
**Anaesthetic and respiratory
equipment — Tracheal tubes and
connectors**

*Matériel d'anesthésie et de réanimation respiratoire — Sondes
trachéales et raccords*

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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 WTO principles in the Technical Barriers to Trade (TBT) see the following URL: [Foreword - Supplementary information](#)

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

This third edition cancels and replaces the second edition (ISO 5361:2012), which has been technically revised.

Throughout this International Standard, terms defined in [Clause 3](#) or in ISO 4135 appear in **bold** type.

Throughout this International Standard, text for which a rationale is provided in [Annex A](#) is indicated by an asterisk (*).

Introduction

This International Standard provides the essential performance and safety requirements for the design of **tracheal tubes** and **tracheal tube connectors**. **Tracheal tubes** are intended to be inserted through the larynx into the trachea to provide a patent airway in patients during spontaneous, assisted or controlled ventilation for short or prolonged durations to convey gases and vapours to and from the trachea.

In addition, **tracheal tubes** with **cuffs** are intended to seal and protect the trachea from aspiration.

A variety of **cuff** designs are available to meet particular clinical requirements. **Cuff** performance requirements with associated test methods remain unchanged from the second edition.

Requirements for paediatric **tracheal tubes**, with and without **cuffs**, have been updated from the second edition to include revised length marks and new provisions for **glottic depth marks** have been added in this edition because these are commercially available and in common use.

Tracheal tubes are also intended to conform as closely as possible to human anatomy when in position.

Clinical considerations have also dictated the specified length of **tracheal tubes** because long **tracheal tubes**, sometimes of relatively narrow diameter, may be required and, therefore, should be readily available. Provision has also been included for pre-cut **tracheal tubes**.

Kink resistance requirements with associated test methods remain unchanged from the second edition to measure the ability of the shaft of the **tracheal tube** to resist collapse and increased breathing resistance when bent or curved.

Radiopacity requirements and test methods remain unchanged from the second edition to characterize the visibility of **tracheal tubes** in X-rays used to determine proper placement of the tube. The requirements of this International Standard were developed using the hazard identification for **risk assessment** in [Annex E](https://standards.iteh.ai/catalog/standards/sist/2caf681-63bf-4188-8486-188ad850cdaf/iso-5361-2016).

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Anaesthetic and respiratory equipment — Tracheal tubes and connectors

1 Scope

This International Standard provides essential performance and safety requirements for **oro-tracheal and naso-tracheal tubes** and **tracheal tube connectors**. **Tracheal tubes** with walls reinforced with metal or nylon, **tracheal tubes** with **shoulders**, tapered **tracheal tubes**, **tracheal tubes** with means for suctioning, monitoring or delivery of drugs or other gases, and the many other types of **tracheal tubes** devised for specialized applications are included in this International Standard, as many specialized **tracheal tubes** are now commonly used, and all share similar essential requirements as defined in this International Standard.

Endobronchial (including tracheobronchial) tubes, tracheostomy tubes, and supralaryngeal airways are excluded from the scope of this International Standard.

Tracheal tubes intended for use with flammable anaesthetic gases or agents, lasers, or electrosurgical equipment are outside the scope of this International Standard.

NOTE References [1] to [4] deal with laser surgery of the airway.

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2 Normative references (standards.iteh.ai)

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 594-1¹⁾, *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 7000²⁾, *Graphical symbols for use on equipment — Registered symbols*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 11135, *Sterilization of health care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 11137-1, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 14971:2007, *Medical devices — Application of risk management to medical devices*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

1) To be replaced by ISO 80369-7.

2) The graphical symbols in ISO 7000 are also available online in the ISO web store. For more information, consult http://www.iso.org/iso/publications_and_e-products/databases.htm?=.

ISO 15223-2, *Medical devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 2: Symbol development, selection and validation*

EN 556-1:2001, *Sterilization of medical devices — Requirements for medical devices to be designated “STERILE” — Part 1: Requirements for terminally sterilized medical devices*

EN 1041, *Information supplied by the manufacturer of medical devices*

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

ASTM D3002-07, *Standard Guide for Evaluation of Coatings Applied to Plastics*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4135, ISO 14971 and the following apply.

