INTERNATIONAL STANDARD

ISO 5366

First edition
2016-10-01

Anaesthetic and respiratory equipment — Tracheostomy tubes and connectors

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

Reference number
ISO 5366:2016(E)

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

Page

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

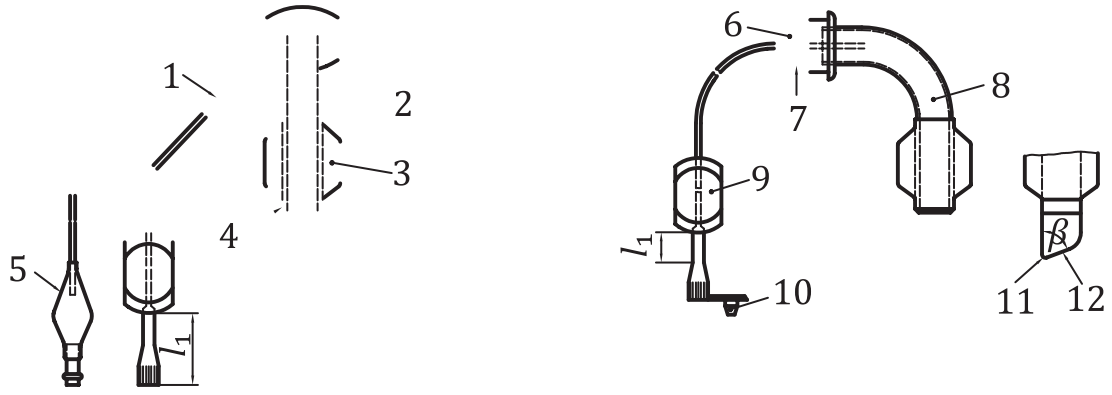
3.9
NECK-PLATE
part of a TRACHEOSTOMY TUBE which is used to secure the tube in position

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

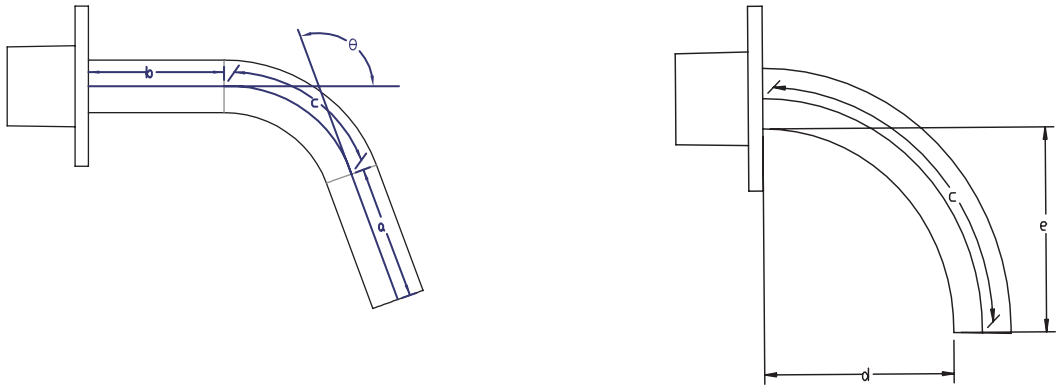


a) b)

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.

6.3.4 *CUFFS

6.3.4.1 CUFFS shall not leak when subjected to an internal pressure of <9,0 kPa or when inflated to a diameter <1,5 times the CUFF diameter (see 8.3.1) over a 10 s interval.

Check compliance by inflating the CUFF to an internal pressure >9,0 kPa or >1,5 times the CUFF diameter, whichever comes sooner, hold for ≥10 s whilst checking for leakage.

6.3.4.2 CUFFS shall not herniate such that any part of the inflated CUFF reaches beyond the opening on the PATIENT END of the tube (see Figure D.1).

Check compliance by the tests given in Annex D.

6.3.4.3 The outer surface of the TRACHEOSTOMY TUBE, where the CUFF is attached, shall be free of sharp edges.

Check compliance by inspection of the risk management file.

6.3.4.4 The cuff resting diameter shall be within +/-15% of the marked value, when inflated to an overpressure of 2,0 ± 0,1 kPa.

