



**SLOVENSKI STANDARD**  
**oSIST prEN ISO 5361:2021**  
**01-maj-2021**

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

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**ICS:**

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment
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# DRAFT INTERNATIONAL STANDARD

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## Anaesthetic and respiratory equipment — Tracheal tubes and connectors

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

ICS: 11.040.10

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Reference number  
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34	<b>Contents</b>	
35	<b>Foreword</b> .....	<b>6</b>
36	<b>Introduction</b> .....	<b>8</b>
37	<b>1 Scope</b> .....	<b>9</b>
38	<b>2 Normative references</b> .....	<b>9</b>
39	<b>3 Terms and definitions</b> .....	<b>9</b>
40	<b>4 *General requirements</b> .....	<b>13</b>
41	<b>4.1 General</b> .....	<b>13</b>
42	<b>4.2 Safety</b> .....	<b>13</b>
43	<b>5 Materials</b> .....	<b>13</b>
44	<b>5.1 General</b> .....	<b>13</b>
45	<b>5.2 *Biological safety testing</b> .....	<b>14</b>
46	<b>6 Design Requirements</b> .....	<b>14</b>
47	<b>6.1 General</b> .....	<b>14</b>
48	<b>6.2 Size designation</b> .....	<b>14</b>
49	<b>6.3 Dimensions</b> .....	<b>14</b>
50	<b>Table 1a — *Basic dimensions of tracheal tubes (see Figures 1a and 1b)</b> .....	<b>15</b>
51	<b>Table 1b — Basic dimensions of Cole-type tracheal tubes (see Figure 1c)</b> .....	<b>16</b>
52	<b>Table 2 — Tracheal tube connectors — Size range and basic dimensions of patient end</b> .....	<b>19</b>
53	<b>Figure 2 — Straight tracheal tube connector</b> .....	<b>20</b>
54	<b>Figure 3 — Example of a curved tracheal tube connector</b> .....	<b>21</b>
55	<b>6.4 *Materials</b> .....	<b>21</b>
56	<b>6.5 Tracheal tube bevel</b> .....	<b>21</b>
57	<b>6.6 *Tracheal tube cuffs</b> .....	<b>22</b>
58	Compliance is checked by inspection.....	Error! Bookmark not defined.
59	<b>6.7 Inflating system for cuffs</b> .....	<b>22</b>
60	<b>6.8 Curvature of the tube</b> .....	<b>23</b>
61	<b>Figure 4 — Typical uncuffed Magill-type tracheal tube</b> .....	<b>24</b>
62	<b>Figure 5 — Typical tracheal tube with straight patient end</b> .....	<b>25</b>
63	<b>6.9 *Radiopaque marker</b> .....	<b>25</b>
64	<b>6.10 *Kink resistance</b> .....	<b>25</b>
65	<b>6.11 Additional requirement for tracheal tubes with a murphy eye</b> .....	<b>25</b>
66	<b>Figure 6 — Patient end of a tracheal tube showing a murphy eye</b> .....	<b>26</b>
67	<b>7 Requirements for tracheal tubes with tracheal tube connectors supplied sterile</b> .....	<b>26</b>
68	<b>8 Packaging for tracheal tubes and tracheal tube connectors supplied sterile</b> .....	<b>26</b>
69	<b>8.1 General</b> .....	<b>26</b>

