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**5366-1**

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## Anaesthetic and respiratory equipment — Tracheostomy tubes —

### Part 1: Tubes and connectors for use in adults

*Matériel d'anesthésie et de réanimation respiratoire — Tubes de  
trachéostomie —  
Partie 1: Tubes et raccords pour adultes*

ISO 5366-1:2000

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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 5366-1 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Tracheal tubes and other equipment*.

This fourth edition cancels and replaces the third edition of ISO 5366-1 and the second edition of ISO 5366-2 (ISO 5366-1:1994 and ISO 5366-2:1993), which have 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* [ISO 5366-1:2000](https://standards.iteh.ai/catalog/standards/sist/f742a921-0f76-49a9-a7a2-a6e350e629c8/iso-5366-1-2000)
- *Part 3: Paediatric tracheostomy tubes* [a6e350e629c8/iso-5366-1-2000](https://standards.iteh.ai/catalog/standards/sist/f742a921-0f76-49a9-a7a2-a6e350e629c8/iso-5366-1-2000)

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

## Introduction

ISO 5366-1 is one of a series of International Standards dealing with anaesthetic equipment, and is concerned with the basic requirements and method of size designation of tracheostomy tubes made of plastics materials and/or rubber. Specialized tubes, for example those without a connector at the machine end intended for spontaneously breathing patients, and those with reinforced walls or tubes made of metal are excluded from the scope of this part of ISO 5366.

This part of ISO 5366 specifies requirements for tracheostomy tubes with an inside diameter of 6,5 mm or greater. ISO 5366-3 specifies requirements for tracheostomy tubes with an inside diameter from 2,0 to 6,0 mm for paediatric use.

The method of describing tube dimensions and configuration has been devised in order to assist 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.

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

The relationship of cuff and tracheal diameters dictates the intra-cuff pressures required to provide a seal. Excessive pressure on the tracheal wall can obstruct capillary blood flow.

A range of cuff designs is available to meet the particular clinical requirements. This part of ISO 5366 requires that the resting diameter of the cuff is marked on the unit package, as this information allows the clinician to match the product to the application. <https://standards.iteh.ai/catalog/standards/sist/f742a921-0f76-49a9-a7a2-a6e350e629c8/iso-5366-1-2000>

A 15 mm male conical connector in accordance with ISO 5356-1 should be used for tracheostomy tubes, as for tracheal tubes, to ensure compatibility with the breathing system of an anaesthetic machine or ventilator.

The tracheostomy tube connector should be permanently attached to the tracheostomy tube to prevent inadvertent disconnection of the connector from the tube.

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

1) See ISO/TR 11991.

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# Anaesthetic and respiratory equipment — Tracheostomy tubes —

## Part 1:

## Tubes and connectors for use in adults

### 1 Scope

This part of ISO 5366 specifies requirements for tracheostomy tubes made of plastics materials and/or rubber having inside diameters of 6,5 mm or greater. Such tubes are primarily designed for patients who require anaesthesia, artificial ventilation or other respiratory support, but need not be restricted to these uses.

This part of ISO 5366 is not applicable to specialized tubes, and does not address flammability of 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.

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ISO 594-1, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements.*

ISO 4135, *Anaesthetic and respiratory equipment — Vocabulary.*

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 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

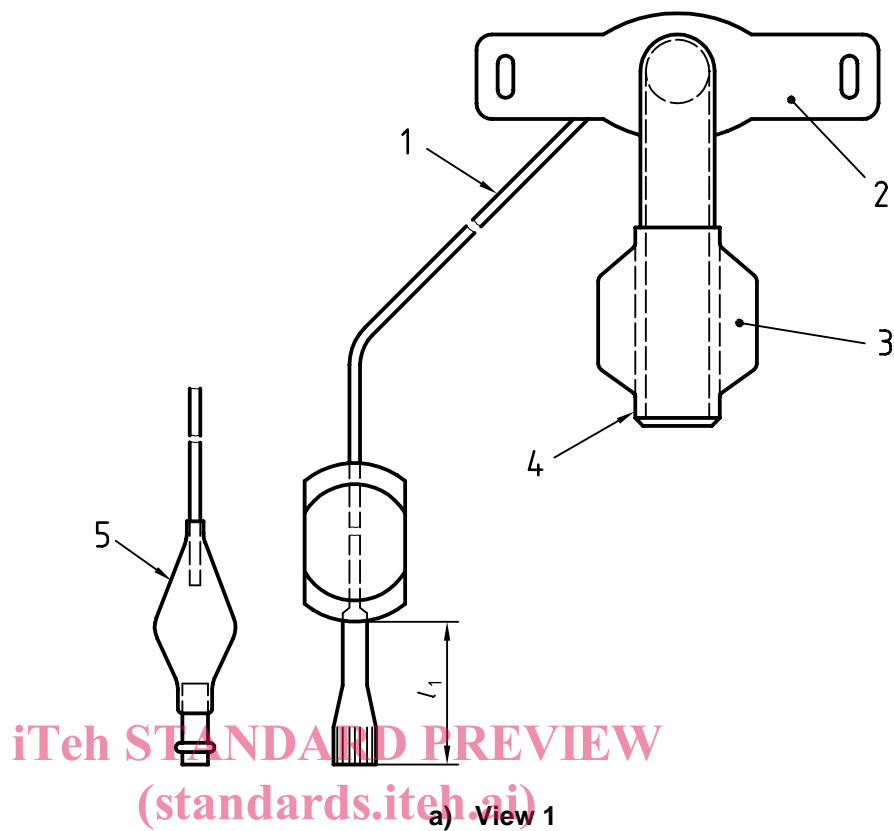
For the purposes of this part of ISO 5366, the terms and definitions given in ISO 4135 and the following apply.