Check compliance by the tests given in Annex C.

6.3.5 INFLATING TUBES for CUFFS

The INFLATING TUBE shall

a) not encroach on the lumen of the TRACHEOSTOMY TUBE by >10 % of the internal dimension, and

b) not project on the outer surface of the TRACHEOSTOMY TUBE by >10 % of the outer dimension.

Check compliance by functional testing.

6.3.6 CUFF INFLATION INDICATOR

6.3.6.1 The INFLATING TUBE shall have a means to indicate whether the CUFF is inflated or deflated.

EXAMPLES PILOT BALLOON, bellows, CUFF pressure indicator.

NOTE Such devices can also serve as a means of indicating or limiting CUFF pressure.

Check compliance by visual inspection.

6.3.6.2 Intentional deflation of the CUFF shall not be prevented by the INFLATING TUBE, inflating valve or any closure device.

6.3.7 *INFLATING TUBE

6.3.7.1 The free end of the INFLATING TUBE shall be compatible with a male Luer connector complying with ISO 80369-7.

Check compliance by functional testing.

6.3.7.2 If an inflation valve or closure device is not provided, the length, dimension l_1 [see Figures 1 a) and b)], shall be ≥40 mm.

NOTE This is to facilitate clamping of the INFLATING TUBE.

Check compliance by functional testing.

6.3.8 PATIENT END

6.3.8.1 If a BEVEL is present, the angle (β) (see Figure 1 b) shall be ≥50°.

Check compliance by functional testing.

6.3.8.2 The PATIENT END shall be free of sharp edges.

Check compliance by inspection of the risk management file.

6.3.9 INTRODUCER

6.3.9.1 An INTRODUCER, when seated, shall not fall out of the TRACHEOSTOMY TUBE under its own weight, when held independently by either the TRACHEOSTOMY TUBE or INTRODUCER under any orientation.

Check compliance by functional testing.

6.3.9.2 The INTRODUCER should be freely removable in use.

6.3.9.3 It shall not be possible to connect the MACHINE END to a breathing system unless the INTRODUCER has been removed.

Check compliance by functional testing.

6.3.10 *Radiopaque marker

TRACHEOSTOMY TUBES shall be detectable by X-ray.

Check compliance by inspection of the TRACHEOSTOMY TUBES using the method described in ASTM F640.

6.3.11 *Kink resistance

6.3.11.1 TRACHEOSTOMY TUBES shall not kink when bent to ±15° from their stated angle [Θ Figure 2 a)] such that a steel ball, with a diameter ≥75 % of the designated size, will not pass through their lumen.

Check compliance by the test method described in Annex E.

6.3.11.2 For devices that include a locking mechanism for an adjustable NECK-PLATE, test the adjustable range limits of the TRACHEOSTOMY TUBE.

Check compliance by the test method described in Annex F.

NOTE TRACHEOSTOMY TUBES made from rigid materials will not be suitable for testing in the test apparatus described in *Annex F* and are therefore exempt from this test.

The design should be such as not to exert undue pressure on the patient's anatomy when correctly placed.

7 Requirements for TRACHEOSTOMY TUBES supplied sterile

7.1 Sterility assurance

TRACHEOSTOMY TUBES supplied and marked as "STERILE" shall satisfy the requirements in ISO 18190.

Check compliance by the relevant requirements in ISO 18190.

7.2 Packaging for TRACHEOSTOMY TUBES supplied sterile

7.2.1 Packaging for TRACHEOSTOMY TUBES supplied sterile shall satisfy the requirements in ISO 18190.

Check compliance by the relevant requirements in ISO 18190.

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

a) the size and pre-formed shape of the TRACHEOSTOMY TUBE;

b) whether a CUFF is provided;

c) for paediatric or specialized TRACHEOSTOMY TUBES, 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.

Check compliance by visual inspection.

8 Information supplied by the manufacturer

8.1 General

8.1.1 Information supplied by the manufacturer shall satisfy the requirements in ISO 18190.

Check compliance by the relevant requirements in ISO 18190.

