



SLOVENSKI STANDARD
oSIST prEN ISO 5361:2010
01-december-2010

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

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

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

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Ta slovenski standard je istoveten z: prEN ISO 5361

ICS:

11.040.10	Anestzijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment
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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.

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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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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.

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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

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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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ISO/DIS 5361

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95

96 Foreword

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

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

104 The main task of technical committees is to prepare International Standards. Draft International Standards
105 adopted by the technical committees are circulated to the member bodies for voting. Publication as an
106 International Standard requires approval by at least 75 % of the member bodies casting a vote.

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

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

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

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

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

115 Throughout this Particular Standard, terms defined in ISO 4135, *Anaesthesiology-vocabulary*, or in this
116 Particular Standard appear in **bold** type.

117 Throughout this Particular Standard, text for which a rationale is provided in Annex A is indicated by an
118 asterisk (*).

119

120 Introduction

121 This standard provides the essential requirements for the design of **tracheal tubes** and **tracheal tube**
122 **connectors**. Tracheal tubes are intended to be inserted through the larynx into the trachea to convey gases
123 and vapours to and from the trachea.

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

127 A variety of **cuff** designs are available to meet particular clinical requirements. **Cuff** performance requirements
128 and new test methods have been added to the second edition of this International Standard to measure the
129 ability of the **cuff** to provide a tracheal seal and prevent the leakage and aspiration of fluids.

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

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

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

136 Clinical considerations have also dictated the specified length of **tracheal tubes** because long **tracheal**
137 **tubes**, sometimes of relatively narrow diameter, may be required and therefore should be readily available.
138 Provision has also been included for pre-cut **tracheal tubes**.

139 Kink resistance requirements and new test methods have also been added to the second edition to measure
140 the ability of the shaft of the **tracheal tube** to resist collapse and increased breathing resistance when bent or
141 curved.

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

145

146

150 **Anaesthetic and respiratory equipment — Tracheal tubes and** 151 **connectors**

152 **1 *Scope**

153 This standard provides the essential requirements for **tracheal tubes** and **tracheal tube connectors**.
154 **Tracheal tubes** with walls reinforced with metal or nylon, **tracheal tubes** with **shoulders**, tapering, **tracheal**
155 **tubes** with provision for suctioning or monitoring or delivery of drugs or other gases, and the many other types
156 of **tracheal tubes** devised for specialized applications are included in this specification, as many specialized
157 **tracheal tubes** are now commonly used, and all share similar essential requirements as defined in this
158 International Standard.

159 Tracheobronchial (endobronchial) tubes, tracheostomy tubes and supralaryngeal airways are excluded from
160 the scope of this International Standard.

161 **Tracheal tubes** for use with flammable anaesthetic gases or agents and laser or electrosurgical equipment
162 are not covered by this standard.

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

164 **2 References**

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

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

173 ISO 4135:2005, *Anaesthesiology-vocabulary.*

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

176 ISO 7000:2004, *Graphical symbols.*

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

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

179 ISO 11371-1:2006, *Sterilization of healthcare products-Requirements for validation and routine control –*
180 *Radiation sterilization.*

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