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## Suction catheters for use in the respiratory tract

*Sondes d'aspiration pour les voies respiratoires*

[Revision of third edition (ISO 8836:2007)]

ICS 11.040.10; 11.040.25

### ISO/CEN PARALLEL PROCESSING

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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.

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58 **Foreword**

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

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

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

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

71 ISO 8836 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*,  
72 Subcommittee SC 2, *Airways and related equipment*.

73 Revisions in this fourth edition are intended to harmonize this international standard with recent amendments  
74 in the European Medical Device Directive.

75 Major technical revisions in this edition include requirements for **closed suction catheters**, new requirements  
76 to harmonize this international standard with requirements for critical care ventilators, and **risk management**.

77 Throughout this Particular Standard, terms defined in Clause 3 or in ISO 4135<sup>[1]</sup> appear in **bold** type.

78  
79 Throughout this Particular Standard, text for which a rationale is provided in Annex A is indicated by an  
80 asterisk (\*).

D  
R  
A  
F  
T

## 81 Introduction

82 This International Standard specifies dimensions and requirements for **suction catheters** for use in the  
83 respiratory tract. It is concerned with the basic requirements and method of size designation of both **open**  
84 and **closed suction catheters** made of plastics materials.

85 The method of describing tube dimensions and configuration has been devised in order to assist clinicians in  
86 the selection of the most suitable **suction catheter** for a particular patient. Size is designated by outside  
87 diameter which is important when selecting catheters because of its relationship to the ease with which the  
88 catheter can be passed through a **tracheal** or **tracheostomy tube** <sup>[2],[3],[4]</sup>.

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# 89 Suction catheters for use in the respiratory tract

## 90 1 Scope

91 This International Standard specifies requirements for **suction catheters**, including **closed suction**  
92 **catheters**, made of plastic materials and intended for use in suction of the respiratory tract.

93 Angled-tip **suction catheters** (e.g. Coudé catheters) and **suction catheters** with aspirator collectors are not  
94 considered to be specialized and are therefore included in the scope of this International Standard.

95 **Suction catheters** intended for use with flammable anaesthetic gases or agents, lasers or electrosurgical  
96 equipment are not covered by this standard.

97 NOTE See ISO/TR 11991-95 for guidance on airway management during laser surgery of the upper airway. <sup>[5]</sup>

## 98 2 Normative references

99 The following referenced documents are indispensable for the application of this document. For dated  
100 references, only the edition cited applies. For undated references, the latest edition of the referenced  
101 document (including any amendments) applies.

102 ISO 594-1, *Luer conical fittings with a 6 % (Luer) taper for syringes, needles and certain other 1146 medical*  
103 *equipment – Part 1: General requirements*

104 ISO 594-2, *Luer conical fittings with a 6 % (Luer) taper for syringes, needles and certain other 1148 medical*  
105 *equipment – Part 1: Luer lock fittings*

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

107 ISO 5367:2013, *Breathing sets and connectors (under development)*

108 ISO 7000, *Graphical symbols for use on equipment -- Index and synopsis.*<sup>1)</sup>

109 ISO 10079-1, *Medical suction equipment — Part 1: Electrically powered suction equipment*

110 ISO 10079-2, *Medical suction equipment — Part 2: Manually powered suction equipment*

111 ISO 10079-3, *Medical suction equipment — Part 3: Suction equipment from vacuum or pressure source*

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

114 ISO 11135-1, *Sterilization of health care products -- Ethylene oxide -- Part 1: Requirements for development,*  
115 *validation and routine control of a sterilization process for medical devices*

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?=) .

- 116 ISO 11137-1, *Sterilization of health care products -- Radiation -- Part 1: Requirements for development,*  
117 *validation and routine control of a sterilization process for medical devices*
- 118 ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile*  
119 *barrier systems and packaging systems*
- 120 ISO 11607-2, *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for*  
121 *forming, sealing and assembly processes*
- 122 ISO 14155 *Clinical investigation of medical devices for human subjects -- Good clinical practice*
- 123 ISO 14971, *Medical Devices - Application of risk management to medical devices*
- 124 ISO 15223-1, *Medical device – Symbols to be used with medical device labels, labelling and information to be*  
125 *supplied – Part 1: General requirements*
- 126 ISO 15223-2, *Medical devices -- Symbols to be used with medical device labels, labelling, and information to*  
127 *be supplied -- Part 2: Symbol development, selection and validation*
- 128 IEC 62366, *Medical devices — Application of usability engineering to medical devices*
- 129 EN 556-1:2001, *Sterilization of medical devices — Requirements for medical devices to be designated*  
130 *“STERILE” — Part 1: Requirements for terminally sterilized medical devices*
- 131 EN 980, *Symbols for use in the labelling of medical devices*
- 132 EN 1041:2008, *Terminology, symbols and information provided with medical devices: Information supplied by*  
133 *the manufacturer with medical devices*
- 134 ASTM D3002-2007, *Standard guide for evaluation of coatings applied to plastics*
- 135 ASTM F640-2007, *Standard test methods for radiopacity of plastics for medical use*

136 **3 Terms and definitions**

137 For the purposes of this document, the terms and definitions given in ISO 4135<sup>[1]</sup> and ISO 14971 and the  
138 following apply.

139 **3.1**  
140 **adaptor**  
141 specialized **connector** to establish functional continuity between otherwise disparate or incompatible  
142 components

143 [ISO 4135:2001, definition 4.2.3.1]

144 **3.2**  
145 **connector**  
146 fitting to join together two or more components

147 [ISO 4135:2001, definition 4.2.2.1]

148 **3.3**  
149 **\*closed suction catheter**  
150 **suction catheter** enclosed within a **protective sleeve** and **patient end adaptor** to allow connection to a  
151 **breathing system** that allows use of the **suction catheter** within the airway without opening the **breathing**  
152 **system** directly to atmosphere.



