



SLOVENSKI STANDARD
oSIST prEN ISO 5361:2014
01-julij-2014

**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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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)]

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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.

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Foreword

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

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

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

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

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

15 This third edition cancels and replaces the second edition (ISO 5361:2012), which has been technically
16 revised.

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

19 Throughout this Particular Standard, terms defined in Clause 3 or in ISO 4135 appear in **bold** type.

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

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

29 Introduction

30 This International Standard provides the essential performance and safety requirements for the design of
31 **tracheal tubes** and **tracheal tube connectors**. **Tracheal tubes** are intended to be inserted through the
32 larynx into the trachea to convey gases and vapours to and from the trachea.

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

36 A variety of **cuff** designs are available to meet particular clinical requirements. **Cuff** performance requirements
37 with associated test methods remain unchanged from the second edition.

38 Requirements for paediatric **tracheal tubes** with and without **cuffs**, have been updated from the
39 second edition to include revised length marks and new provisions for **glottic depth marks** have been added
40 in this edition because these are commercially available and in common use.

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

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

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

48 Radiopacity requirements and test methods remain unchanged from the second edition, to characterize the
49 visibility of **tracheal tubes** in X-rays used to determine proper placement of the tube. The requirements of this
50 International Standard were developed using the hazard identification for **risk assessment** in Annex F.

51

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?="](http://www.iso.org/iso/publications_and_e-products/databases.htm?=).

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82 ISO 14155, *Clinical investigation of medical devices for human subjects – Good clinical practice*

83 ISO 14971, *Medical Devices - Application of risk management to medical devices*

84 ISO 15223-1, *Medical devices – Symbols to be used with medical device labels, labelling and information to*
85 *be supplied – Part 1: General requirements*

86 ISO 15223-2, *Medical devices – Symbols to be used with medical device labels, labelling, and information to*
87 *be supplied – Part 2: Symbol development, selection and validation*

88 EN 556-1:2001, *Sterilization of medical devices - Requirements for medical devices to be designated*
89 *“STERILE” -Part 1: Requirements for terminally sterilized medical devices*

90 EN 1041, *Terminology, symbols and information provided with medical devices: Information supplied by the*
91 *manufacturer of medical devices*

92 ASTM F640-2007, *Standard test methods for radiopacity for medical use*

93 ASTM D3002-2007, *Standard guide for evaluation of coatings applied to plastics*

94 3 Terms and definitions

95 For the purposes of this document, the terms and definitions given in ISO 4135^[5] and ISO 14971 and the
96 following apply.

97 3.1 98 angle of bevel

99 acute angle between the plane of the **bevel** and the longitudinal axis of the **tracheal tube** at the **patient end**

100 [ISO 4135:2001, definition 6.3.5]

101 See Figures 1 a), 1 b) and 4.

102 3.2

103 bevel

104 slanted portion at the **patient end** of a **tracheal tube**

105 [ISO 4135:2001, definition 6.3.4]

106 See Figures 1 a), 1 b) and 4.

107 3.3

108 Cole-type tracheal tube

109 **tracheal tube** combining a short **laryngo-tracheal portion** of small diameter and a longer **oral portion** of
110 larger diameter with transition from one to the other resulting in a **shoulder**

111 See Figure 1 c).

112 3.4

113 cuff

114 inflatable balloon permanently attached around the **tracheal tube** near the **patient end** and used to provide
115 an effective seal between the tube and the trachea