## ISO/DIS 5361:2021(E)

70	<b>9</b>	<b>Information supplied by the manufacturer</b> .....	<b>26</b>
71		<b>Marking</b> .....	<b>26</b>
72	<b>9.1</b>	<b>26</b>	
73	<b>9.2</b>	<b>Marking on the <i>tracheal tube</i> individual pack or any insert</b> .....	<b>28</b>
74	<b>9.3</b>	<b>Marking on <i>tracheal tube connectors</i></b> .....	<b>29</b>
75		<b>Annex A (informative) Rationale</b> .....	<b>30</b>
76		<b>Annex B (normative) Determination of <i>cuff</i> diameter</b> .....	<b>35</b>
77	<b>B.1</b>	<b>Principle</b> .....	<b>35</b>
78	<b>B.2</b>	<b>Apparatus</b> .....	<b>35</b>
79	<b>B.3</b>	<b>Procedure</b> .....	<b>35</b>
80	<b>B.4</b>	<b>Expression of results</b> .....	<b>35</b>
81		<b>Annex C (normative) Test method for cuffed tube collapse</b> .....	<b>36</b>
82	<b>C.1</b>	<b>Principle</b> .....	<b>36</b>
83	<b>C.2</b>	<b>Apparatus</b> .....	<b>36</b>
84		<b>Table C.1 — Selection of test inflation pressures</b> .....	<b>36</b>
85	<b>C.3</b>	<b>Procedure</b> .....	<b>36</b>
86		<b>Figure C.1 —B. Apparatus for tube collapse test</b> .....	<b>37</b>
87	<b>C.4</b>	<b>Expression of results</b> .....	<b>38</b>
88		<b>Annex D (normative) *Test method for <i>cuff</i> herniation</b> .....	<b>39</b>
89	<b>D.1</b>	<b>Principle</b> .....	<b>39</b>
90	<b>D.2</b>	<b>Apparatus</b> .....	<b>39</b>
91	<b>D.3</b>	<b>Procedure</b> .....	<b>39</b>
92	<b>D.4</b>	<b>Expression of results</b> .....	<b>39</b>
93		<b>Figure D.1 — Apparatus for <i>cuff</i> herniation test</b> .....	<b>40</b>
94		<b>Annex E (informative) Guidance on the design of <i>tracheal tube</i> and <i>connectors</i></b> .....	<b>41</b>
95		<b>Annex F (informative) Hazard identification for <i>risk</i> assessment</b> .....	<b>46</b>
96	<b>F.1</b>	<b>Potential hazards associated with the placement, removal, and use of <i>tracheal tubes</i></b> .....	<b>46</b>
97	<b>F.2</b>	<b>Potential device hazards</b> .....	<b>47</b>
98		<b>Annex G (normative) *Test method for tracheal seal</b> .....	<b>49</b>
99	<b>G.1</b>	<b>Principle</b> .....	<b>49</b>
100	<b>G.2</b>	<b>Apparatus</b> .....	<b>49</b>

101	<b>G.3</b>	<b>Procedure.....</b>	<b>49</b>
102	<b>G.4</b>	<b>Expression of results.....</b>	<b>50</b>
103		<b>Figure G.1 — Tracheal seal test apparatus.....</b>	<b>51</b>
104		<b>Annex H (normative) Test method to determine kink resistance.....</b>	<b>52</b>
105	<b>H.1</b>	<b>Principle .....</b>	<b>52</b>
106	<b>H.2</b>	<b>Apparatus.....</b>	<b>52</b>
107	<b>H.2.1</b>	<b>Kink resistance test apparatus .....</b>	<b>52</b>
108		<b>Table H.1 — Dimensions of radius of curvature.....</b>	<b>52</b>
109	<b>H.3</b>	<b>Procedure.....</b>	<b>52</b>
110	<b>H.4</b>	<b>Expression of results.....</b>	<b>52</b>

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## ISO/DIS 5361:2021(E)

113 **Foreword**

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

121 The procedures used to develop this document and those intended for its further maintenance are  
122 described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the  
123 different types of ISO documents should be noted. This document was drafted in accordance with the  
124 editorial rules of the ISO/IEC Directives, Part 2 (see [www.iso.org/directives](http://www.iso.org/directives)).

125 Attention is drawn to the possibility that some of the elements of this document may be the subject of  
126 patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any  
127 patent rights identified during the development of the document will be in the Introduction and/or on  
128 the ISO list of patent declarations received (see [www.iso.org/patents](http://www.iso.org/patents)).

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

131 For an explanation on the meaning of ISO specific terms and expressions related to conformity  
132 assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers  
133 to Trade (TBT) see [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html)

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

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

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

- 139 — alignment with the general standard for airway devices ISO 18190, *Anaesthetic and respiratory  
140 equipment – General requirements for airways and related equipment*;
- 141 — To provide additional requirements and design guidance for *tracheal tubes* designed for use in  
142 paediatric and neonatal care
- 143 — To clarify the requirements for speciality *tracheal tubes* such as *magill-type tracheal tube* and  
144 *performed tracheal tubes*
- 145 — updating of references.

146 Any feedback or questions on this document should be directed to the user's national standards body. A  
147 complete listing of these bodies can be found at [www.iso.org/members.html](http://www.iso.org/members.html).

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176 **Introduction**

177 This provides the essential performance and safety requirements for the design of *tracheal tubes* and  
 178 *tracheal tube connectors*. *Tracheal tubes* are intended to be inserted through the larynx into the trachea  
 179 to provide a patent airway in patients during spontaneous, assisted or controlled ventilation for short or  
 180 prolonged durations to convey gases and vapours to and from the trachea.

181 In addition, *tracheal tubes* with *cuffs* are intended to seal and protect the trachea from aspiration.

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

184 Requirements for paediatric *tracheal tubes*, with and without *cuffs*, have been updated from the third  
 185 edition to include new guidance on the design of *tracheal tubes* for used in paediatric and neonatal  
 186 patients. The maximum distance from the *patient end* of the *tracheal tube* to the *machine end* of the  
 187 inflatable length of the *cuff* has been revised in this edition to minimise the *risk* of the inflatable length of  
 188 the *cuff* aligning with the larynx of neonatal and paediatric patients.