3.1 angle of bevel

acute angle between the plane of the *bevel* (3.2) and the longitudinal axis of the *tracheal tube* (3.27) at the *patient end* (3.16)

[SOURCE: ISO 4135:2001, 6.3.5]

Note 1 to entry: See [Figures 1a](#), [1b](#), and [4](#).

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3.2 bevel

slanted portion at the *patient end* (3.16) of a *tracheal tube* (3.27)

[SOURCE: ISO 4135:2001, 6.3.4]

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Note 1 to entry: See [Figures 1a](#), [1b](#), and [4](#).

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3.3 Cole-type tracheal tube

tracheal tube (3.27) combining a short *laryngo-tracheal portion* (3.8) of small diameter and a longer *oral portion* (3.14) of larger diameter with transition from one to the other resulting in a *shoulder* (3.25)

Note 1 to entry: See [Figure 1c](#).

3.4 cuff

inflatable balloon permanently attached around the *tracheal tube* (3.27) near the *patient end* (3.16) and used to provide an effective seal between the tube and the trachea

Note 1 to entry: See [Figures 1a](#) and [1b](#).

3.5 glottic depth mark

indicator on the *tracheal tube* (3.27) to assist in determining the tip insertion depth beyond the vocal cords

3.6 inflating tube

tube through which the *cuff* (3.4) is inflated

[SOURCE: ISO 4135:2001, 6.3.6.1]

Note 1 to entry: See [Figures 1a](#) and [1b](#).

3.7**inflation lumen**

lumen within the wall of the *tracheal tube* (3.27) for inflating the *cuff* (3.4)

3.8**laryngo-tracheal portion**

that portion of a *Cole-type tracheal tube* (3.3) of small diameter and extending from the *bevel* (3.2) tip to the point at which there is an increase in the outside diameter

3.9**machine end**

that end of a *tracheal tube* (3.27) which is intended to project from a patient

[SOURCE: ISO 4135:2001, 6.3.3]

Note 1 to entry: See [Figures 1a, 1b](#), and [4](#).

3.10**machine end of the tracheal tube connector**

that portion of the *tracheal tube connector* (3.28) intended to mate with an anaesthetic breathing system (ABS) or ventilator breathing system (VBS)

3.11**Magill-type tracheal tube**

curved *tracheal tube* (3.27) with a radius and having a *bevel* (3.2) at the *patient end* (3.16)

Note 1 to entry: See [5.7.2](#) and See [Figures 1a, 1b](#), and [4](#).

3.12**Murphy eye**

hole through the wall of a *tracheal tube* (3.27) near the *patient end* (3.16) and on the side opposite to the *bevel* (3.2)

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Note 1 to entry: See [Figure 6](#).

3.13**naso-tracheal tube**

tracheal tube (3.27) for insertion through the nose into the trachea

[SOURCE: ISO 4135:2001, 6.3.1.2]

3.14**oral portion**

that portion of a *Cole-type tracheal tube* (3.3) of a larger diameter extending from the *machine end* (3.9) to the point at which there is a decrease in the outside diameter

3.15**oro-tracheal tube**

tracheal tube (3.27) for insertion through the mouth into the trachea

[SOURCE: ISO 4135:2001, 6.3.1.1]

3.16**patient end**

that end of a *tracheal tube* (3.27) which is intended to be inserted into the trachea

[SOURCE: ISO 4135:2001, 6.3.2]

Note 1 to entry: See [Figures 1a, 1b](#), and [4](#).

3.17

patient end of the connector

that end of the *tracheal tube connector* (3.28) intended to be inserted into the *tracheal tube* (3.27)

3.18

pilot balloon

balloon fitted to an *inflating tube* (3.6) to indicate inflation of the *cuff* (3.4)

[SOURCE: ISO 4135:2001, 6.3.6.2]

Note 1 to entry: See [Figure 1b](#).

