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Anaesthetic and respiratory equipment — Tracheostomy tubes and connectors

Matériel d'anesthésie et de réanimation respiratoire — Raccords et tubes de trachéostomie

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

The committee responsible for this document is ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Airways and related equipment*.

This first edition of ISO 5366 cancels and replaces ISO 5366-1 and ISO 5366-3, which have been technically revised.

Introduction

This International Standard provides the essential requirements for the design of cuffed and uncuffed TRACHEOSTOMY TUBES and connectors. These devices are intended to be inserted through a stoma in the trachea to convey gases and vapours to and from the trachea. Cuffed devices are designed to seal and protect the trachea from aspiration and to provide an unobstructed airway in patients during spontaneous, assisted or controlled ventilation for short or prolonged durations. Specialized tubes with walls reinforced with metal or nylon, tubes with shoulders, tapering tubes, tubes with provision for suctioning or monitoring or delivery of drugs or other gases and the many other types of TRACHEOSTOMY TUBES devised for specialized applications are included in this specification, as many specialized TRACHEOSTOMY TUBES are now commonly used, and all share similar essential requirements defined in this International Standard.

The method of describing tube dimensions and configuration has been devised in order to assist clinicians in the selection of the most suitable tube for a particular patient's anatomy. Size is designated by the internal dimension, which is important because of its relationship to resistance to gas flow. Because stoma and tracheal sizes are also important factors when selecting a TRACHEOSTOMY TUBE, it is considered essential that the outside dimension for each size of tube is also made known to the user.

Cuffed TRACHEOSTOMY TUBES can be characterized by a combination of the tube inside and outside dimensions and by the diameter of the CUFF.

A variety of CUFF designs are available to meet particular clinical requirements. This International Standard encompasses requirements for both paediatric and adult TRACHEOSTOMY TUBES. They share many common requirements that can be standardized and which are important for patient safety. An infant or child differs from an adult, not only in size, but also with regard to airway anatomy and respiratory physiology; thus, airway equipment for paediatric patients differs from that for adults, both in size and in basic design. This International Standard does not require the connector to be permanently attached to the tube, as this can be impractical with infants and small children. Other acceptable methods of connecting these components are available, and this International Standard makes provision for them. This International Standard does not limit the range of tube designs needed to match the variations in paediatric anatomy, lesions and space limitations encountered.

Kink resistance requirements with associated test methods have also been added to this International Standard to measure the ability of the shaft of the TRACHEOSTOMY TUBE to resist collapse and increased breathing resistance when bent or curved.

Requirements for TRACHEOSTOMY TUBES that are common to other airway and related devices have been removed from this International Standard as these are now included in ISO 18190, which is cross referenced where appropriate.

Throughout this International Standard, the following print types are used:

— requirements and definitions: roman type;

— *test specifications: italic type*;

— informative material appearing outside of tables, such as notes, examples and references: smaller type. The Normative text of tables is also in smaller type;

— TERMS DEFINED IN CLAUSE 3: SMALL CAPS.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex A.

Anaesthetic and respiratory equipment — Tracheostomy tubes and connectors

1 *Scope

This International Standard specifies requirements for adult and paediatric TRACHEOSTOMY TUBES and connectors. Such tubes are primarily designed for patients who require anaesthesia, artificial ventilation or other respiratory support.

This International Standard is also applicable to specialized TRACHEOSTOMY TUBES that share common attributes, 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 or tubes with shoulders, tapering tubes, tubes with provision for suctioning or monitoring or delivery of drugs or other gases.

Flammability of TRACHEOSTOMY TUBES is a well recognized hazard (for example, when electrosurgical units or lasers are used with flammable anaesthetic agents in oxidant-enriched atmospheres) that is addressed by appropriate clinical management and is outside the scope of this International Standard.