116 See Figures 1 a) and 1 b).

- 117 **3.5**
118 **glottic depth mark**
119 an indicator on the tracheal tube to assist in determining the insertion beyond the vocal chords
- 120 **3.6**
121 **inflating tube**
122 tube through which the **cuff** is inflated
- 123 [ISO 4135:2001, definition 6.3.6.1]
- 124 See Figures 1 a) and 1 b).
- 125 **3.7**
126 **inflation lumen**
127 lumen within the wall of the **tracheal tube** for inflating the **cuff**
- 128 **3.8**
129 **laryngo-tracheal portion**
130 that portion of a **Cole-type tracheal tube** of small diameter and extending from the **bevel** tip to the point at
131 which there is an increase in the outside diameter
- 132 **3.9**
133 **machine end**
134 that end of a **tracheal tube** which is intended to project from a patient
- 135 [ISO 4135:2001, definition 6.3.3]
- 136 See Figures 1 a), 1 b) and 4.
- 137 **3.10**
138 **machine end of the tracheal tube connector**
139 that portion of the **tracheal tube connector** intended to mate with an anaesthetic breathing system (ABS) or
140 ventilator breathing system (VBS)
- 141 **3.11**
142 **Magill-type tracheal tube**
143 curved **tracheal tube** with a radius without a **Murphy eye** and having a **bevel** at the **patient end**
- 144 See 5.7.2 and Figures 1 a), 1 b) and 4.
- 145 **3.12**
146 **Murphy eye**
147 hole through the wall of a **tracheal tube** near the **patient end** and on the side opposite to the **bevel**
- 148 See Figure 6.
- 149 **3.13**
150 **naso-tracheal tube**
151 **tracheal tube** for insertion through the nose into the trachea
- 152 [ISO 4135:2001, definition 6.3.1.2]
- 153 **3.14**
154 **oral portion**
155 that portion of a **Cole-type tracheal tube** of a larger diameter extending from the **machine end** to the point at
156 which there is a decrease in the outside diameter

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157 **3.15**158 **oro-tracheal tube**159 **tracheal tube** for insertion through the mouth into the trachea

160 [ISO 4135:2001, definition 6.3.1.1]

161 **3.16**162 **patient end**163 that end of a **tracheal tube** which is intended to be inserted into the trachea

164 [ISO 4135:2001, definition 6.3.2]

165 See Figures 1 a), 1 b) and 4.

166 **3.17**167 **patient end of the connector**168 that end of the **tracheal tube connector** intended to be inserted into the **tracheal tube**169 **3.18**170 **pilot balloon**171 balloon fitted to an **inflating tube** to indicate inflation of the **cuff**

172 [ISO 4135:2001, definition 6.3.6.2]

173 See Figure 1 b).

174 **3.19**175 **risk**

176 combination of the probability of occurrence of harm and the severity of that harm

177 [ISO 14971:2007, definition 2.16]

178 **3.20**179 **risk analysis**180 systematic use of available information to identify hazards and to estimate the **risk**

181 [ISO 14971:2007, definition 2.17]

182 NOTE **Risk analysis** includes examination of different sequences of events that can produce hazardous situations
183 and harm (see Annex F and ISO 14971:2007, Annex E).184 **3.21**185 **risk assessment**186 overall process comprising a **risk analysis** and a **risk evaluation**

187 [ISO 14971:2007, definition 2.18]

188 **3.22**189 **risk evaluation**190 process of comparing the estimated **risk** against given **risk** criteria to determine the acceptability of the **risk**

191 [ISO 14971:2007, definition 2.21]

192 **3.23**193 **risk management**194 systematic application of management policies, procedures and practices to the tasks of analysing,
195 evaluating, controlling and monitoring **risk**

196 [ISO 14971:2007, definition 2.22]

197 **3.24**
198 **risk management file**
199 set of records and other documents that are produced by **risk management**

200 [ISO 14971:2007, definition 2.23]

201 **3.25**
202 **shoulder**
203 that portion of a **Cole-type tracheal tube** at which transition from the **oral portion** to the **laryngo-tracheal**
204 **portion** occurs

205 **3.26**
206 **single-fault condition**
207 condition in which a single means for reducing a **risk** is defective or a single abnormal condition is present

208 **3.27**
209 **tracheal tube**
210 tube designed for insertion through the larynx into the trachea to convey gases and vapours to and from the
211 trachea

212 [ISO 4135:2001, definition 6.3.1]

213 **3.28**
214 **tracheal tube connector**
215 tubular component that fits directly into the **machine end** of a **tracheal tube**

216 [ISO 4135:2005, definition 6.3.8]

217 See Figures 2 and 3.

218 **4 *General requirements for tracheal tubes and tracheal tube connectors**

219 This International Standard specifies requirements that are generally applicable to **risks** associated with
220 **tracheal tubes** and **tracheal tube connectors**.

221 **4.1 Risk assessment**

222 **4.1.1** An established **risk assessment** process shall be applied to the design of the device.