#### 3.1

##### **tracheostomy tube**

tube designed for insertion into the trachea through a tracheostomy

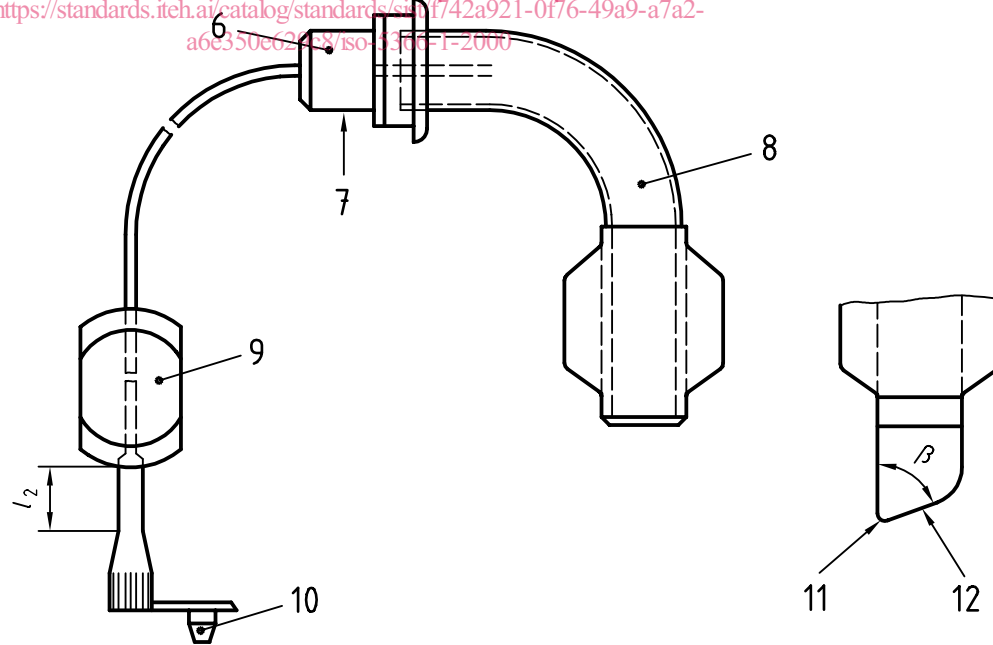
NOTE See Figure 1 a) and b) for an illustration of a typical tracheostomy tube and the associated nomenclature.



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**Key**

- 1 Inflating tube
- 2 Neck-plate
- 3 Cuff, if present
- 4 Patient end
- 5 Alternative integral pilot balloon/valve assembly
- 6 15 mm male conical fitting in accordance with ISO 5356-1
- 7 Machine end
- 8 Outer tube
- 9 Pilot balloon
- 10 Inflation valve or closure device
- 11 Tip rounded
- 12 Bevel, if present



**Figure 1 — Typical tracheostomy tube**

**3.2****machine end**

(of a tracheostomy tube) that end which is intended to project from the neck of a patient

**3.3****machine end**

(of a connector or an adaptor) that end intended to mate with the breathing system of an anaesthetic machine or ventilator

