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ISO 5361

Second edition
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Anaesthetic and respiratory equipment — Tracheal tubes and connectors

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

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. 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 document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

This second edition cancels and replaces the first edition (ISO 5361:1999), which has been technically revised.

The requirements of ISO 5361-4, ***Tracheal tubes*** — *Part 4: Cole type*, have been included in this second edition because **Cole type tracheal tubes** are specialized tubes, and as such, are now included in the scope of this International Standard.

Throughout this Particular Standard, terms defined in Clause 3 or in ISO 4135 appear in **bold** type.

Throughout this Particular 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 convey gases and vapours to and from the trachea.

Tracheal tubes with **cuffs** are intended to seal and protect the trachea from aspiration of secretions and to provide an unobstructed airway in patients during spontaneous, assisted, or controlled ventilation for short or prolonged durations.

A variety of **cuff** designs are available to meet particular clinical requirements. **Cuff** performance requirements with associated test methods have been added to this second edition.

Requirements for paediatric **tracheal tubes** with **cuffs** have been added 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 have also been added to 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 have been added to this 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 F.

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 or 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.

Tracheobronchial (endobronchial) 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 ISO/TR 11991, ISO 11990-1, ISO 11990-2, and ISO 14408 cover this[1][2][3][4].

2 Normative references

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

ISO 594-1, *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 7000, *Graphical symbols for use on equipment – Index and synopsis*[1)]

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

ISO 11135-1, *Sterilization of health care products – Ethylene oxide – Part 1: Requirements for 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, *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*

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*

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

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 980, *Symbols for use in the labelling of medical devices*

EN 1041, *Terminology, symbols and information provided with medical devices: Information supplied by the manufacturer of medical devices*

ASTM F640-2007, *Standard test methods for radiopacity for medical use*

ASTM D3002-2007, *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[5] and ISO 14971 and the following apply.

3.1
angle of bevel
acute angle between the plane of the **bevel** and the longitudinal axis of the **tracheal tube** at the **patient end**

[ISO 4135:2001, definition 6.3.5]

See Figures 1 a), 1 b) and 4.

3.2
bevel
slanted portion at the **patient end** of a **tracheal tube**

[ISO 4135:2001, definition 6.3.4]

See Figures 1 a), 1 b) and 4.

3.3
Cole-type tracheal tube
tracheal tube combining a short **laryngo-tracheal portion** of small diameter and a longer **oral portion** of larger diameter with transition from one to the other resulting in a **shoulder**

See Figure 1 c).

3.4
cuff
inflatable balloon permanently attached around the **tracheal tube** near the **patient end** and used to provide an effective seal between the tube and the trachea

See Figures 1 a) and 1 b).

3.5
inflating tube
tube through which the **cuff** is inflated

[ISO 4135:2001, definition 6.3.6.1]

See Figures 1 a) and 1 b).

3.6
inflation lumen
lumen within the wall of the **tracheal tube** for inflating the **cuff**

3.7
laryngo-tracheal portion
that portion of a **Cole-type tracheal tube** of small diameter and extending from the **bevel** tip to the point at which there is an increase in the outside diameter

3.8
machine end
that end of a **tracheal tube** which is intended to project from a patient

[ISO 4135:2001, definition 6.3.3]

See Figures 1 a), 1 b) and 4.

3.9
machine end of the tracheal tube connector
that portion of the **tracheal tube connector** intended to mate with an anaesthetic breathing system (ABS) or ventilator breathing system (VBS)

3.10
Magill-type tracheal tube
curved **tracheal tube** with a radius without a **Murphy eye** and having a **bevel** at the **patient end**

See 5.7.2 and Figures 1 a), 1 b) and 4.

3.11
Murphy eye
hole through the wall of a **tracheal tube** near the **patient end** and on the side opposite to the **bevel**

See Figure 6.

