SLOVENSKI STANDARD
oSIST prEN ISO 5361:2014

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Anestezijska in dihalna oprema - Sapnični (endotrahealni) tubusi in priključki (ISO/DIS 5361:2014)

Anaesthetic and respiratory equipment - Tracheal tubes and connectors (ISO/DIS 5361:2014)

Anästhesieund Beatmungsgeräte - Trachealtuben und Verbindungsstücke (ISO/DIS 5361:2014)

Matériel d'anesthésie et de réanimation respiratoire - Sondes trachéales et raccords (ISO/DIS 5361:2014)

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11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment

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DRAFT INTERNATIONAL STANDARD

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Anaesthetic and respiratory equipment — Tracheal tubes and connectors

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

[Revision of second edition (ISO 5361:2012)]

ICS: 11.040.10

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Reference number
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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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

ISO 5361 was prepared by Technical Committee 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.

Major changes in this International Standard are highlighted in a BLUE box during the Enquiry phase only. These highlights will be removed during the approval and publication phases.

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 (*).

The attention of Member Bodies and National Committees is drawn to the fact that equipment MANUFACTURERS and testing organizations may need a transitional period following publication of a new, amended or revised ISO or IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication not be adopted for mandatory implementation nationally earlier than 3 years from the date of publication for equipment newly designed and not earlier than 5 years from the date of publication for equipment already in production.

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 methodsremain unchanged from the second editoin.

Requirements for paediatric **tracheal tubes** with and without **cuffs,** have been 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 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*

[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?=.

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*

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, *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
glottic depth mark
an indicator on the tracheal tube to assist in determining the insertion beyond the vocal chords

3.6
inflating tube
tube through which the **cuff** is inflated

[ISO 4135:2001, definition 6.3.6.1]

See Figures 1 a) and 1 b).

3.7
inflation lumen
lumen within the wall of the **tracheal tube** for inflating the **cuff**

3.8
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

3.9
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.

3.10
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)

3.11
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.

3.12
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.

3.13
naso-tracheal tube
tracheal tube for insertion through the nose into the trachea

[ISO 4135:2001, definition 6.3.1.2]

3.14
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

3.15
oro-tracheal tube
tracheal tube for insertion through the mouth into the trachea

[ISO 4135:2001, definition 6.3.1.1]

3.16
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.

3.17
patient end of the connector
that end of the **tracheal tube connector** intended to be inserted into the **tracheal tube**

3.18
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).

3.19
risk
combination of the probability of occurrence of harm and the severity of that harm

[ISO 14971:2007, definition 2.16]

3.20
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).

3.21
risk assessment
overall process comprising a **risk analysis** and a **risk evaluation**

[SO 14971:2007, definition 2.18]

3.22
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]

3.23
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]

3.24
risk management file
set of records and other documents that are produced by **risk management**

[ISO 14971:2007, definition 2.23]

3.25
shoulder
that portion of a **Cole-type tracheal tube** at which transition from the **oral portion** to the **laryngo-tracheal portion** occurs

3.26
single-fault condition
condition in which a single means for reducing a **risk** 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

[ISO 4135:2001, definition 6.3.1]

3.28
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.