INTERNATIONAL STANDARD

ISO 5366-3

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Tracheostomy tubes —

Part 3:
Paediatric tracheostomy tubes

Tubes de trachéostomie —

Partie 3: Tubes de trachéostomie pédiatriques

Reference number
ISO 5366-3:1994(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 5366-3 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Sub-Committee SC 2, *Tracheal tubes and other equipment*.

This first edition of International Standard ISO 5366-3 specifies requirements for paediatric tracheostomy tubes made of plastics materials and/or rubber, and includes the requirements for connectors for paediatric tubes that were previously contained in ISO 5366-1.

ISO 5366 consists of the following parts, under the general title *Tracheostomy tubes*:

— *Part 1: Connectors for tubes for adults*

— *Part 2: Basic requirements for tubes for adults*

— *Part 3: Paediatric tracheostomy tubes*

Annex A forms an integral part of this part of ISO 5366. Annex B is for information only.

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Introduction

Paediatric tracheostomy 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. Airway equipment for paediatric patients involves differences not only of size but also of basic design. These differences created a demand for a separate standard for tracheostomy tubes for paediatric use. It should be noted that, although this part of ISO 5366 specifies some requirements for cuffs, cuffs are seldom provided on the smaller sizes of paediatric tubes.

This part of ISO 5366 specifies requirements for those characteristics of tracheostomy tubes that can be standardized and which are important for patient safety. It does not, however, limit the variety of tube designs necessary to conform to paediatric anatomy and the variety of lesions and space limitations encountered.

A tracheostomy tube may 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.

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Tracheostomy tubes —

Part 3:
Paediatric tracheostomy tubes

1 Scope

This part of ISO 5366 specifies requirements for cuffed and plain paediatric tracheostomy tubes made of plastics materials and/or rubber having inside diameters from 2 mm to 6 mm.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 5366. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 5366 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 594-1:1986, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements.*

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

ISO 5361-5:1984, *Tracheal tubes — Part 5: Requirements and methods of test for cuffs and tubes.*

ISO 5366-2:1993, *Tracheostomy tubes — Part 2: Basic requirements for tubes for adults.*

3 Definitions

For the purposes of this part of ISO 5366, the definitions given in ISO 5366-2 and the following apply.

3.1 paediatric tracheostomy tube: Tube designed for insertion into the trachea of an infant or child though a tracheostomy.

4 Size

4.1 Designation of size of tube

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.

4.2 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.

NOTE 1 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* shall be the marked outside diameter, subject to a tolerance of ± 0,2 mm.

Table 1 — Size range of paediatric tracheostomy tubes

Dimensions in millimetres

Designated size (nominal inside diameter, ID)	Inside diameter	
		tol.
2,0	2,0	$^{+0,2}_{0}$
2,5	2,5	$^{+0,2}_{0}$
3,0	3,0	$^{+0,2}_{0}$
3,5	3,5	$^{+0,2}_{0}$
4,0	4,0	$^{+0,2}_{0}$
4,5	4,5	$^{+0,3}_{0}$
5,0	5,0	$^{+0,3}_{0}$
5,5	5,5	$^{+0,3}_{0}$
6,0	6,0	$^{+0,3}_{0}$

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

4.3 Length

4.3.1 The centreline length (dimensions $A + B + C$ 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 inset), and expressed in millimetres.

4.3.2 The actual centreline length shall not vary by more than 1,5 mm from the marked length for tubes with a marked inside diameter of less than 4,5 mm, or by more than 2 mm for tubes with a marked inside diameter of 4,5 mm, or greater.

4.3.3 Dimensions A, B and C shall be expressed in millimetres.

NOTE 2 Dimensions A and/or B may be, or approach, zero.

4.3.4 For tubes with an adjustable neck-plate, the range of measurements for centreline lengths shall be expressed in millimetres.

4.4 Angle θ

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

5 Materials

The materials of paediatric tracheostomy tubes shall comply with the requirements specified in ISO 5366-2.

6 General requirements

6.1 Connectors

6.1.1 The machine end of a paediatric tracheostomy tube shall either

a) be a 15 mm male conical connector complying with the requirements specified in ISO 5356-1; or

b) mate with an adaptor having a 15 mm male conical connector complying with the requirements specified in ISO 5356-1 at its machine end (see 6.2).

NOTE 3 Connectors need not be permanently attached to the tube.

6.1.2 The connector, if provided with the tube, shall have an inside diameter not less than the inside diameter of the tube stated by the manufacturer [see 8.2 b)]. Any transition in inside diameter shall be tapered to give an adequate lead-in for passage of a suction catheter.

