SLOVENSKI STANDARD
oSIST prEN ISO 5361:2010

01-december-2010

Anestezijska in dihalna oprema - Sapnični (endotrahealni) tubusi in priključki (ISO/DIS 5361:2010)

Anaesthetic and respiratory equipment - Tracheal tubes and connectors (ISO/DIS 5361:2010)

Matériel d'anesthésie et de réanimation respiratoire - Sondes trachéales et raccords (ISO/DIS 5361:2010)

Ta slovenski standard je istoveten z: **prEN ISO 5361**

ICS:

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

oSIST prEN ISO 5361:2010 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

DRAFT
prEN ISO 5361

October 2010

ICS

English Version

Anaesthetic and respiratory equipment - Tracheal tubes and connectors (ISO/DIS 5361:2010)

Matériel d'anesthésie et de réanimation respiratoire - Sondes trachéales et raccords (ISO/DIS 5361:2010)

This draft European Standard is submitted to CEN members for parallel enquiry. It has been drawn up by the Technical Committee CEN/TC 215.

If this draft becomes a European Standard, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

This draft European Standard was established by CEN in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Warning : This document is not a European Standard. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a European Standard.

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

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Ref. No. prEN ISO 5361:2010: E

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Foreword

This document (prEN ISO 5361:2010) 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 document is currently submitted to the parallel Enquiry.

Endorsement notice

The text of ISO/DIS 5361:2010 has been approved by CEN as a prEN ISO 5361:2010 without any modification.

DRAFT INTERNATIONAL STANDARD ISO/DIS 5361

ISO/TC **121**/SC **2** Secretariat: **ANSI**

Voting begins on: **2010-10-21**

Voting terminates on: **2011-03-21**

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION

Anaesthetic and respiratory equipment — Tracheal tubes and connectors

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

[Revision of first edition (ISO 5361:1999)]

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.

Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.

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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.

ISO 5361 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Airways and related equipment*.

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

The requirements of this standard were developed using the Hazard Identification for **Risk assessment** in Annex F.

Annexes, B, C, D, G, and H form normative parts of this International Standard.

Annexes A, E, and F are for information only.

Throughout this Particular Standard, terms defined in ISO 4135, *Anaesthesiology-vocabulary,* or in this Particular Standard 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 standard provides the essential 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 and new test methods have been added to the second edition of this International Standard to measure the ability of the **cuff** to provide a tracheal seal and prevent the leakage and aspiration of fluids.

Requirements for **cuff** placement for paediatric **tracheal tubes** with **cuffs** have been added because these are commercially available and in common use.

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

The requirements of ISO 5361-4:2003, ***Tracheal tubes*** *— Part 4: Cole type*, have been included in this revision because **Cole type tracheal tubes** are specialized tubes, and as such, are now included in the scope of this International Standard.

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 and new 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 existing test methods have been added to the second edition to characterize the visibility of **tracheal tubes** in x-rays used to determine proper placement of the tube. These requirements were originally published in early ANSI Z-79 standards for **tracheal tubes** in the 1970's and 1980's.[2]

Anaesthetic and respiratory equipment — Tracheal tubes and connectors

1 *Scope

This standard provides the essential requirements for **tracheal tubes** and **tracheal tube connectors.** **Tracheal tubes** with walls reinforced with metal or nylon, **tracheal tubes** with **shoulders**, tapering, **tracheal tubes** with provision 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 specification, 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 for use with flammable anaesthetic gases or agents and laser or electrosurgical equipment are not covered by this standard.

NOTE ISO 11990-1, ISO 11990-2, and ISO 14408 cover this.

2 References

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 594-1 :1996, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements*.

ISO 4135:2005, *Anaesthesiology-vocabulary*.

ISO 5356-1:2004, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets.*

ISO 7000:2004, *Graphical symbols.*

ISO 10993-1:2003*, Biological evaluation of medical devices — Part 1: Guidance on selection of tests.*

ISO 11135-1:2007, *Medical Devices – Validation and routine control of ethylene oxide sterilization.*

ISO11371-1:2006, *Sterilization of healthcare products-Requirements for validation and routine control – Radiation sterilization.*

ISO 11607-1:2006*, Packaging for terminally sterilized medical devices. Part 1: Requirements for materials, sterile barrier systems and packaging systems*