8.1.2 TRACHEOSTOMY TUBES, for use in Magnetic Resonance Imaging (MRI) environments, shall be marked to designate their suitability in accordance with ASTM F2503 and ASTM F2052.

Check compliance by visual inspection.

8.1.3 The instructions for use shall identify the risks associated with excessive CUFF pressure.

Check compliance by visual inspection of the instructions for use.

8.2 Marking of NECK-PLATE

8.2.1 The following information shall be marked on the NECK-PLATE and shall be visible from the MACHINE END:

a) the name and/or trade mark of the manufacturer;

b) the designated size in accordance with 6.2.1;

c) if practicable, the outside dimension, expressed in millimetres in accordance with 6.2.2;

d) if practicable, the NOMINAL LENGTH (or the range of lengths for tubes with an adjustable NECK-PLATE), expressed in millimetres in accordance with 6.2.3.

Check compliance by visual inspection.

8.3 Marking on the INFLATION INDICATOR

8.3.1 The INFLATION INDICATOR shall be marked with the designated size, where practicable.

Check compliance by visual inspection.

8.3.2 Cuffed tubes shall be marked with the diameter of the CUFF, expressed in millimetres to two significant figures in accordance with 6.3.4.4, where practicable.

Check compliance by visual inspection and the tests given in Annex C.

8.4 Marking of TRACHEOSTOMY TUBE connectors

The TRACHEOSTOMY TUBE connector, if not fitted to the TRACHEOSTOMY TUBE, shall be marked with its minimum inside diameter, expressed in millimetres (see 6.3.1.2).

Check compliance by visual inspection.

8.5 Additional labelling of unit packs

In addition to the general labelling requirements of ISO 18190, individual packs or a package insert shall be clearly labelled to indicate the following:

a) the designated size in accordance with 6.2.1;

b) the outside dimension, expressed in millimetres in accordance with 6.2.2;

c) the NOMINAL LENGTH, (or the range of lengths for TRACHEOSTOMY TUBES with an adjustable NECK-PLATE), expressed in millimetres in accordance with 6.2.3;

d) if a connector is not provided, a statement to this effect;

e) a figure with the dimensions, in millimetres, indicated in Figure 2, as a, b, c, d and e, if applicable. For tubes with an adjustable NECK-PLATE, the maximum dimension, b [see Figures 2 a) or b)].

f) angle Θ (see Figure 2) measured in degrees;

g) for cuffed tubes, the diameter of the CUFF, determined in accordance with Annex C, and expressed in millimetres to two significant figures;

h) if an INNER TUBE is provided in the TRACHEOSTOMY TUBE unit pack, the nominal inside dimension of the INNER TUBE, expressed in millimetres.

Check compliance by visual inspection and the relevant requirements in ISO 18190.

8.6 Labelling of INNER TUBE unit packs

In addition to the general labelling requirements of ISO 18190, INNER TUBE unit packs shall be clearly labelled to indicate the following:

a) the designated size of the OUTER TUBE into which it is designed to fit;

b) the nominal inside dimension of the INNER TUBE, expressed in millimetres.

Check compliance by visual inspection and the relevant requirements in ISO 18190.

8.7 Labelling of TRACHEOSTOMY TUBE inserts

In addition to the general labelling requirements of ISO 18190, the following shall be marked on the TRACHEOSTOMY TUBE insert:

a) instructions for preparation of the TRACHEOSTOMY TUBE prior to use. If the instructions for preparation recommend the use of an additive substance, the type and amount of any applied substance;

b) for TRACHEOSTOMY TUBES with protuberances (e.g. suction tube), the maximum outside dimension including the protuberance.

The performance information shown below was collected using a bench test that is intended to provide a comparison of the sealing characteristics of TRACHEOSTOMY TUBE CUFFS only in a laboratory setting. The bench test is not configured or intended to predict performance in the clinical setting.

TRACHEOSTOMY TUBE CUFF performance for a 7.5 TRACHEOSTOMY TUBE					
Minimum trachea diameter: 18 mm			**Maximum trachea diameter: 22 mm**		
CUFF pressure	Leakage Rate Range (ml/h)		**CUFF** pressure	Leakage Rate Range (ml/h)	
hPa (cmH_2O)	50th percentile	90th percentile	hPa (cmH_2O)	50th percentile	90th percentile
25	**6 mL/h**	**20 mL/h**	**25**	**10 mL/h**	**30 mL/h**

Check compliance by visual inspection and the relevant requirements in ISO 18190.