223 EXAMPLE ISO 14971.

224 Check compliance by inspection of the **risk management file**. If clinical studies are performed, these studies
225 shall document measurements taken during the conditions for which performance is claimed. The clinical
226 studies shall comply with the requirements of ISO 14155.

227 NOTE See Annex F.

228 **4.1.2 Tracheal tubes** shall, when transported, stored, installed, operated in normal use and maintained
229 according to the instructions of the manufacturer, present no risks that are not reduced to an acceptable level
230 using risk management procedures in accordance with ISO 14971 and which are connected with their
231 intended application, in normal and in **single fault condition**.

232 NOTE A situation in which a fault is not detected is considered a normal condition. Fault conditions/hazardous
233 situations might remain undetected over a period of time and, as a consequence, might lead to an unacceptable risk. In
234 that case, a subsequent detected fault condition needs to be considered as a single fault condition. Specific risk control
235 measures need to be determined within the risk management process to deal with such situations.

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236 **4.1.3** Where requirements in this International Standard refer to freedom from unacceptable **risk**, the
 237 acceptability or unacceptability of this **risk** shall be determined by the manufacturer in accordance with the
 238 manufacturer's policy for determining acceptable **risk**.

239 Check compliance by inspection of the **risk management file**.

240 **4.1.4** If required by a competent authority, the manufacturer shall address in a usability engineering process
 241 the risk resulting from poor usability (see IEC 62366).

242 Check compliance by inspection of the usability engineering file.

243 **4.1.5** If required by a competent authority, a clinical evaluation shall be performed and documented in the
 244 technical documentation of the device.

245 Check compliance by inspection of the technical documentation.

246 **4.1.6** If required by a competent authority, and where appropriate, validated biophysical or modelling
 247 research shall be carried out.

248 Check compliance by inspection of the technical documentation.

249 4.2 Safety

250 ***4.2.1 Tracheal tubes**, when transported, stored, installed, operated in their normal intended use, and
 251 maintained according to the instructions of the manufacturer, shall minimize safety hazards which could
 252 reasonably be foreseen to occur, in normal and **single-fault conditions**.

253 Check compliance by inspection of the **risk management file**.

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

256 **4.2.2** The manufacturer may use type tests different from those detailed within this International Standard, if
 257 an equivalent degree of safety is obtained. Alternative test methods shall be validated against the test
 258 methods specified in this International Standard.

259 5 Specific requirements for tracheal tubes and tracheal tube connectors

260 5.1 Size designation

261 The size of **tracheal tubes** and **tracheal tube connectors** shall be designated in accordance with Table 1a
 262 for **tracheal tubes**, Table 1b for **Cole-type tracheal tubes**, and Table 2 for **tracheal tube connectors**.

263 5.2 Dimensions

264 5.2.1 Tracheal tubes

265 **5.2.1.1** The basic dimensions of **Magill-type tracheal tubes** shall be in accordance with Tables 1a and 1b.

266 **5.2.1.2** The basic dimensions of **Cole-type tracheal tubes** shall be in accordance with Table 1b.

267 **5.2.1.3** The designated size of the **tracheal tube** shall be the marked inside diameter subject to a tolerance of
 268 $\pm 0,15$ mm for sizes 6,0 and smaller, and subject to a tolerance of $\pm 0,20$ mm for sizes 6,5 and larger.

269 NOTE The lumen of the **tracheal tube** should be essentially circular in a plane at right angles to the long axis.

270 **5.2.1.4** For **Magill-type tracheal tubes**, the nominal outside diameter (OD) shall be the marked outside
271 diameter (OD) subject to a tolerance of $\pm 0,15$ mm for sizes 6,0 and smaller, or subject to a tolerance of $\pm 0,20$
272 mm for sizes 6,5 and larger [see 8.2.1.1 b) 1)]. For **Cole-type tracheal tubes**, the maximum outside diameter
273 of the **laryngo-tracheal portion** (OD) shall be the marked outside diameter (OD) [see 8.2.1.1 b) 2)].

274 **5.2.1.5** For **Cole-type tracheal tubes**, the axial length of the outside surface of the **shoulder** region, S_1 S_2
275 [see Figure 1 c)], shall not exceed 4 mm for sizes up to and including size 3.

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