3.19

risk

combination of the probability of occurrence of harm and the severity of that harm

[SOURCE: ISO 14971:2007, 2.16]

3.20

risk analysis

systematic use of available information to identify hazards and to estimate the *risk* (3.19)

[SOURCE: ISO 14971:2007, 2.17]

Note 1 to entry: **Risk analysis** includes examination of different sequences of events that can produce hazardous situations and harm (see [Annex F](#) and ISO 14971:2007, Annex E).

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3.21

risk assessment

overall process comprising a *risk analysis* (3.20) and a *risk evaluation* (3.22)

[SOURCE: ISO 14971:2007, 2.18]

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3.22

risk evaluation

process of comparing the estimated *risk* (3.19) against given **risk** criteria to determine the acceptability of the **risk**

[SOURCE: ISO 14971:2007, 2.21]

3.23

risk management

systematic application of management policies, procedures, and practices to the tasks of analysing, evaluating, controlling, and monitoring *risk* (3.19)

[SOURCE: ISO 14971:2007, 2.22]

3.24

risk management file

set of records and other documents that are produced by *risk management* (3.23)

[SOURCE: ISO 14971:2007, 2.23]

3.25

shoulder

that portion of a *Cole-type tracheal tube* (3.3) at which transition from the *oral portion* (3.14) to the *laryngo-tracheal portion* (3.8) occurs

3.26

single-fault condition

condition in which a single means for reducing a *risk* (3.19) is defective or a single abnormal condition is present

3.27**tracheal tube**

tube designed for insertion through the larynx into the trachea to convey gases and vapours to and from the trachea

[SOURCE: ISO 4135:2001, 6.3.1]

3.28**tracheal tube connector**

tubular component that fits directly into the *machine end* (3.9) of a *tracheal tube* (3.27)

[SOURCE: ISO 4135:2005, 6.3.8]

Note 1 to entry: See [Figures 2](#) and [3](#).

4 *General requirements for tracheal tubes and tracheal tube connectors

This International Standard specifies requirements that are generally applicable to **risks** associated with **tracheal tubes** and **tracheal tube connectors**.

4.1 Risk assessment

4.1.1 An established **risk assessment** process shall be applied to the design of the device.

EXAMPLE ISO 14971.

Check compliance by inspection of the **risk management file**. If clinical studies are performed, these studies shall document measurements taken during the conditions for which performance is claimed. The clinical studies shall comply with the requirements of ISO 14155.

NOTE See [Annex F](https://standards.iteh.ai/catalog/standards/sist/2caf6f81-63bf-4188-8486-188ad850cdaf/iso-5361-2016).

4.1.2 Tracheal tubes shall, when transported, stored, installed, operated in normal use, and maintained according to the instructions of the manufacturer, present no risks that are not reduced to an acceptable level using risk management procedures in accordance with ISO 14971 and which are connected with their intended application, in normal and in **single fault condition**.

NOTE A situation in which a fault is not detected is considered a normal condition. Fault conditions/hazardous situations might remain undetected over a period of time and, as a consequence, might lead to an unacceptable risk. In that case, a subsequent detected fault condition needs to be considered as a single fault condition. Specific risk control measures need to be determined within the risk management process to deal with such situations.

4.1.3 Where requirements in this International Standard refer to freedom from unacceptable **risk**, the acceptability or unacceptability of this **risk** shall be determined by the manufacturer in accordance with the manufacturer's policy for determining acceptable **risk**.

Check compliance by inspection of the **risk management file**.

4.1.4 If required by a competent authority, the manufacturer shall address in a usability engineering process the risk resulting from poor usability (see IEC 62366).

Check compliance by inspection of the usability engineering file.

4.1.5 If required by a competent authority, a clinical evaluation shall be performed and documented in the technical documentation of the device.

Check compliance by inspection of the technical documentation.

4.1.6 If required by a competent authority, and where appropriate, validated biophysical or modelling research shall be carried out.