- 153 **3.4**  
 154 **eye**  
 155 side hole near the **patient end** of the **suction catheter**
- 156 [ISO 4135:2001, definition 8.3.6]
- 157 **3.5**  
 158 **machine end**  
 159 (suction catheter) that end of the catheter which is intended to be connected to a source of vacuum
- 160 [ISO 4135:2001, definition 8.3.2]
- 161 **3.6**  
 162 **open suction catheter**  
 163 **suction catheter** that is not enclosed within a **protective sleeve** and **patient end adaptor** or attached to a  
 164 **VBS**.
- 165 **3.7**  
 166 **patient-connection port**  
 167 (closed suction catheter) opening at the **patient end** of a breathing system  
 168 port of a **ventilator breathing system** intended for connection to an airway device
- 169 [ISO 4135:2001, definition 4.2.1.2]
- 170 **3.8**  
 171 **patient end**  
 172 (suction catheter) that end of the **suction catheter** which is intended to be inserted into a patient
- 173 [ISO 4135:2001, definition 8.3.3]
- 174 **3.9**  
 175 **patient end**  
 176 (closed suction catheter) the **patient-connection port** of the **closed suction catheter patient end adaptor**  
 177 intended to be connected to the conical **connector** of an artificial airway (tracheostomy or tracheal tube).
- 178 **3.10**  
 179 **\*patient end adaptor**  
 180 tubular **connector** with multiple ports, one of which is a **patient connection port**
- 181 **3.11**  
 182 **protective sleeve**  
 183 flexible barrier that encloses the **suction catheter** shaft to prevent contact with the user while connected to  
 184 the **VBS**.
- 185 **3.12**  
 186 **residual vacuum**  
 187 negative pressure at the **patient end** of the **suction catheter** when the **vacuum control device** is in the relief  
 188 position
- 189 **3.13**  
 190 **risk**  
 191 combination of the probability of occurrence of harm and the severity of that harm
- 192 [ISO 14971:2007]
- 193 **3.14**  
 194 **risk analysis**  
 195 systematic use of available information to identify hazards and to estimate the **risk**

196 NOTE **Risk analysis** includes examination of different sequences of events that can produce hazardous situations  
 197 and harm. (See ISO 14971:2007, Annex F)

198 [ISO 14971:2007]

199 **3.15**  
 200 **risk assessment**  
 201 overall process comprising a **risk analysis** and a **risk evaluation**

202 [ISO 14971:2007]

203 **3.16**  
 204 **risk evaluation**  
 205 process of comparing the estimated **risk** against given **risk** criteria to determine the acceptability of the **risk**

206 [ISO 14971:2007]

207 **3.17**  
 208 **risk management**  
 209 systematic application of management policies, procedures and practices to the tasks of analysing,  
 210 evaluating, controlling and monitoring **risk**

211 [ISO 14971:2007]

212 **3.18**  
 213 **risk management file**  
 214 set of records and other documents that are produced by **risk management**

215 [ISO 14971:2007, definition 2.23]

216 **3.19**  
 217 **shaft**  
 218 main part of the **suction catheter** which is of uniform outside diameter

219 **3.20**  
 220 **single-fault condition**  
 221 a condition in which a single means for reducing a **risk** is defective or a single abnormal condition is present.

222 **3.21**  
 223 **suction**  
 224 application of vacuum to remove gas, liquids or solid particles

225 [ISO 4135, definition 8.1.2]

226 **3.22**  
 227 **suction catheter**  
 228 flexible tube designed for introduction into the respiratory tract or an airway device to remove material by  
 229 suction.

230 [ISO 4135]

231 **3.23**  
 232 **\*suction catheter connector**  
 233 **connector** at the **machine end** of the **suction catheter** that allows a connection to a vacuum source

234 **3.24**  
 235 **terminal orifice**  
 236 central aperture at the **tip** of the **suction catheter**

237 [ISO 4135:2001, definition 8.3.5]

238 **3.25**

239 **tip**

240 extremity of the **patient end** of a **suction catheter**

241 [ISO 4135:2001, definition 8.3.4]

242 **3.26**

243 **vacuum**

244 pressure less than atmospheric pressure

245 NOTE It is usually expressed as a difference from atmospheric pressure.

246 [ISO 4135:2001, definition 8.1.1]

247 **3.27**

248 **vacuum control device**

249 means provided at or near the **machine end** of a **suction catheter** to control the flow of air and entrained  
250 material

251 [ISO 4135:2001, definition 8.3.9]

252 **3.28**

253 **ventilator breathing system**

254 **VBS**

255 inspiratory or expiratory pathways through which gas flows at respiratory pressures and bounded by the port  
256 through which **fresh gas** enters, the **patient-connection port** and the **exhaust port**

257 [ISO 80601-2-12<sup>[6]</sup>, definition 201.3.221, and ISO 4135:2001, definition 4.1.1 modified]

258 **3.29**

259 **wiper**

260 means for removing secretion residues from the surface of the **suction catheter**

261 **4 \*General Requirements for open and closed suction catheters**

262 **4.1 Risk assessment**

263 **4.1.1** An established **risk assessment** process shall be applied to the design of the device.

264 EXAMPLE ISO 14971

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

268 NOTE See Annex E

269 **4.1.2 Open and closed suction catheters** shall, when transported, stored, installed, operated in normal use  
270 and maintained according to the instructions of the manufacturer, present no **risks** that are not reduced to an  
271 acceptable level using **risk management** procedures in accordance with ISO 14971 and which are connected  
272 with their intended application, in normal and in **single fault condition**.

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