6.2 Adaptor

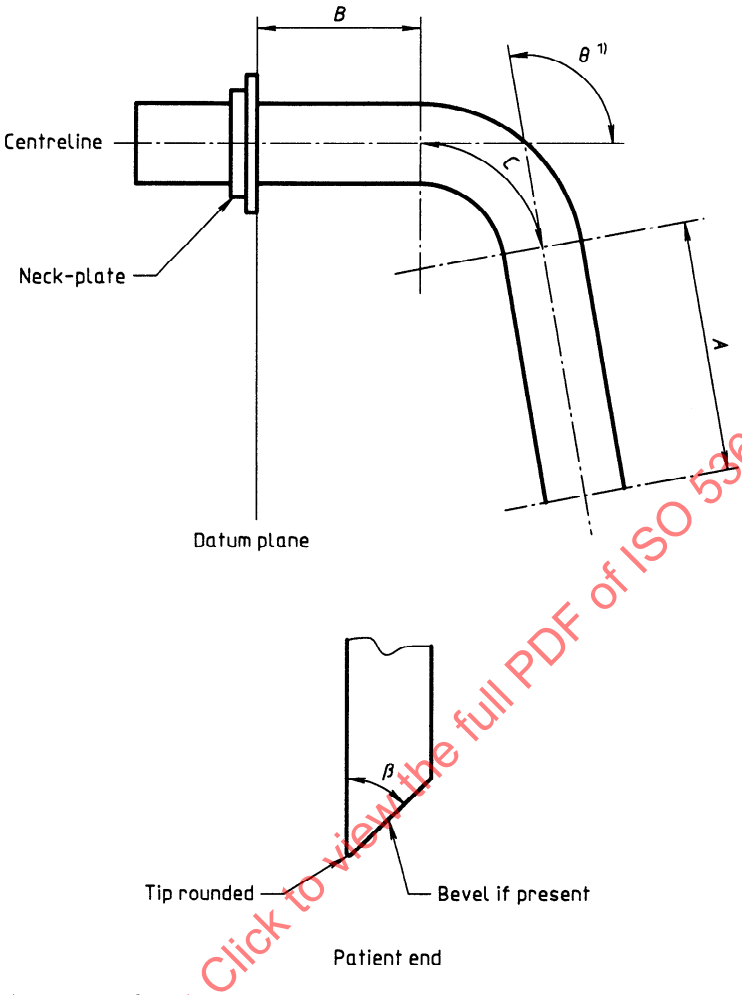
6.2.1 If provided with the tube [see 6.1.1 b)], an adaptor shall have an inside diameter not less than the inside diameter of the tube stated by the manufacturer [see 8.2 b)].

6.2.2 Any transition in inside diameter 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, shall extend to within 0,5 mm of the patient end of the tracheostomy (outer) tube and not more than 1,5 mm beyond the patient end.

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



1) The angle θ is the obtuse angle formed between the long axes of the tube at the machine and patient ends.

Figure 1 — Basic dimensions of paediatric tracheostomy tubes

6.4 Neck-plate

6.4.1 Tracheostomy tubes shall have a neck-plate (see figure 1) which may be 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.

6.5 Cuff

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

6.5.2 Cuffs of tracheostomy tubes shall comply with the requirements specified in ISO 5361-5.

6.5.3 The cuff resting diameter shall be within ± 15 % of the marked value when determined as in annex A.

6.6 Inflating tubes for cuffs

6.6.1 Inflating tube

The inflating tube, if fitted, shall have an outside diameter of not more than 2,5 mm. The wall around the secondary (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 wall around the secondary (inflation) lumen should not project substantially on the outside surface.

6.6.2 Pilot balloon

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

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

6.6.2.2 Neither the inflating tube nor any device shall act as a non-return valve to prevent the intentional evacuation of the cuff.

6.6.3 Free end of inflating tubes for cuffs

The end of the inflating tube may be 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 ISO 5366-2:1993, figure 1, dimension l_1) 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 ISO 5366-2:1993, figure 1, dimension l_2) between the pilot balloon (or other device) and the 6 % conical fitting shall be not less than 10 mm (for clamping) unless the pilot balloon and valve or closure device are integral.

6.7 Patient end

If a bevel is present, the angle of the bevel β shall be not less than 50° (see figure 1 inset).

7 Introducer (obturator)

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

The introducer should be freely removable in use.

8 Unit container

8.1 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 or adaptor is provided.

NOTE 4 For example, the unit container may be transparent and the tube visible, or a drawing to scale, preferably full scale, may be used.