3.12
naso-tracheal tube
tracheal tube for insertion through the nose into the trachea

[ISO 4135:2001, definition 6.3.1.2]

3.13
oral portion
that portion of a **Cole-type tracheal tube** of a larger diameter extending from the **machine end** to the point at which there is a decrease in the outside diameter

3.14
oro-tracheal tube
tracheal tube for insertion through the mouth into the trachea

[ISO 4135:2001, definition 6.3.1.1]

3.15
patient end
that end of a **tracheal tube** which is intended to be inserted into the trachea

[ISO 4135:2001, definition 6.3.2]

See Figures 1 a), 1 b) and 4.

3.16
patient end of the connector
that end of the **tracheal tube connector** intended to be inserted into the **tracheal tube**

3.17
pilot balloon
balloon fitted to an **inflating tube** to indicate inflation of the **cuff**

[ISO 4135:2001, definition 6.3.6.2]

See Figure 1 b).

3.18
risk
combination of the probability of occurrence of harm and the severity of that harm

[ISO 14971:2007, definition 2.16]

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

[ISO 14971:2007, definition 2.17]

NOTE **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).

3.20
risk assessment
overall process comprising a **risk analysis** and a **risk evaluation**

[SO 14971:2007, definition 2.18]

3.21
risk evaluation
process of comparing the estimated **risk** against given **risk** criteria to determine the acceptability of the **risk**

[ISO 14971:2007, definition 2.21]

3.22
risk management
systematic application of management policies, procedures and practices to the tasks of analysing, evaluating, controlling and monitoring **risk**

[ISO 14971:2007, definition 2.22]

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

[ISO 14971:2007, definition 2.23]

3.24
shoulder
that portion of a **Cole-type tracheal tube** at which transition from the **oral portion** to the **laryngo-tracheal portion** occurs

3.25
single-fault condition
condition in which a single means for reducing a **risk** is defective or a single abnormal condition is present

3.26
tracheal tube
tube designed for insertion through the larynx into the trachea to convey gases and vapours to and from the trachea

[ISO 4135:2001, definition 6.3.1]

3.27
tracheal tube connector
tubular component that fits directly into the **machine end** of a **tracheal tube**

[ISO 4135:2005, definition 6.3.8]

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.

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, installed, 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

5.2.1 Tracheal tubes

5.2.1.1 The basic dimensions of **Magill-type tracheal tubes** shall be in accordance with Tables 1a and 1b.

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 ± 0,15 mm for sizes 6,0 and smaller, and subject to a tolerance of ± 0,20 mm for sizes 6,5 and larger.

NOTE 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 ± 0,15 mm for sizes 6,0 and smaller, or subject to a tolerance of ± 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 1 c)], 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 Figure 1 a) and b)]		**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 1 a) and 1 b)]	**Dimension** S_1 [a, b] **Minimum distance** of point of separation of the **inflating tube** from the **patient end** of the tube [see Figures 1 a) and 1 b)]
	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.