Annex A
(informative)

Rationale

This annex provides a concise rationale for the important requirements of this International Standard and is intended for use by those who are familiar with the subject of this International Standard, but who have not participated in its development. An understanding of the reasons for the main requirements is considered essential for its proper application. Furthermore, as clinical practices and technologies change, it is believed that rationales for the present requirements will facilitate any revisions of this International Standard necessitated by those developments.

The clauses in this annex have been so numbered to correspond to the clauses in this International Standard to which they refer. The numbering is, therefore, not consecutive.

A.1 Scope

The scope has been expanded to include so-called specialty TRACHEOSTOMY TUBES because they share many of the same requirements.

A.4 General requirements for TRACHEOSTOMY TUBES and connectors

This section has been revised to include essential performance and risk management principles associated with airways and related equipment. ISO 18910 describes the need for a risk management file as a well recognized process through which the manufacturer of a medical device can identify hazards associated with a medical device, estimate and evaluate the risks associated with these hazards, control these risks and monitor the effectiveness of that control. Clinical evaluation may also be necessary to confirm the adequacy of the controls (see ISO 18190 for additional information).

Safety examples of an intended use that may deviate from the currently accepted medical practice may include (but are not limited to) the following:

— specific recommendations for the patient population of intended use;

— a requirement that the CUFF pressure should be limited;

— a recommendation that the CUFF should not be fully deflated while *in vivo*;

— a recommendation that the TRACHEOSTOMY TUBE is not intended for use in a specific population of patients such as premature infants or small-for-age infants and children.

A.5 Materials

Although material biocompatibility is important for all tracheal tubes and other airways, it was considered of special importance for TRACHEOSTOMY TUBES that might remain *in situ* for weeks.

A.6.2.1 Designated size

The term ”diameter” previously used in this International Standard has been changed to size or dimension as some TRACHEOSTOMY TUBES are oval. The marked size is the designated size and represents the narrowest dimension throughout the lumen of the tube. This will assure the proper selection of an INNER TUBE or accessory that fits within the tube. This will also identify the narrowest restriction that may create breathing resistance.

A.6.3.3.3 Inner tube

If the inner cannula is not *in situ*, there is a greater risk that the TRACHEOSTOMY TUBE can become blocked. It is difficult to see whether the INNER TUBE is *in situ*, or not without undertaking a very close and intrusive inspection of the patients' TRACHEOSTOMY TUBE especially when the patient is connected to a ventilator.

For example, making it visibly obvious by using a bright contrasting colour for the INNER TUBE so that it can be seen from a distance, at a glance by the doctors and nursing staff is a possible way to meeting this recommendation.

A.6.3.4 Cuffs

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; therefore, identification of the risk associated with excessive pressure in the CUFF has been included.

Requirements for the performance of TRACHEOSTOMY TUBE CUFFS have been added due to the critical function of the CUFF to secure the airway, limit gas leakage and limit aspiration of liquids.

Requirements for the performance of TRACHEOSTOMY TUBES relate to the well recognized need to seal the trachea using CUFFS to reduce the risk of hypoventilation and aspiration while limiting damage to the tracheal mucosa. The requirements and test methods are similar to those reported by many researchers over 30 years. Early researchers employed the use of anatomically scaled D-shaped trachea models suitable for evaluating only a limited range of TRACHEOSTOMY TUBE sizes. The use of glass or plastic cylinders as trachea models is recommended to reduce inter-laboratory variability associated with more complex models and to standardize on more widely available ranges of cylindrical trachea model sizes.

