SLOVENSKI STANDARD
SIST EN ISO 5361:2023

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Nadomešča:
SIST EN ISO 5361:2016

Anestezijska in dihalna oprema - Sapnični (endotrahealni) tubusi in priključki (ISO 5361:2023)

Anaesthetic and respiratory equipment - Tracheal tubes and connectors (ISO 5361:2023)

Anästhesie- und Beatmungsgeräte - Trachealtuben und Verbindungsstücke (ISO 5361:2023)

Matériel d'anesthésie et de réanimation respiratoire - Sondes trachéales et raccords (ISO 5361:2023)

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

SIST EN ISO 5361:2023 **en,fr,de**

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Anaesthetic and respiratory equipment - Tracheal tubes and connectors (ISO 5361:2023)

Matériel d'anesthésie et de réanimation respiratoire - Sondes trachéales et raccords (ISO 5361:2023)

Anästhesie- und Beatmungsgeräte - Trachealtuben und Verbindungsstücke (ISO 5361:2023)

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (EN ISO 5361:2023) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment” the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by August 2023, and conflicting national standards shall be withdrawn at the latest by August 2023.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 5361:2016.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

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Endorsement notice

The text of ISO 5361:2023 has been approved by CEN as EN ISO 5361:2023 without any modification.

INTERNATIONAL STANDARD

ISO 5361

Fourth edition
2023-01

Anaesthetic and respiratory equipment — Tracheal tubes and connectors

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

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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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).

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

For an explanation of the voluntary nature of standards, 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 www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Airways and related equipment,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This fourth edition cancels and replaces the third edition (ISO 5361:2016), which has been technically revised.

The main changes are as follows:

— alignment with the general standard for airway devices ISO 18190;

— to provide additional requirements and design guidance for *tracheal tubes* designed for use in paediatric and neonatal patients;

— to clarify the requirements for speciality *tracheal tubes* such as *preformed tracheal tubes;*

— updating of references.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

This document provides the essential performance and safety requirements of *tracheal tubes* and *tracheal tube connectors*. *Tracheal tubes* are intended to be inserted orally or nasally through the larynx into the trachea to convey gases and vapours to and from a patient's lungs during spontaneous, assisted or controlled ventilation for short or prolonged durations.

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 third edition to include new guidance on the design of *tracheal tubes* used in paediatric and neonatal patients. The maximum distance from the *patient end* of the *tracheal* tube to the *machine end* of the inflatable length of the *cuff* has been revised in this edition to minimise the *risk* of the inflatable length of the *cuff* aligning with the larynx of neonatal and paediatric patients.

Clinical considerations have also dictated the historical maximum distance from the *patient end* of the *tracheal* tube to the *machine end* of the inflatable length of the *cuff* be maintained for tracheal tubes designed for the general population. Anatomical abnormalities or disease states can require smaller tracheal tube sizes to be used in adult patients than would typically be appropriate. Because long *tracheal tubes*, sometimes of relatively narrow diameter, can be required, *tracheal tubes* designed to the historical specification should be readily available.

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

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

Radiopacity requirements and test methods to characterize the visibility of *tracheal tubes* in X-rays used to determine proper placement of the tube remain unchanged from the second edition.

Where applicable a rationale for some of the requirements in this document are included in Annex A

The requirements of this document were developed using the hazard identification for *risk assessment* in Annex G.

Throughout this document the following print types are used:

— Requirements and definitions: roman 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: italics.*

Anaesthetic and respiratory equipment — Tracheal tubes and connectors

1 Scope

This document provides specific requirements for the basic safety and essential performance for *oro-tracheal* and *naso-tracheal tubes* and *tracheal tube connectors*, *tracheal tubes* with walls reinforced with metal or plastic, *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.

Tracheobronchial (including endobronchial) tubes (see ISO 16628), tracheostomy tubes (see ISO 5366), and supralaryngeal airways (see ISO 11712) are excluded from the scope of this document.

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

NOTE 1 There is guidance or rationale for this clause contained in Annex A.2.