Check compliance by inspection of the technical documentation.

4.2 Safety

4.2.1 ***Tracheal tubes**, when transported, stored, inserted, operated in their normal intended use, and maintained according to the instructions of the manufacturer, shall minimize safety hazards which could reasonably be foreseen to occur, in normal and **single-fault conditions**.

Check compliance by inspection of the **risk management file**.

NOTE Attention is drawn to any intended use that may deviate from the currently accepted medical practice. See [Annex A](#) for examples.

4.2.2 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.

5 Specific requirements for tracheal tubes and tracheal tube connectors

5.1 Size designation

The size of **tracheal tubes** and **tracheal tube connectors** shall be designated in accordance with [Table 1a](#) for **tracheal tubes**, [Table 1b](#) for **Cole-type tracheal tubes**, and [Table 2](#) for **tracheal tube connectors**.

5.2 Dimensions

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5.2.1 Tracheal tubes

5.2.1.1 The basic dimensions of **Magill-type tracheal tubes** shall be in accordance with [Table 1a](#).

5.2.1.2 The basic dimensions of **Cole-type tracheal tubes** shall be in accordance with [Table 1b](#).

5.2.1.3 The designated size of the **tracheal tube** shall be the marked inside diameter subject to a tolerance of $\pm 0,15$ mm for sizes 6,0 and smaller, and subject to a tolerance of $\pm 0,20$ mm for sizes 6,5 and larger.

The lumen of the tracheal tube should be essentially circular in a plane at right angles to the long axis.

5.2.1.4 For **Magill-type tracheal tubes**, the nominal outside diameter (OD) shall be the marked outside diameter (OD) subject to a tolerance of $\pm 0,15$ mm for sizes 6,0 and smaller, or subject to a tolerance of $\pm 0,20$ mm for sizes 6,5 and larger [see 8.2.1.1 b) 1)]. For **Cole-type tracheal tubes**, the maximum outside diameter of the **laryngo-tracheal portion** (OD) shall be the marked outside diameter (OD) [see 8.2.1.1 b) 2)].

5.2.1.5 For **Cole-type tracheal tubes**, the axial length of the outside surface of the **shoulder** region, S_1 S_2 (see [Figure 1c](#)), shall not exceed 4 mm for sizes up to and including size 3.

Table 1a — *Basic dimensions of tracheal tubes (see Figures 1a and 1b)

Dimensions in millimetres

Designated size (nominal inside diameter)	Dimension A Minimum length of tube (see Figures 1a and 1b)		Dimension C Maximum distance from the patient end of the tracheal tube to the machine end of the inflatable length of the cuff ^b (see Figures 1a and 1b)	Dimension S _{1a, b} Minimum distance of point of separation of the inflating tube from the patient end of the tube (see Figures 1a and 1b)
	Nasal or oral/nasal	Oral ^a		
2,0	130	110	—	—
2,5	140	110	—	—
3,0	160	120	33	—
3,5	180	130	35	—
4,0	200	140	41	—
4,5	220	150	45	—
5,0	240	160	56	110
5,5	270	170	56	120
6,0	280	190	58	125
6,5	290	210	62	135
7,0	300	230	66	140
7,5	310	240	69	145
8,0	320	250	72	150
8,5	320	260	75	155
9,0	320	270	78	160
9,5	320	280	81	165
10,0	320	280	85	170
10,5	320	280	85	170
11,0	320	280	85	170

^a Manufacturers wishing to market packaged sterile **tracheal tubes** with **tracheal tube connectors** inserted are guided by the tube lengths shown in the table. However, the user is cautioned that anatomical variations, conditions of use, the length of the tube inserted, or other factors may result in the use of a **tracheal tube** either too long or too short for a given patient. Selecting the size and length of a **tracheal tube** still requires expert clinical knowledge and judgment to ensure that it is appropriate to the needs of a specific patient.

^b Clinical literature suggests that a shorter Dimension C may decrease likelihood of endobronchial intubations for paediatric patients (see Annex A).