A.6.3.7 Inflating tubes

The committee understood that it is necessary to provide a means to quickly and safely inflate the CUFF that is readily available to all operators, under all conditions, especially in airway emergencies. The common intravenous syringe with a Luer connector was chosen because it is readily available to all health care providers worldwide and this provides a wide margin of safety and usability. The significance of the risk associated with the hazardous condition of misconnection was considered and judged to be very low due to low frequency. Use of unique small-bore connectors designed to prevent misconnection was considered, but the committee believed that the residual risk associated with a requirement for special inflation devices that employ these unique connectors was greater than the risk of misconnection. However, it is recognized that high pressures can be achieved with syringes, which has led to a requirement to identify the risks associated with over inflation of the CUFF in the instructions for use.

A.6.3.10 Radiopaque marker

During extensive discussion, the clinical value of the detection of TRACHEOSTOMY TUBES was identified, especially if they are lost in the airway.

A.6.3.11 Kink resistance

It is recognized that TRACHEOSTOMY TUBES are manufactured from a variety of materials ranging from the inflexible (metal) to the very flexible. It is essential that those made from more flexible materials do not kink during use, thereby, increasing the patient's resistance to breathing. Therefore, a test has been devised to test the degree of resistance to kinking.

Annex B
(normative)

Test method for the security of attachment of a fitted connector and NECK-PLATE to the TRACHEOSTOMY TUBE

B.1 Principle

The security of attachment of both a fitted connector and the NECK-PLATE to the TRACHEOSTOMY TUBE is tested by applying an increasing axial load and determining the load at which disconnection or breakage occurs.

B.2 Apparatus

B.2.1 Means of conditioning the TRACHEOSTOMY TUBE at (39 ± 1) °C and 90 % to 100 % relative humidity (RH) for 24 h.

B.2.2 Means of securing the connector and TRACHEOSTOMY TUBE and applying an axial separation force >50 N at a rate of (50 ± 5) mm·min^{-1}.

B.2.3 Means of securing the NECK-PLATE and TRACHEOSTOMY TUBE and applying an axial separation force of between 15 N and 50 N at a rate of (50 ± 5) mm·min^{-1}.

B.3 Procedure

B.3.1 Condition the TRACHEOSTOMY TUBE at (39 ± 1) °C and 90 % to 100 % (RH) for 24 h.

B.3.2 Remove the TRACHEOSTOMY TUBE from the conditioning chamber and secure the connector and TRACHEOSTOMY TUBE (B.2.2).

For TRACHEOSTOMY TUBES with the conical connector fitted to the INNER TUBE, the mechanism which secures the INNER TUBE within the OUTER TUBE should first be engaged in accordance with manufacturer's instructions before securing the connector and TRACHEOSTOMY TUBE.

B.3.3 Within 1 min of removing the TRACHEOSTOMY TUBE from the conditioning chamber, apply an axial load to the TRACHEOSTOMY TUBE relative to the connector at a rate of (50 ± 5) mm·min^{-1}.

Verify that the connector does not become detached from the tube at a separation force of <50 N.

B.3.4 Secure the NECK-PLATE and TRACHEOSTOMY TUBE (B.2.3).

B.3.5 Within 1 min of removing the TRACHEOSTOMY TUBE from the conditioning chamber, apply an axial separation force to the TRACHEOSTOMY TUBE relative to the NECK-PLATE as follows:

a) for tracheostomy tubes with an adjustable NECK-PLATE, apply an axial force ≥15 N at a rate of (50 ± 5) mm·min^{-1};

b) verify that the NECK-PLATE has not moved at a force <15 N;

c) for TRACHEOSTOMY TUBES with a non-adjustable NECK-PLATE, apply an axial force of (50 ± 5) N at a rate of (50 ± 5) mm·min^{-1};

d) verify that the NECK-PLATE has not moved at a force <50 N.

Annex C
(normative)

Test method for determining the diameter of the CUFF

C.1 Principle

To determine the diameter of the CUFF as measured when the CUFF is inflated with a pressure, which is intended to remove creases while minimizing stretching of its walls.

C.2 Apparatus

C.2.1 Means to inflate the CUFF.

C.2.2 Means of measuring the pressure within the CUFF.

C.3 Procedure

C.3.1 Inflate the CUFF with sufficient air to create an internal over-pressure of (2,0 ± 0,1) kPa and allow to stabilize for 5 min at (39 ± 1) °C and 90 % to 100 % RH, maintaining that over-pressure.