8.2 The following information shall be provided either on the unit container or on an insert with the unit container:

a) a description of the 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 centreline length, expressed in millimetres (see 4.3). For tubes with an adjustable neck-plate, the range of centreline lengths shall also be given;

e) dimensions A and B as shown in figure 1;

f) the angle θ in accordance with 4.4 (see figure 1);

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

h) the batch number;

NOTE 5 It is strongly recommended that the expiry date be given.

i) if relevant, instructions for cleaning and disinfection or sterilization;

j) the word "STERILE" or "NON-STERILE", as appropriate;

k) for tubes not intended for re-use, the words "SINGLE USE" or equivalent;

NOTE 6 Symbol No.1051 ("Do not re-use") given in ISO 7000 [2] should additionally be used (see figure 2).

l) for cuffed tubes, the resting diameter of the cuff, determined in accordance with annex A and expressed in millimetres;

m) if an inner tube is provided in the unit pack, the nominal inside diameter of the inner tube.

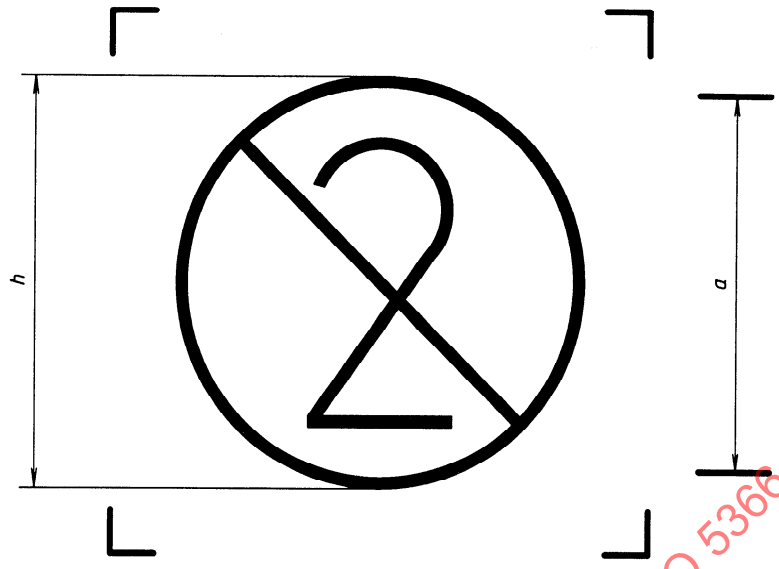


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Figure 2 — ISO symbol 7000/1051 "Do not re-use"

9 Marking

9.1 Neck-plate

The following information shall be marked on the neck-plate 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 (see 4.2);

NOTE 7 The centreline length (or the maximum length for tubes having an adjustable neck-plate), expressed in millimetres (see 4.3), may also be marked.

c) the name and/or trademark of the manufacturer.

9.2 Inner tube unit containers

Inner tube unit containers shall be clearly labelled to indicate the following information:

a) a description of the contents;

b) the designated size (nominal inside diameter) of the tracheostomy tube (outer tube) into which it is designed to fit (see 4.1);

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;

NOTE 8 It is strongly recommended that the expiry date be given.

f) if relevant, instructions for cleaning and disinfection or sterilization;

g) the word "STERILE" or "NON-STERILE", as appropriate;

h) for inner tubes not intended for re-use, the words "SINGLE USE" or equivalent;

NOTE 9 Symbol No.1051 ("Do not re-use") given in ISO 7000 [2] should additionally be used (see figure 2).

9.3 Shelf or multi-unit containers

Shelf or multi-unit containers shall be marked with the following information:

a) a description of the contents, size designation in accordance with 4.1, nominal outside diameter, expressed in millimetres (see 4.2) and the nominal centreline length, expressed in millimetres (see 4.3);

NOTE 10 For tubes with an adjustable neck-plate, the range of centreline lengths should also be given.

b) the name and address of the manufacturer or supplier;

c) the batch number;

NOTE 11 It is strongly recommended that the expiry date be given.

d) the word "STERILE" or "NON-STERILE", as appropriate;

e) for tubes not intended for re-use, the words "SINGLE USE" or equivalent.

NOTE 12 Symbol No.1051 ("Do not re-use") given in ISO 7000 [2] should additionally be used (see figure 2).

Annex A
(normative)

Method for determining resting diameter of cuff

A.1 Principle

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

A.2 Apparatus

Means to inflate the cuff with sufficient air to create an internal overpressure of 2 kPa (20 cmH_2O) ± 5 %.

A.3 Procedure

A.3.1 Inflate the cuff with sufficient air to create an internal overpressure of 2 kPa (20 cmH_2O) ± 5 % and leave to stabilize for 5 min at (23 ± 2) °C, maintaining that overpressure.

A.3.2 Measure the maximum cuff diameter in a plane perpendicular to the axis of the tube at intervals of 45°.

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
(informative)

Bibliography

[1] ISO 4135:—[1], *Anaesthesiology — Vocabulary.*

[2] ISO 7000:1989, *Graphical symbols for use on equipment — Index and synopsis.*

1) To be published. (Revision of ISO 4135:1979)