NOTE ISO/TR 11991 gives guidance on avoidance of airway fires.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 4135, *Anaesthetic and respiratory equipment — Vocabulary*

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

ISO 18190:2016, *Anaesthetic and respiratory equipment — General requirements for airways and related equipment*

ISO 80369-7, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

ASTM F2052, *Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment*

ASTM F2503, *Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment*

3 Terms and definitions

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

NOTE See Figure 1 for illustrations of typical TRACHEOSTOMY TUBES and associated nomenclature.

3.1
ANGLE OF BEVEL
angle between the plane of the BEVEL (3.2) and the longitudinal axis of a TRACHEOSTOMY TUBE (3.13)

3.2
BEVEL
slanted portion at the PATIENT END (3.12) of a TRACHEOSTOMY TUBE (3.13)

3.3
CUFF
inflatable balloon around a TRACHEOSTOMY TUBE (3.13) near the PATIENT END (3.12) to provide a seal between the tube and the trachea

3.4
INFLATING TUBE
tube through which a CUFF (3.3) is inflated

3.5
INFLATION INDICATOR
PILOT BALLOON
device attached to an INFLATING TUBE (3.4) to indicate CUFF inflation

3.6
INNER TUBE
tube or cannula which fits closely to the inside contours of an OUTER TUBE (3.11)

3.7
INTRODUCER
stylet to facilitate the introduction of an OUTER TUBE (3.11) into the trachea

3.8
MACHINE END
end of a TRACHEOSTOMY TUBE (3.13) which is intended to project from the neck of a patient

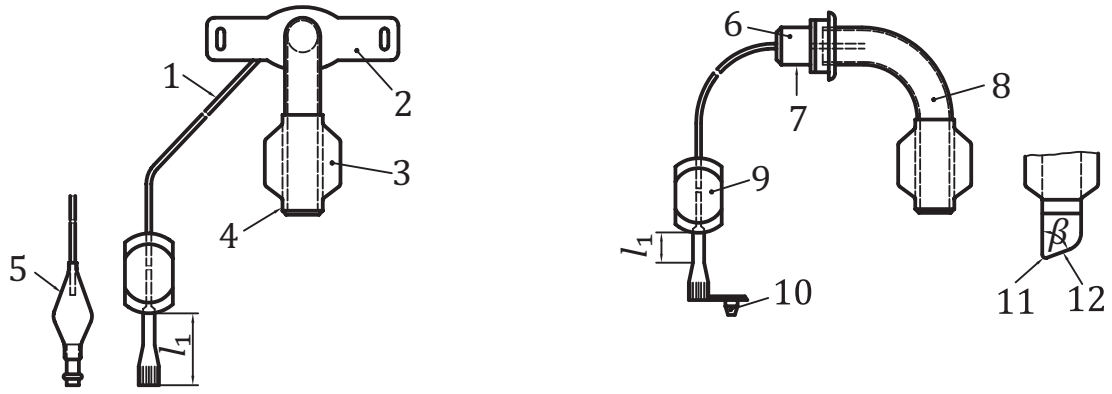
3.9
NECK-PLATE
part of a TRACHEOSTOMY TUBE which is used to secure the tube in position

3.10
NOMINAL LENGTH
distance from the patient side of the NECK-PLATE (3.9) to the PATIENT END (3.12) along the centre line