C.3.2 Locate the plane of maximum CUFF diameter perpendicular to the axis of the tube. Measure the CUFF diameters at intervals of 45° in the located plane.

C.4 Expression of results

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

Annex D
(normative)

Test method for CUFF herniation

D.1 Principle

The tendency of a CUFF to herniate beyond the PATIENT END is tested by applying an axial force with the CUFF inflated within a transparent tube.

D.2 Apparatus

D.2.1 Weights (see Table D.1 for mass of weights per designated size).

D.2.2 Transparent cylinder made of glass or rigid plastic material, having a length of at least twice the effective length of the CUFF and an inside diameter of within 5 % of the difference between the **CUFF** diameter and 50 % of the difference of CUFF diameter and the marked outside diameter of the TRACHEOSTOMY TUBE under test.

D.2.3 CUFF inflation device.

D.2.4 Pressure-measuring device, accurate to within 10 % of full scale.

D.2.5 Temperature-controlled water bath, accurate to within ±1 °C.

D.2.6 Timer, accurate to within 1 min/24 h.

D.3 Procedure

D.3.1 With the TRACHEOSTOMY TUBE in the transparent cylinder (D.2.2), inflate the CUFF with air at the test inflation pressure (see Table D.2), but using a minimum of 5,4 kPa and maintain the pressure for ≥24 h in the water bath at (39 ± 1) °C.

D.3.2 At the end of the 24 h, remove the TRACHEOSTOMY TUBE and transparent tube from the water bath. Check the CUFF inflation pressure and adjust if necessary.

D.3.3 Suspend the appropriate mass so that it is as closely aligned with the vertical axis through the centre of the test cylinder as possible to minimise rotation (see Table D.1) from the TRACHEOSTOMY TUBE, as shown in Figure D.1, for ≥60 s.

Table D.1 — Test weights for designated sizes of TRACHEOSTOMY TUBES

Designated size	Mass (g)
2,5 – 3,5	40
4,0 – 5,0	65
5,5 – 6,0	90
6,5	100

D.3.4 Observe whether any part of the inflated CUFF reaches beyond the nearest edge of the PATIENT END.

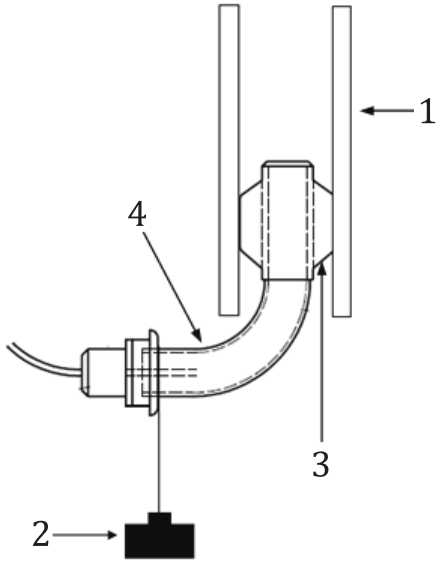
D.3.5 Continue the test by progressively deflating the CUFF over a period of not less than 10 s while continuously observing the configuration of the CUFF.

D.4 Expression of results

Record whether any part of the inflated CUFF reaches beyond the PATIENT END.

Table D.2 — 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



Key

1 transparent cylinder
2 mass/weight
3 CUFF
4 TRACHEOSTOMY TUBE

Figure D.1 — Apparatus for CUFF herniation test

Annex E
(normative)

Test method for determining kink resistance

E.1 Principle

A TRACHEOSTOMY TUBE is subjected to a bending force at approximately body temperature and then tested to see if it has kinked by attempting to pass a steel ball, with a diameter of 75 % of the internal dimension of the TRACHEOSTOMY TUBE, through the tube.

E.2 Apparatus

E.2.1 **Test rig** (see Figure E.1 for an example), with a range of transparent cylinders made of rigid material. The inside diameters of the transparent cylinders shall be equivalent to the maximum and minimum diameters of the trachea in which the tracheostomy tube under test is intended for use.

E.2.2 **Steel ball**, ≥75 % of the nominal internal dimension of the tracheal tube under test (see Table 1).

E.2.3 **Cuff inflation device**.