**3.4****patient end**

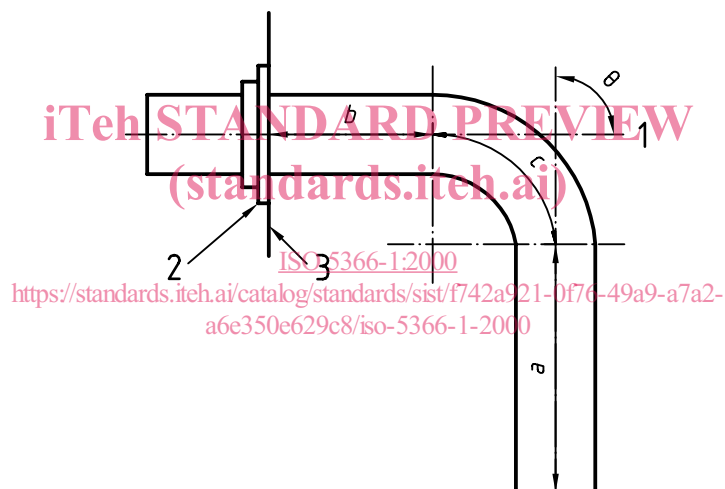
that end of a tracheostomy tube which is intended to be inserted into the trachea

**3.5****nominal length**

distance from the patient side of the neck-plate to the patient end along the centreline

See Figure 2.

NOTE When the neck-plate is movable, the nominal length is variable.

**Key**

- 1 Centreline
- 2 Neck-plate
- 3 Datum plane

NOTE The angle  $\theta$  is the obtuse angle formed between the long axes of the tube at the machine and patient ends.

**Figure 2 — Basic dimensions of tracheostomy tubes**

**3.6**

**outer tube**

that part of the tracheostomy tube which is normally in contact with the tissues

**3.7**

**inner tube**

tube which fits closely to the inside contours of the outer tube (i.e. a tracheostomy tube)

**3.8**

**cuff**

inflatable balloon permanently attached around the tracheostomy tube near the patient end to provide a seal between the tube and the trachea

**3.9**

**inflating tube**

tube through which a cuff is inflated

**3.10**

**pilot balloon**

balloon fitted to an inflating tube to indicate inflation of a cuff

**3.11**

**neck-plate**

**shield**

that part of a tracheostomy tube which approximates to the contour of a patient's neck and is used to secure the tube in position

**3.12**

**introducer**

**obturator**

specially adapted stylet to facilitate the introduction of the outer tube into the trachea

**3.13**

**bevel**

slanted portion at the patient end of a tracheostomy tube

**3.14**

**angle of bevel**

acute angle between the plane of the bevel and the longitudinal axis of a tracheostomy tube at the patient end

## **4 Size designation and dimensions**

### **4.1 Inside diameter**

**4.1.1** The size of the tracheostomy tube (outer tube) shall be designated by the nominal inside diameter (ID) of the tube, expressed in millimetres, as measured at the minimum inside diameter, in accordance with Table 1, excluding any encroachment allowed by 6.5.1.

**4.1.2** For tracheostomy tubes with the conical connector permanently attached to the inner tube, 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 of tracheostomy tubes — Dimensions and tolerances**

Dimensions in millimetres

Designated size	Inside diameter and tolerance
6,5	$6,5 \pm 0,2$
7,0	$7,0 \pm 0,2$
7,5	$7,5 \pm 0,2$
8,0	$8,0 \pm 0,2$
8,5	$8,5 \pm 0,2$
9,0	$9,0 \pm 0,2$
9,5	$9,5 \pm 0,2$
10,0	$10,0 \pm 0,2$
10,5	$10,5 \pm 0,2$
11,0	$11,0 \pm 0,2$

## 4.2 Outside diameter

**4.2.1** The outside diameter (OD) of sections *a* and *c* (see Figure 2) of the tube, other than at the cuff, if provided, shall be expressed in millimetres to the nearest 0,1 mm.

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

**4.2.2** The actual outside diameter of section *a* (see Figure 2) other than at the cuff, if provided, shall be the marked outside diameter subject to a tolerance of  $\pm 0,2$  mm.

**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 nominal length (dimensions  $a + b + c$  in Figure 2) shall be measured from the patient side of the neck-plate to the patient end including the bevel, if present, and expressed in millimetres.

**4.3.2** The actual nominal length (dimensions  $a + b + c$  in Figure 2) shall be the marked nominal length subject to a tolerance of  $\pm 2$  mm.

**4.3.3** For tubes with an adjustable neck-plate, the range of measurements for nominal length (see Figure 2) shall be expressed in millimetres.

**4.3.4** Dimensions *a*, *b* and *c* shall be expressed in millimetres (see Figure 2).

NOTE Dimensions *a* and/or *b* can be, or approach, zero.

## 4.4 Angle $\theta$

The angle  $\theta$  (see Figure 2) shall be expressed in degrees.