm to 6,0 mm.

Paediatric tracheotomy tubes are primarily intended for use with infants and children who may require anaesthesia, artificial ventilation, relief of upper airway obstruction or other respiratory therapy.

An infant or child differs from an adult, not only in size but especially with regard to airway anatomy and respiratory physiology; thus airway equipment for paediatric patients differs from that for adults in size and also in basic design. It should be noted that, although this part of ISO 5366 gives some requirements for cuffs, cuffs are seldom provided on the smaller sizes of paediatric tubes.

This part of ISO 5366 gives requirements for those characteristics of tracheostomy tubes that can be standardized and which are important for patient safety. It does not require the connector to be permanently attached to the tube, as this may be impractical with infants and small children. Other acceptable methods of connecting these components are available, and this part of ISO 5366 makes provision for them. This part of ISO 5366 does not limit the range of tube designs needed to match the variety of paediatric anatomy, lesions and space limitations encountered.

The method of describing tube dimensions and configuration has been devised with the aim of assisting the clinician in the selection of a suitable tube to conform as far as possible to a particular patient's anatomy. Size is designated by inside diameter, which is important because of its relation to resistance to gas flow. Because the stomal and tracheal diameters are important when selecting tubes, it is considered essential that the outside diameter be stated for each size of tube.

A tracheostomy tube can increase resistance to gas flow. For tubes with a given outside diameter, differences in wall thickness have a major influence on the resistance to gas flow, especially in the smaller sizes of paediatric tracheostomy tubes.

Flammability of tracheostomy tubes, for example if flammable anaesthetics, electrosurgical units or lasers are used in oxidant-enriched atmospheres, is a well-recognized hazard[1)] addressed by appropriate clinical management, which is outside the scope of this part of ISO 5366.

1) See ISO/TR 11991.

Anaesthetic and respiratory equipment — Tracheostomy tubes —

Part 3:
Paediatric tracheostomy tubes

1 Scope

This part of ISO 5366 gives requirements for paediatric tracheostomy tubes made of plastics materials and/or rubber having inside diameters from 2,0 mm to 6,0 mm. Requirements for paediatric tracheostomy tube connectors and adaptors are also given.

This part of ISO 5366 is not applicable to specialized tracheostomy tubes.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 5366. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 5366 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 5361, *Anaesthetic and respiratory equipment — Tracheal tubes and connectors*.

ISO 5366-1:2000, *Anaesthetic and respiratory equipment — Tracheostomy tubes — Part 1: Tubes and connectors for use in adults*.

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

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 part of ISO 5366, the terms and definitions given in ISO 5366-1 and the following apply.

3.1
paediatric tracheostomy tube
tube designed for insertion into the trachea of an infant or child through a tracheostomy

3.2
paediatric tracheostomy tube connector
tubular component which fits directly into the paediatric tracheostomy tube

3.3

machine end

⟨paediatric tracheostomy tube connector⟩ end of the component nearest the machine which is intended to mate with the breathing system of an anaesthetic machine or lung ventilator

3.4

patient end

⟨paediatric tracheostomy tube connector⟩ end of the component nearest the patient which is inserted into the paediatric tracheostomy tube

4 Size designation and dimensions

4.1 Designation of size of tube

4.1.1 The size of a tracheostomy tube (outer tube) shall be designated by the nominal inside diameter (ID) of the tube expressed in millimetres, as measured at the minimum diameter, in accordance with Table 1, excluding any encroachment allowed by 6.6.1.

4.1.2 For tracheostomy tubes provided with an inner tube to which is attached a 15 mm male conical connector complying with the requirements of ISO 5356-1 [see 6.1 a)], the size shall be designated by the nominal inside diameter (ID) of the inner tube expressed in millimetres in accordance with Table 1.

Table 1 — Size designation, inside diameter and tolerances of paediatric tracheostomy tubes

Dimensions in millimetres

Designated size	Inside diameter	Tolerance
2,0	2,0	$^{+0,2}_{0}$
2,5	2,5	
3,0	3,0	
3,5	3,5	
4,0	4,0	
4,5	4,5	$^{+0,3}_{0}$
5,0	5,0	
5,5	5,5	
6,0	6,0	