E.2.4 **Pressure measuring device**, accurate to within 10 % of full scale.

E.2.5 **Temperature-controlled water bath**, accurate to within ±1 °C.

E.2.6 **Timer**, accurate to within 1 min/24 h.

E.3 Procedure

E.3.1 Place the tube under test in the rig (E.2.1). If necessary depending on the actual fixture design, use spacers under the flange, if needed, to attain the required depth of the cannula within the cylinder during the test.

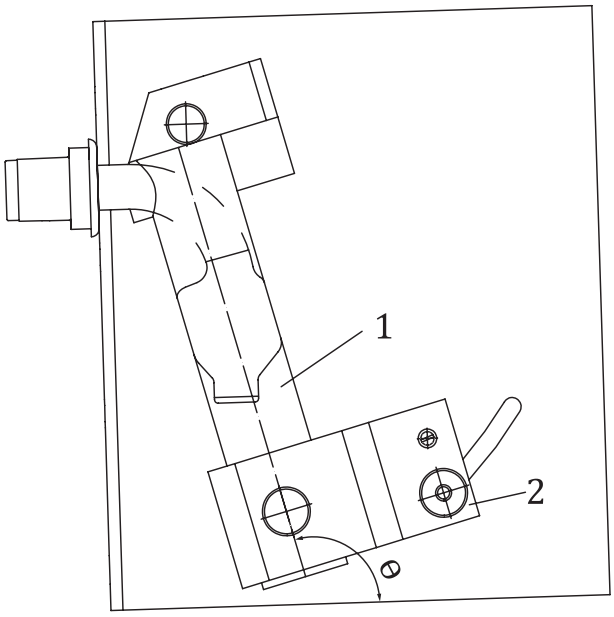
E.3.2 Fix the flange with a tie.

E.3.3 Inflate the CUFF to test pressure (see Table D.2).

E.3.4 Place the whole rig (E.2.1) in a water bath at (39 ± 1) °C for at least 2 h.

E.3.5 At the end of this period, ensure the passage of the steel ball (E.2.2).

E.3.6 Repeat the test on new tubes over the range of angles that the tube is intended for.



Key

1 tube diameter to be approx. 1 1/2 times the outer diameter of the TRACHEOSTOMY TUBE being tested, but more than 12,7 mm for adult sizes

2 midpoint movement to be ±15°

θ 105°

Figure E.1 — Example of test rig for kink resistance testing

Annex F
(informative)

Guidance on materials and design

F.1 Materials

F.1.1 The materials used for the manufacture of the tubes should have sufficient rigidity to allow the construction of a tube with the thinnest possible wall, which at the same time maintains resistance to kinking. When in place, the design should prevent undue pressure on the body tissues.

F.1.2 Unless intended and marked for single use, TRACHEOSTOMY TUBES should be reasonably resistant to deterioration by methods of cleaning, disinfection and sterilization as recommended by the manufacturer. Such tubes should withstand accepted methods of steam sterilization.

The recommended method or methods of sterilization should not produce changes in the tube material, which will compromise the biological safety of the TRACHEOSTOMY TUBE (see Clause 5).

F.1.3 TRACHEOSTOMY TUBES under normal conditions of use should be reasonably resistant to deterioration by clinically used concentrations of anaesthetic vapours and gases.

F.1.4 TRACHEOSTOMY TUBES should be readily detectable by X-ray, either by the nature of the material of which they are made or by the provision of a marker at the PATIENT END.

F.1.5 When not in use, the TRACHEOSTOMY TUBE should maintain its intended shape when stored in accordance with the manufacturer's instructions.

F.2 Design

F.2.1 TRACHEOSTOMY TUBES, including the CUFF and the NECK-PLATE, should have smooth external and internal surfaces.

F.2.2 The PATIENT END of the TRACHEOSTOMY TUBE should be free from sharp edges.

F.2.3 The NECK-PLATE should be rounded at the edges, and its shape should adapt to the contour of the patient's neck.

F.2.4 For TRACHEOSTOMY TUBES with an adjustable NECK-PLATE, use of the mechanism for securing the NECK-PLATE should not cause a significant reduction of the inside dimension of the tube.