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

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

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

196 Radiopacity requirements and test methods to characterize the visibility of *tracheal tubes* in X-rays used  
 197 to determine proper placement of the tube remain unchanged from the second edition. The requirements  
 198 of this International Standard were developed using the hazard identification for *risk assessment* in  
 199 [Annex F](#).

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201 Throughout this document the following print types are used:

- 202 — Requirements and definitions: roman type;
- 203 — *Test specifications: italic type;*
- 204 — Informative material appearing outside of tables, such as notes, examples and references: smaller type.  
 205 The normative text of tables is also in smaller type;
- 206 — *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

## ISO/DIS 5361:2021(E)

244 **angle of bevel**

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

247 [SOURCE: ISO 4135:2001, 6.3.5]

248 Note 1 See [Figures 1a, 1b](#), and [4](#).

249 **3.2**250 **bevel**

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

252 [SOURCE: ISO 4135:2001, 6.3.4]

253 Note 1 See [Figures 1a, 1b](#), and [4](#).

254 **3.3**255 **cole-type tracheal tube**

256 *tracheal tube* (3.29) combining a short *laryngo-tracheal portion* (3.8) of small diameter and a longer *oral*  
257 *portion* (3.14) of larger diameter with transition from one to the other resulting in a *shoulder* (3.26)

258 Note 1 to entry: See [Figure 1c](#).

259 **3.4**260 **cuff**

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

263 Note See [Figures 1a](#) and [1b](#).

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264 **3.5**265 **glottic depth mark**

266 indicator on the *tracheal tube* (3.29) to assist in determining the tip insertion depth beyond the vocal  
267 cords

268 **3.6**269 **inflating tube**

270 tube through which the *cuff* (3.4) is inflated

271 [SOURCE: ISO 4135:2001, 6.3.6.1]

272 Note See [Figures 1a](#) and [1b](#).

273 **3.7**274 **inflation lumen**

275 lumen within the wall of the *tracheal tube* (3.29) for inflating the *cuff* (3.4)

276 **3.8**277 **laryngo-tracheal portion**

278 that portion of a *Cole-type tracheal tube* (3.3) of small diameter and extending from the *bevel* (3.2) tip to  
279 the point at which there is an increase in the outside diameter

280 **3.9**281 **machine end**

282 that end of a *tracheal tube* (3.29) which is intended to project from a patient

283 [SOURCE: ISO 4135:2001, 6.3.3]

284 Note 1 See [Figures 1a, 1b](#), and [4](#).

### 285 3.10

#### 286 machine end of the tracheal tube connector

287 that portion of the *tracheal tube connector* ([3.30](#)) intended to mate with an anaesthetic breathing system  
288 (ABS) or ventilator breathing system (VBS)

### 289 3.11

#### 290 magill-type tracheal tube

291 a subset of curved *tracheal tubes* ([3.29](#)) with a particular radius ([6.7.2](#)) and having a particular *bevel* ([3.2](#))  
292 at the *patient end* ([3.16](#))

293 Note See [6.7.4](#) and see [Figures 1a, 1b](#), and [4](#).

### 294 3.12

#### 295 murphy eye

296 hole through the wall of a *tracheal tube* ([3.29](#)) near the *patient end* ([3.16](#)) and on the side opposite to the  
297 *bevel* ([3.2](#))

298 Note See [Figure 6](#).

### 299 3.13

#### 300 naso-tracheal tube

301 *tracheal tube* ([3.29](#)) for insertion through the nose into the trachea

302 [SOURCE: ISO 4135:2001, 6.3.1.2]

### 303 3.14

#### 304 oral portion

305 that portion of a *Cole-type tracheal tube* ([3.3](#)) of a larger diameter extending from the *machine end* ([3.9](#))  
306 to the point at which there is a decrease in the outside diameter

### 307 3.15

#### 308 oro-tracheal tube

309 *tracheal tube* ([3.29](#)) for insertion through the mouth into the trachea

310 [ISO 4135:2001, 6.3.1.1]

### 311 3.16

#### 312 patient end

313 that end of a *tracheal tube* ([3.29](#)) which is intended to be inserted into the trachea

314 [SOURCE: ISO 4135:2001, 6.3.2]

315 Note See [Figures 1a, 1b](#), and [4](#).

### 316 3.17

#### 317 patient end of the connector

318 that end of the *tracheal tube connector* ([3.30](#)) intended to be inserted into the *tracheal tube* ([3.29](#))