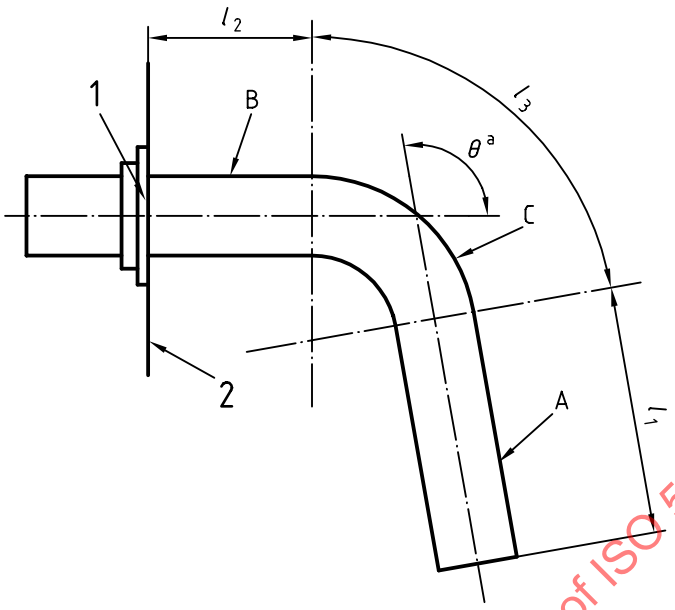
4.2 Outside diameter

4.2.1 The outside diameter (OD) of sections A and C (see Figure 1) of the tube, other than at the cuff if provided, shall be expressed in millimetres to the nearest 0,1 mm.

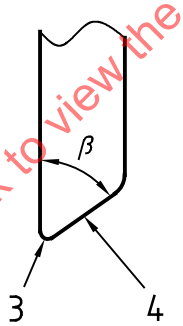
NOTE The marked outside diameter relates to that portion of the tube intended to be within the wall and lumen of the trachea.

4.2.2 The actual outside diameter of section A, other than at the cuff if provided, shall be the marked outside diameter subject to a tolerance of ± 0,2 mm.

4.2.3 The actual outside diameter of section C shall be the marked outside diameter subject to a tolerance of ± 0,5 mm.



a) Paediatric tracheostomy tube



b) Patient end

Key

1	Neck-plate
2	Datum plane
3	Tip rounded
4	Bevel, if present

[a] Obtuse angle formed between the long axes of the tube at the machine and patient ends.

Figure 1 — Basic dimensions of paediatric tracheostomy tubes

4.3 Length

4.3.1 The nominal length ($l_1 + l_2 + l_3$ in Figure 1) shall be measured from the patient side of the neck-plate to the patient end, including the bevel if present (see Figure 1), and expressed in millimetres.

4.3.2 The actual nominal length ($l_1 + l_2 + l_3$ in Figure 1) shall be the marked nominal length subject to a tolerance of $\pm$ 1,5 mm for tubes with a marked inside diameter of less than 4,5 mm, or subject to a tolerance of $\pm$ 2 mm for tubes with a marked inside diameter of 4,5 mm or greater.

4.3.3 For tubes with an adjustable neck-plate, the range of measurements for nominal length (see Figure 1) shall be expressed in millimetres.

4.3.4 Dimensions l_1, l_2 and l_3 shall be expressed in millimetres [see Figure 1 a)].

NOTE Dimensions l_1 and/or l_2 can be, or approach, zero.

4.4 Angle θ

The angle θ (see Figure 1) shall be expressed in degrees.

5 Materials

Tracheostomy tubes, including cuffs and tracheostomy tube connectors provided with the tube, 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 C for guidance on materials and design.

6 Design and finish

6.1 Machine end

The machine end of a paediatric tracheostomy tube shall

a) have a permanently attached 15 mm male conical connector complying with the requirements of ISO 5356-1, or

NOTE In this context, permanently attached means it does not become detached when subject to the forces described in the test method given in annex A.

b) accept a paediatric tracheostomy tube connector in accordance with 6.2.

6.2 Paediatric tracheostomy tube connector

6.2.1 The nominal size of a paediatric tracheostomy tube connector shall be designated by its inside diameter in accordance with Table 2.

NOTE A connector is intended to fit a tracheostomy tube of the same designated size.

6.2.2 The connector supplied with a tracheostomy tube shall have an inside diameter not less than the inside diameter of that tube as stated by the manufacturer [see 8.1 a)].

Table 2 — Size designation, inside diameter and tolerances of paediatric tracheostomy tube connectors

Dimensions in millimetres

Designated size	Inside diameter of patient end ± 0,15
2,0	2,0
2,5	2,5
3,0	3,0
3,5	3,5
4,0	4,0
4,5	4,5
5,0	5,0
5,5	5,5
6,0	6,0

6.2.3 The machine end shall be a 15 mm male conical connector complying with ISO 5356-1. The inside diameter of the conical connector at the machine end shall be not less than that allowed by Table 2 for the patient end.