3.11
OUTER TUBE
part of a TRACHEOSTOMY TUBE (3.13) which is normally in contact with the tissues

3.12
PATIENT END
end of a TRACHEOSTOMY TUBE (3.13) which is intended to be inserted into the trachea

3.13
TRACHEOSTOMY TUBE
tube designed for insertion into the trachea through a tracheostomy

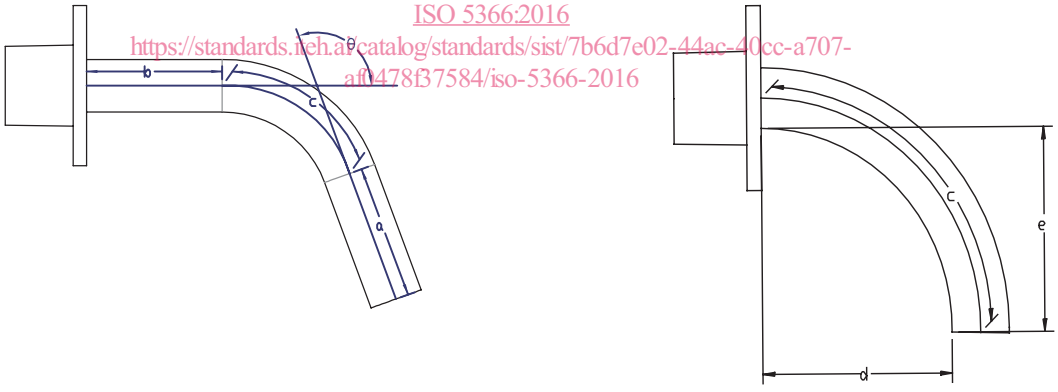


a) b)

Key

1	INFLATING TUBE	8	OUTER TUBE
2	NECK-PLATE	9	INFLATION INDICATOR
3	CUFF	10	inflation valve or closure device
4	PATIENT END	11	tip
5	INFLATION INDICATOR/PILOT BALLOON	12	BEVEL
6	breathing system connector	β	ANGLE OF BEVEL (see 6.3.7)
7	MACHINE END	l_1	clamping length (see 6.3.7.2)

Figure 1 — Typical TRACHEOSTOMY TUBE



a) b)

Key

Θ angle formed between the long axes of the TRACHEOSTOMY TUBE at the MACHINE END and the PATIENT END

NOTE Figure 2 a) NOMINAL LENGTH = b + c + a; Figure 2 b) NOMINAL LENGTH = c.

Figure 2 — Basic dimensional datum references of a TRACHEOSTOMY TUBE

4 *General requirements for TRACHEOSTOMY TUBES and connectors

4.1 TRACHEOSTOMY TUBES and connectors shall satisfy the general requirements for airways and related equipment for risk management, usability, clinical evaluation and biophysical or modelling research listed in ISO 18190.

NOTE Annex G covers hazard identification for risk assessment of TRACHEOSTOMY TUBES.

Check compliance by the relevant requirements in ISO 18190.

4.2 The manufacturer may use type tests different from those detailed within this International Standard if an equivalent degree of safety is obtained. Alternative test methods shall be validated against the test methods specified in this International Standard.

Check compliance by inspection of the manufacturer's technical file.

5 Materials

TRACHEOSTOMY TUBES and connectors shall satisfy the general requirements for materials specified in ISO 18190:2016, Clause 5.

Check compliance by the relevant requirements in ISO 18190.

6 Design requirements for TRACHEOSTOMY TUBES and connectors

6.1 General design requirements

TRACHEOSTOMY TUBES and connectors shall satisfy the general design requirements for airways and related equipment specified in ISO 18190.

Check compliance by the relevant requirements in ISO 18190.

6.2 Size designation and dimensions

6.2.1 *Designated size

Designated sizes of TRACHEOSTOMY TUBES shall be within the tolerances for the internal dimensions specified in Table 1, including the connector, if fitted according to 6.3.1.1, but excluding any encroachment allowed by 6.3.5 a).

Check compliance by functional testing.

Table 1 — Size designations of TRACHEOSTOMY TUBES: Dimensions and tolerances

Dimensions in millimetres

Designated size	Nominal internal dimension and tolerance	Designated size	Nominal internal dimension and tolerance
2,0	2,0 + 0,2/–0,0	6,5	6,5 ± 0,2
2,5	2,5 + 0,2/–0,0	7,0	7,0 ± 0,2
3,0	3,0 + 0,2/–0,0	7,5	7,5 ± 0,2
3,5	3,5 + 0,2/–0,0	8,0	8,0 ± 0,2
4,0	4,0 + 0,2/–0,0	8,5	8,5 ± 0,2
4,5	4,5 + 0,3/–0,0	9,0	9,0 ± 0,2
5,0	5,0 + 0,3/–0,0	9,5	9,5 ± 0,2
5,5	5,5 + 0,3/–0,0	10,0	10,0 ± 0,2
6,0	6,0 + 0,3/–0,0	10,5	10,5 ± 0,2
		11,0	11,0 ± 0,2
		>11,0	>11,0 ± 0,2

6.2.2 Outside dimension

The actual measurement, of a and b (see Figure 2), shall be at the widest cross-sectional dimension along its length (excluding any protuberance caused by INFLATING TUBE, suction line, etc., other than at the CUFF, if provided), shall be the marked outside dimension subject to a tolerance of ±0,2 mm.

