SLOVENSKI STANDARD
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Anestezijska in dihalna oprema - Sapnični (endotrahealni) tubusi in priključki (ISO/DIS 5361:2021)

Anaesthetic and respiratory equipment - Tracheal tubes and connectors (ISO/DIS 5361:2021)

Anästhesie- und Beatmungsgeräte - Trachealtuben und Verbindungsstücke (ISO/DIS 5361:2021)

Matériel d'anesthésie et de réanimation respiratoire - Sondes trachéales et raccords (ISO/DIS 5361:2021)

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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 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*.

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

The main changes compared to the previous edition are as follows:

— alignment with the general standard for airway devices ISO 18190, Anaesthetic and respiratory equipment – General requirements for airways and related equipment;

— To provide additional requirements and design guidance for *tracheal tubes* designed for use in paediatric and neonatal care

— To clarify the requirements for speciality *tracheal tubes* such as *magill-type tracheal tube* and *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 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 third edition to include new guidance on the design of *tracheal tubes* for 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.

Tracheal tubes are 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 therefore been included for pre-cut *tracheal tubes.*

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. The requirements of this International Standard were developed using the hazard identification for *risk assessment* in Annex F.

Throughout this document 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: italics*.

Anaesthetic and respiratory equipment — Tracheal tubes and connectors

1 Scope

This document 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 document, as many specialized *tracheal tubes* are now commonly used, and all share similar essential requirements as defined in this document.

Tracheobronchial (including Endobronchial) tubes, tracheostomy tubes, and supralaryngeal airways 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 Bibliography references [1] to [4] 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 80369-7, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements*

ISO 4135:2001, Anaesthetic and respiratory equipment — Vocabulary

ISO 5356-1, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*

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

ISO 14971:2019, *Medical devices — Application of risk management to medical devices*

ISO 18190, *Anaesthetic and respiratory equipment – General requirements for airway and related equipment*

ISO 18562-1:2017, *Biocompatibility evaluation of breathing gas pathways in healthcare application – Part 1: Evaluation and testing within a risk management process*

ASTM F640-12, *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 18190:2016 and the following apply:

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

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

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

3.1

angle of bevel
acute angle between the plane of the *bevel* (3.2) and the longitudinal axis of the *tracheal tube* (3.29) at the *patient end* (3.16)

[SOURCE: ISO 4135:2001, 6.3.5]

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

3.2
bevel
slanted portion at the *patient end* (3.16) of a *tracheal tube* (3.29)

[SOURCE: ISO 4135:2001, 6.3.4]

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

3.3
cole-type tracheal tube
tracheal tube (3.29) 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* (3.26)

Note 1 to entry: See Figure 1c.

3.4
cuff

inflatable balloon permanently attached around the *tracheal tube* (3.29) near the *patient end* (3.16) and used to provide an effective seal between the tube and the trachea

Note See Figures 1a and 1b.

3.5
glottic depth mark
indicator on the *tracheal tube* (3.29) 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 See Figures 1a and 1b.

3.7
inflation lumen
lumen within the wall of the *tracheal tube* (3.29) 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* (3.29) which is intended to project from a patient

[SOURCE: ISO 4135:2001, 6.3.3]

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

3.10
machine end of the tracheal tube connector
that portion of the *tracheal tube connector* (3.30) intended to mate with an anaesthetic breathing system (ABS) or ventilator breathing system (VBS)

3.11
magill-type tracheal tube
a subset of curved *tracheal tubes* (3.29) with a particular radius (6.7.2) and having a particular *bevel* (3.2) at the *patient end* (3.16)

Note See 6.7.4 and see Figures 1a, 1b, and 4.

3.12
murphy eye
hole through the wall of a *tracheal tube* (3.29) near the *patient end* (3.16) and on the side opposite to the *bevel* (3.2)

Note See Figure 6.

3.13
naso-tracheal tube
tracheal tube (3.29) 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 (3.29) for insertion through the mouth into the trachea

[ISO 4135:2001, 6.3.1.1]

3.16
patient end
that end of a *tracheal tube* (3.29) which is intended to be inserted into the trachea

[SOURCE: ISO 4135:2001, 6.3.2]

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

3.17
patient end of the connector
that end of the *tracheal tube connector* (3.30) intended to be inserted into the *tracheal tube* (3.29)

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 See Figure 1b.

3.19*
preformed tracheal tubes
a subset of curved *tracheal tubes* (3.29) with an acute radius of curvature intended to direct the *machine end* (3.9) of the tracheal tube in a specific direction.

3.20
risk
combination of the probability of occurrence of harm and the severity of that harm

[SOURCE: ISO 14971:2019, 3.18]

3.21
risk analysis
systematic use of available information to identify hazards and to estimate the *risk* (3.20)

[SOURCE: ISO 14971:2019, 3.19]

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 14971:2019, Annex C).

3.22
risk assessment
overall process comprising a *risk analysis* (3.21) and a *risk evaluation* (3.23)

[SOURCE: ISO 14971:2019, 3.20]

3.23
risk evaluation
process of comparing the estimated *risk* (3.20) against given *risk* criteria to determine the acceptability of the *risk*

[SOURCE: ISO 14971:2019, 3.23]

3.24
risk management
systematic application of management policies, procedures, and practices to the tasks of analysing, evaluating, controlling, and monitoring *risk* (3.20)

[SOURCE: ISO 14971:2019, 3.23]

3.25
risk management file
set of records and other documents that are produced by *risk management* (3.24)

[SOURCE: ISO 14971:2019, 3.25]

3.26
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

3.27
single fault condition
condition in which a single means for reducing a *risk* (3.20) is defective or a single abnormal condition is present

[SOURCE: ISO 18190:2016, 3.9]

3.28
Subglottic suction port
An opening in the *tracheal tube* (3.29), proximal to the *machine end* of the inflatable potion of the *cuff* (3.4)intended for the suctioning of secretions.

3.29
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]

3.30
tracheal tube connector
tubular component that fits directly into the *machine end* (3.9) of a *tracheal tube* (3.29)

[SOURCE: ISO 4135:2005, 6.3.8]

Note 1 to entry: See Figures 2 and 3.

4 *General requirements

4.1 General

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

4.1.1 *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 1 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.

NOTE 2 Attention is drawn to any intended use that may deviate from the currently accepted medical practice. See Annex A for examples.

4.1.2 Where requirements in this document 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*.

4.2 Safety

4.2.1 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 International Standard.

5 Materials

5.1 General

The applicable requirements of clause 5 of ISO 18190 apply.