### 319 3.18

#### 320 pilot balloon

321 balloon fitted to an *inflating tube* ([3.6](#)) to indicate inflation of the *cuff* ([3.4](#))

322 [SOURCE: ISO 4135:2001, 6.3.6.2]

323 Note See [Figure 1b](#).

## ISO/DIS 5361:2021(E)

- 324 **3.19\***  
 325 **preformed tracheal tubes**  
 326 a subset of curved *tracheal tubes* (3.29) with an acute radius of curvature intended to direct the *machine*  
 327 *end* (3.9) of the tracheal tube in a specific direction.
- 328 **3.20**  
 329 **risk**  
 330 combination of the probability of occurrence of harm and the severity of that harm
- 331 [SOURCE: ISO 14971:2019, 3.18]
- 332 **3.21**  
 333 **risk analysis**  
 334 systematic use of available information to identify hazards and to estimate the *risk* (3.20)
- 335 [SOURCE: ISO 14971:2019, 3.19]
- 336 Note 1 to entry: *risk analysis* includes examination of different sequences of events that can produce hazardous  
 337 situations and harm (see [Annex F](#) and ISO 14971:2019, Annex C).
- 338 **3.22**  
 339 **risk assessment**  
 340 overall process comprising a *risk analysis* (3.21) and a *risk evaluation* (3.23)
- 341 [SOURCE: ISO 14971:2019, 3.20]
- 342 **3.23**  
 343 **risk evaluation**  
 344 process of comparing the estimated *risk* (3.20) against given *risk* criteria to determine the acceptability  
 345 of the *risk*
- 346 [SOURCE: ISO 14971:2019, 3.23]
- 347 **3.24**  
 348 **risk management**  
 349 systematic application of management policies, procedures, and practices to the tasks of analysing,  
 350 evaluating, controlling, and monitoring *risk* (3.20)
- 351 [SOURCE: ISO 14971:2019, 3.23]
- 352 **3.25**  
 353 **risk management file**  
 354 set of records and other documents that are produced by *risk management* (3.24)
- 355 [SOURCE: ISO 14971:2019, 3.25]
- 356 **3.26**  
 357 **shoulder**  
 358 that portion of a *Cole-type tracheal tube* (3.3) at which transition from the *oral portion* (3.14) to the  
 359 *laryngo-tracheal portion* (3.8) occurs
- 360 **3.27**  
 361 **single fault condition**  
 362 condition in which a single means for reducing a *risk* (3.20) is defective or a single abnormal condition is  
 363 present

364 [SOURCE: ISO 18190:2016, 3.9]

### 365 **3.28**

#### 366 **Subglottic suction port**

367 An opening in the *tracheal tube* (3.29), proximal to the *machine end* of the inflatable portion of the *cuff*  
368 (3.4) intended for the suctioning of secretions.

### 369 **3.29**

#### 370 **tracheal tube**

371 tube designed for insertion through the larynx into the trachea to convey gases and vapours to and from  
372 the trachea

373 [SOURCE: ISO 4135:2001, 6.3.1]

### 374 **3.30**

#### 375 **tracheal tube connector**

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

377 [SOURCE: ISO 4135:2005, 6.3.8]

378 Note 1 to entry: See [Figures 2](#) and [3](#).

## 379 **4 \*General requirements**

### 380 **4.1 General**

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

382 **4.1.1** *Tracheal tubes* shall, when transported, stored, installed, operated in normal use, and  
383 maintained according to the instructions of the manufacturer, present no risks that are not reduced to  
384 an acceptable level using *risk management* procedures in accordance with ISO 14971 and which are  
385 connected with their intended application, in normal and in *single fault condition*.

386 NOTE 1 A situation in which a fault is not detected is considered a normal condition. Fault conditions/hazardous  
387 situations might remain undetected over a period of time and, as a consequence, might lead to an unacceptable *risk*.  
388 In that case, a subsequent detected fault condition needs to be considered as a *single fault condition*. Specific *risk*  
389 control measures need to be determined within the *risk management* process to deal with such situations.

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

392 **4.1.2** Where requirements in this document refer to freedom from unacceptable *risk*, the acceptability  
393 or unacceptability of this *risk* shall be determined by the manufacturer in accordance with the  
394 manufacturer's policy for determining acceptable *risk*.

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

### 396 **4.2 Safety**

397 **4.2.1** The manufacturer may use type tests different from those detailed within this document, if an  
398 equivalent degree of safety is obtained. Alternative test methods shall be validated against the test  
399 methods specified in this International Standard.

## 400 **5 Materials**

### 401 **5.1 General**

402 The applicable requirements of clause 5 of ISO 18190 apply.