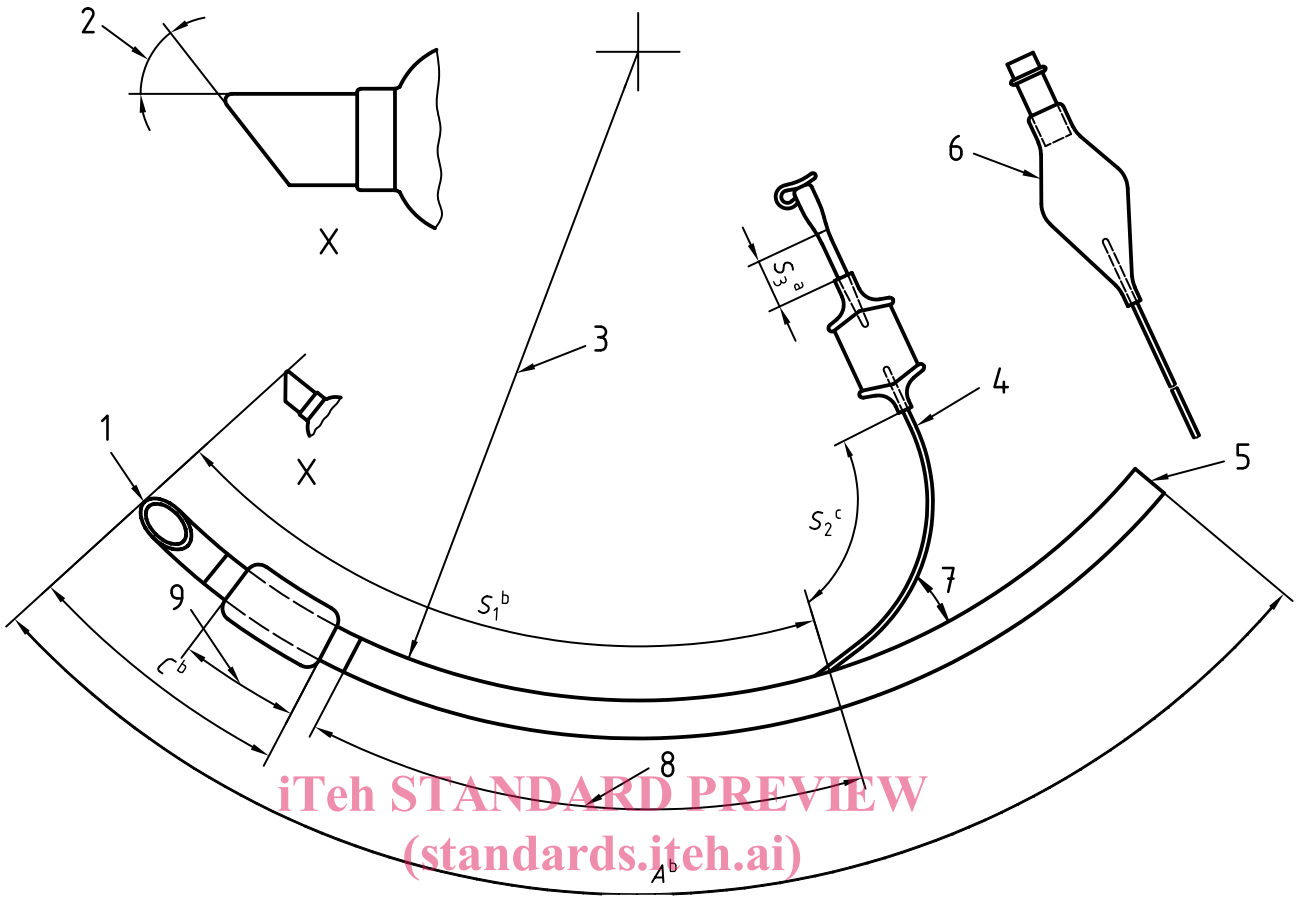
[b] Clinical literature suggests that a shorter Dimension C may decrease likelihood of endobronchial intubations for paediatric patients (see Annex A).

Table 1b — Basic dimensions of Cole-type tracheal tubes (see Figure 1c)

Dimensions in millimetres

Designated size[a] (nominal inside diameter of tracheal portion) d_1	**Length of laryngo-tracheal portion** *C*		**Oral portion** *B*			**Overall length** *A*	
			Inside diameter d_2		**Outside diameter of the oral portion** d_3		
	min	max	min	max	max	min	max
1,5	20	24	3,9	5,0	7,0	110	140
1,75	20	24	4,1	5,0	7,0	110	140
2,0	20	25	4,2	5,0	7,0	120	140
2,25	25	30	4,3	5,0	7,0	120	140
2,5	25	30	4,3	5,0	7,5	125	140
3,0	25	30	4,3	5,0	7,5	125	140
3,5	25	35	5,0	6,0	9,5	130	150
4,0	25	35	5,5	6,5	9,5	140	160
4,5	28	38	6,5	7,0	10,5	150	170

[a] For convenience in size designation, the second decimal place may be omitted.



Key

1 patient end
2 angle of the bevel (see 5.4)
3 radius of curvature (see 5.7)
4 inflating tube
5 machine end
6 alternative integral pilot balloon/valve assembly
7 separating angle (see 5.6.2)
8 region for marking size [see 8.2.1.1 b)]
9 inflatable length of cuff

[a] See 5.6.6.

[b] See Table 1a.

[c] Minimum value for $S_2 = A - S_1$.

Figure 1 a) — Typical cuffed Magill-type tracheal tube