6.2.4 Any transition from one inside diameter to another shall be tapered to give an adequate lead-in for passage of a suction catheter.

6.3 Inner tube

6.3.1 The inner tube, if provided with the outer tube, shall extend to within 1,0 mm of the patient end of the tracheostomy (outer) tube and not more than 1,0 mm beyond the patient end.

6.3.2 The machine end of the inner tube shall either comply with 6.1 or shall not prevent the tracheostomy (outer) tube connector, if provided, mating with the breathing system of an anaesthetic machine or lung ventilator.

6.4 Neck-plate

6.4.1 Tracheostomy tubes shall have a neck-plate that shall be either adjustable or permanently attached to the tube.

6.4.2 The neck-plate shall be provided with holes or other means to permit attachment to the patient.

6.4.3 If a tracheostomy tube has an adjustable neck-plate, it shall be securable to the tube (but see C.2.4).

6.4.4 When tested in accordance with annex A, the neck-plate shall not move longitudinally relative to the tube.

6.5 Cuff

6.5.1 A cuff, if provided, shall be permanently attached to the tube.

6.5.2 Cuffs of tracheostomy tubes shall satisfy the requirements of ISO 5361.

6.5.3 The cuff resting diameter shall be within ± 15 % of the marked value [see 8.3.2 m)] when determined in accordance with annex B.

6.6 Inflating tubes for cuffs

6.6.1 Inflating tubes

The inflating tube, if fitted, shall have an outside diameter of not more than 2,5 mm. The wall around the inflation lumen shall not encroach on the lumen of the tracheostomy tube by more than 10 % of the inside diameter of the tracheostomy tube.

The intentional deflation of the cuff shall not be prevented by the inflating tube, inflating valve or any closure device.

6.6.2 Pilot balloon

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

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

6.6.3 Free end of inflating tubes for cuffs

The 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 % taper (Luer), complying with the requirements

specified in ISO 594-1. The length [see Figure 1 a), dimension l_1 of ISO 5366-1:2000] of the free end of the inflating tube shall be not less than 40 mm unless an inflation valve or closure device is provided.

If an inflation valve or closure device is provided, the length [see Figure 1 b), dimension l_2 of ISO 5366-1:2000] between the pilot balloon (or other device) and the female fitting which accepts a male Luer conical fitting shall be not less than 10 mm unless the pilot balloon and valve or closure device are integral.

NOTE This is to facilitate clamping of the inflating tube.

6.7 Patient end

If a bevel is present, the angle of the bevel β shall be not less than 50° [see Figure 1 b)].

6.8 Introducer

If provided, the introducer, when correctly seated, shall not fall out of the paediatric tracheostomy tube under its own weight when the tube is held by the neck-plate with the patient end uppermost.

The introducer should be freely removable in use.

7 Requirements for tracheostomy tubes supplied sterile

7.1 Sterility assurance

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

7.2 Packaging for tracheostomy tubes supplied sterile

7.2.1 The following information shall be apparent on visual examination of the intact unit container:

a) the size and pre-formed shape of the tube;

b) whether a cuff is provided;

c) whether a connector is provided.

NOTE For example, the unit container can be transparent and the tube visible, or a drawing to scale (preferably full-scale) can be used.

7.2.2 Each tracheostomy tube supplied and marked “STERILE” shall be contained in a unit container. The container 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.

8 Marking

8.1 Marking of tracheostomy tube

The following information shall be marked on the neck-plate and/or tube and shall be visible from the machine end of the tube:

a) the designated size (nominal inside diameter) expressed in millimetres in accordance with 4.1;

b) the nominal outside diameter expressed in millimetres in accordance with 4.2;

c) the name and/or trade mark of the manufacturer.

8.2 Marking of tracheostomy tube connectors

The tracheostomy tube connector, if not permanently attached to the tracheostomy tube, shall be marked with its designated size (see 6.2.1).

8.3 Marking of unit packs

8.3.1 General

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

The requirements of 8.3.2 and 8.3.3 may be met by use of appropriate symbols as given in EN 980.