NOTE 2 ISO 11990-1, ISO 11990-2, and ISO 14408 deal with laser surgery of the airway.

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

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

ISO 18562 (all parts), *Biocompatibility evaluation of breathing gas pathways in healthcare applications*

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

ASTM F640-20, *Standard test methods for determining radiopacity for medical use*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4135, ISO 14971, ISO 18190 and the following apply:

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
Cole-type tracheal tube
tracheal tube combining a short *laryngo-tracheal portion* (3.5) of small diameter and a longer *oral portion* (3.9) of larger diameter with transition from one to the other resulting in a *shoulder* (3.12)

Note 1 to entry: See Figure 2.

3.2
cut line
point where a *tracheal tube* can be reduced to its minimum length

Note 1 to entry: The cut line on a cuffed *tracheal tube* is adjacent to the inflating tube separation point and towards the *machine end.*

3.3
glottic depth mark
indicator on the *tracheal tube* to assist in determining the tip insertion depth beyond the vocal cords (VC)

3.4
inflation lumen
lumen within the wall of the *tracheal tube* for inflating the *cuff*

3.5
laryngo-tracheal portion
portion of a *Cole-type tracheal tube* (3.1) of small diameter and extending from the *bevel* tip to the point at which there is an increase in the outside diameter

3.6
machine end of the tracheal tube connector
portion of the *tracheal tube connector* intended to mate with an anaesthetic breathing system (ABS) or ventilator breathing system (VBS)

3.7
Magill-type tracheal tube
subset of curved *tracheal tubes* with a particular radius (6.7.2) and having a particular *bevel* at the *patient end*

Note 1 to entry: See Figure 5.

3.8
Murphy eye
hole through the wall of a *tracheal tube* near the *patient end* and on the side opposite to the *bevel*

Note 1 to entry: See Figure 7.

3.9
oral portion
portion of a *Cole-type tracheal tube* (3.1) of a larger diameter extending from the *machine end* to the point at which there is a decrease in the outside diameter

3.10
patient end of the connector
end of the *tracheal tube connector* intended to be inserted into the *tracheal tube*

3.11
preformed tracheal tube
subset of curved *tracheal tubes* with an acute radius of curvature intended to direct the *machine end* of the *tracheal tube* in a specific direction

Note 1 to entry: See Annex A.3 for rationale.

3.12
shoulder
portion of a *Cole-type tracheal tube* (3.1) at which transition from the *oral portion* (3.9) to the *laryngo-tracheal portion* (3.5) occurs

3.13
subglottic suction port
opening in the *tracheal tube*, proximal to the *machine end* of the inflatable portion of the *cuff* intended for the suctioning of secretions

4 General requirements

NOTE There is guidance or rationale for this clause contained in Annex A.4.

4.1 General

The requirements of ISO 18190:2016, Clause 4 shall apply.

Check conformance by inspection of the risk management file.

4.2 Safety

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

5 Materials

NOTE There is guidance or rationale for this clause contained in Annex A.5.

5.1 General

The applicable requirements of ISO 18190:2016, Clause 5 shall apply.

5.2 Biological safety testing

NOTE There is guidance or rationale for this subclause contained in Annex A.6.

Material used to manufacture *tracheal tubes connectors* shall be tested and evaluated for biocompatibility of the breathing gas pathways as specified in the ISO 18562 series as appropriate.

Check conformance by inspection of the technical file.

5.3 Reuse requirements

Tracheal tubes and *tracheal tube connectors* marked for reuse shall be resistant to deterioration by the methods of cleaning, disinfection, and sterilization recommended by the manufacturer. The recommended method or methods of sterilization shall not produce material changes which will compromise the biological safety.

5.4 Flexibility

Tracheal tubes constructed from materials and at dimensions which enhance flexibility for the purpose of minimizing tracheal trauma, the *risks* associated with the flexibility of the tube and implication on the user's ability to insert the *tracheal tube* through the larynx into the trachea shall be assessed and documented.