F.2.5 A retaining or latching device may be incorporated in the design to provide added security of attachment of the conical connectors. Such a device may, however, introduce other hazards such as that of accidental extubation. It should, therefore, be as light and compact as possible. Any projections (for example, hooks, lugs or studs) should be designed so as to minimize the risk of catching on surgical dressings or other equipment.

Annex G
(informative)

Hazard identification for risk assessment

NOTE This list is not intended to be comprehensive for all devices within the scope of this International Standard, but to provide guidance for risk assessment. Not all hazards will apply to each type of TRACHEOSTOMY TUBE.[4]

G.1 Potential hazards associated with the placement, removal and use of TRACHEOSTOMY TUBES

a) Trauma to surrounding tissue causing

   1) minor abrasions, oedema, and inflammation (trachea, bronchus),

   2) bleeding and hematoma (trachea, bronchus),

   3) infection (cellulitis, abscess, trachea, bronchus),

   4) neuropathy, temporary or permanent, cranial or peripheral nerves,

   5) injury to the cervical spine or cord resulting in paralysis, parethesis or neuropathy,

   6) tracheal damage (ulcers, web, necrosis, granuloma, scar, fibrosis, erosions, burns, additional perforation, stenosis), and

   7) vascular fistula formation.

b) Inadequate oxygenation and/or ventilation resulting in hypoxia and/or hypercarbia due to

   1) leakage of respiratory gases due to inadequate seal,

   2) obstruction due to kinking, foreign body or secretions,

   3) bronchospasm, laryngospasm, stridor, hiccup, coughing or breath holding,

   4) pulmonary oedema (due to negative intrathoracic pressure in the presence of obstruction),

   5) rebreathing due to excessive dead space,

   6) increased work of breathing,

   7) increased intrathoracic pressure, and

   8) barotrauma leading to pneumothorax or emphysema.

c) Aspiration or regurgitation due to inadequate CUFF seal:

   1) aspiration of secretions or regurgitated intestinal contents.

d) Toxicity:

   1) allergy, including allergy to natural rubber latex;

   2) tissue sensitivity: inflammation or necrosis;

   3) systemic absorption of toxic substances.

G.2 Potential device hazards

a) Failure or loss of the tracheal seal caused by

   1) misplacement or displacement,
   2) malposition of the head,
   3) repositioning of the patient,
   4) loss of CUFF seal pressure,
   5) incorrect size,
   6) material failure of the TRACHEOSTOMY TUBE connector,
   7) reuse failures (exceeds number of reuse cycles),
   8) CUFF degradation,
   9) inflation valve failure, and
   10) hole, rip or tear in TRACHEOSTOMY TUBE shaft or CUFF.

b) Loss of patency caused by

   1) malposition of the head,
   2) obstruction of the lumen by debris or fluid,
   3) CUFF over-inflation leading to tube narrowing or CUFF herniation,
   4) kinking, and
   5) fracture of the shaft of the TRACHEOSTOMY TUBE.

c) CUFF over-inflation caused by

   1) excessive manual inflation,
   2) malposition of the TRACHEOSTOMY TUBE,
   3) failure of the INFLATING TUBE or valve, and
   4) pressure from compressing the CUFF INFLATION INDICATOR/PILOT BALLOON.

d) CUFF under-inflation caused by

   1) undetected leak,
   2) sealing surface twisted or folded,
   3) failure of the INFLATING TUBE or valve, and
   4) excessive resistance.

e) Incorrect size for a specific patient caused by

   1) inadequate disclosure of size requirements by manufacturer,

   2) patient variability,

   3) inappropriate selection of inner cannula,

   4) tracheal wall, and

   5) inappropriate selection of tube size.

Bibliography

[1] ISO 5361, *Tracheal tubes and connectors*

[2] ISO/TR 11991, *Guidance on airway management during laser surgery of upper airway*

[3] ASTM F640-12, *Standard Test Methods for Determining Radiopacity for Medical Use*

[4] Engels P.T. Tracheostomy: from insertion to decannulation. Can. J. Surg. 2009 October, **52** (5) pp. 427–433

ICS 11.040.10

Price based on 25 pages