8.3.2 Marking of tracheostomy tube unit packs

Unit containers or a package insert shall be clearly marked to indicate the following:

a) a description of contents;

b) the designated size, expressed in millimetres in accordance with 4.1;

c) the nominal outside diameter, expressed in millimetres (see 4.2);

d) the nominal length, expressed in millimetres (see 4.3.1). For tubes with an adjustable neck-plate, the range of nominal lengths shall be given;

e) if a connector (see 6.1) is not provided, a statement to this effect shall be marked on the unit container;

f) dimension A as shown in Figure 1; for tubes with a fixed neck-plate, dimension B; for tubes with an adjustable neck-plate, the maximum dimension B;

g) the angle θ in accordance with 4.4;

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

i) the batch number;

j) unless the tracheostomy tube is intended and marked as being for single use, instructions for cleaning and disinfection or sterilization;

k) the word “STERILE” if appropriate (see EN 1041);

l) for tubes not intended for re-use, the words “single use” or equivalent;

m) for cuffed tubes, the resting diameter of the cuff, determined in accordance with annex B and expressed in millimetres to two significant figures;

n) if an inner tube is provided in the unit container, the nominal inside diameter of the inner tube;

o) the presence of natural rubber (latex), if present in the device.

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

8.3.3 Marking of inner tube unit packs

Inner tube unit packs shall be clearly marked to indicate the following:

a) a description of contents;

b) the designated size (nominal inside diameter) of the tracheostomy tube (outer tube) into which it is designed to fit;

c) the nominal inside diameter of the inner tube;

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

e) the batch number;

f) unless the tracheostomy tube is intended and marked as being for single use, instructions for cleaning and disinfection or sterilization;

g) the word “STERILE” if appropriate (see EN 1041);

h) for inner tubes not intended for re-use, the words “single use”, or equivalent;

i) the presence of natural rubber (latex), if present in the device.

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

Annex A
(normative)

Test for security of attachment of permanently attached connector, if provided, and neck-plate to tracheostomy tube

A.1 Principle

The security of attachment of the neck-plate to the tracheostomy tube is tested by applying an axial separation force to the neck-plate. If a permanently attached connector is provided, the security of attachment to the tracheostomy tube is tested by applying an axial separation force to the connector.

A.2 Apparatus

A.2.1 Means of conditioning the tracheostomy tube at (37 ± 2) °C at not less than 80 % relative humidity for 24 h.

A.2.2 Means of securing the connector, if provided, to the tracheostomy tube and applying an axial separation force of (50 ± 5) N at a rate of (50 ± 5) mm·min^{-1}.

A.2.3 Means of securing the neck-plate to the tracheostomy tube and applying an axial separation force of $(15 \pm 1{,}5)$ N or (50 ± 5) N at a rate of (50 ± 5) mm·min^{-1}.

A.3 Procedure

A.3.1 Condition the tracheostomy tube at (37 ± 2) °C at not less than 80 % relative humidity for 24 h.

A.3.2 Remove the tracheostomy tube from the conditioning chamber and separately secure the connector and tracheostomy tube (A.2.2).

NOTE For tracheostomy tubes with the conical connector permanently attached to the inner tube, the mechanism which secures the inner tube within the outer (tracheostomy) tube should first be engaged in accordance with manufacturers' instructions before securing the connector and tracheostomy tube.

A.3.3 Within 10 min of removing the tracheostomy tube from the conditioning chamber, apply an axial separation force of (50 ± 5) N to the connector at a rate of (50 ± 5) mm·min^{-1}.

A.3.4 Having already removed the tracheostomy tube from the conditioning chamber, secure the neck-plate and tracheostomy tube (A.2.3).

A.3.5 Within 10 min of removing the tracheostomy tube from the conditioning chamber, apply an axial separation force to the neck-plate as follows:

a) for tracheostomy tubes with an adjustable neck-plate, apply an axial force of $(15 \pm 1{,}5)$ N at a rate of (50 ± 5) mm·min^{-1};

b) for tracheostomy tubes with a permanently attached neck-plate, apply an axial force of (50 ± 5) N at a rate of (50 ± 5) mm·min^{-1}.

A.4 Expression of results

Record whether or not the connector, if provided, or neck-plate moves longitudinally relative to the tracheostomy tube.

Annex B
(normative)

Test method for determining the resting diameter of the cuff

B.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 to minimize stretching of its walls.

B.2 Apparatus

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

B.3 Procedure

B.3.1 Inflate the cuff with sufficient air to create an internal overpressure of 2,0 kPa ± 5 % and leave to stabilize for 5 min at (23 ± 2) °C, at not less than 80 % relative humidity, maintaining that overpressure.

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

B.4 Expression of results

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