The actual outside dimension of section c shall be the marked outside dimension subject to a tolerance of +/-0,5 mm.

Check compliance by functional testing.

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

6.2.3 NOMINAL LENGTH

The NOMINAL LENGTH, [see Figures 2 a) and b)], shall be within ±1,5 mm of the manufacturer's declared length [see 8.2.1 d)] for tubes with a designated size of <4,5 mm and within ±2,0 mm for tubes with a designated size of ≥4,5 mm measured from the patient side of the NECK-PLATE to the PATIENT END including the BEVEL, if present, and expressed in millimetres.

Check compliance by functional testing.

6.3 Design

6.3.1 Connector

6.3.1.1 TRACHEOSTOMY TUBES or their INNER TUBES designed for use with a breathing system shall be fitted, at the MACHINE END, with a conical connector having a 15 mm cone complying with ISO 5356-1.

The connector shall not detach from the TRACHEOSTOMY TUBE or INNER TUBE at a separation force <50 N when applied at a rate of (50 ± 5) mm min^{-1}.

Check compliance by the test method given in Annex B.

6.3.1.2 The minimum inside diameter of the connector shall be ≥ the designated size of the TRACHEOSTOMY TUBE.

Check compliance by functional testing.

6.3.1.3 Any transition in inside diameter shall be tapered to facilitate the passage of a device (e.g. suction catheter).

Check compliance by inspection.

6.3.1.4 Assessment of the risk of misconnection between the ID of the 15 mm connector to the ISO 80369 series small-bore connector, shall be addressed by the manufacturer during the risk management process. Reduction of the risk should be addressed by design if practicable.

Check compliance by inspection of the risk management file.

6.3.2 NECK PLATE

6.3.2.1 A non-adjustable NECK-PLATE shall not detach from the TRACHEOSTOMY TUBE at an axial force of <50 N applied at a rate of (50 ± 5) mm min^{-1}.

Check compliance by the test method given in Annex B.

6.3.2.2 An adjustable NECK-PLATE shall not move, when in a locked position, at an axial force of <15 N applied at a rate of (50 ± 5) mm min^{-1}.

Check compliance by the test method given in Annex B.

6.3.2.3 The locking mechanism for an adjustable NECK-PLATE shall not cause a reduction in the internal dimension of the TRACHEOSTOMY TUBE of more than 10 %.

Check compliance by functional testing.

6.3.2.4 The NECK-PLATE shall be provided with means to facilitate attachment to the patient.

6.3.3 INNER TUBE

6.3.3.1 The length of an INNER TUBE shall be within ±1,0 mm of the PATIENT END of the OUTER TUBE.

Check compliance by functional testing.

6.3.3.2 The MACHINE END of the INNER TUBE shall either comply with 6.3.1 or shall not prevent the TRACHEOSTOMY (OUTER) TUBE connector mating with the breathing system of an anaesthetic machine or lung ventilator

Check compliance by functional testing.

6.3.3.3 *There should be a means to ascertain visually whether the INNER TUBE is present when the TRACHEOSTOMY TUBE is *in situ* without disconnecting the breathing system.

Check compliance by functional testing.

6.3.3.4 Assessment of the risk of misconnection between the ID of the INNER TUBE to the ISO 80369 series small-bore connector, shall be addressed by the manufacturer during the risk management process. Reduction of the risk should be addressed by design if practicable.

Check compliance by inspection of the risk management file.