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Anaesthetic and respiratory equipment — Breathing sets and connectors

Matériel d'anesthésie et de réanimation respiratoire — Circuits respiratoires et de connecteurs

[Revision of fourth edition (ISO 5367:2000)]

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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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1 Foreword

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

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

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

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

14 ISO 5367 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*,
15 Subcommittee SC 2, *Airways and related equipment*, Working Group (WG 3) which consisted of experts from
16 ISO/TC 121 subcommittees SC 1, SC 2, and SC 3.

17 This fifth edition cancels and replaces the fourth edition (ISO 5367:2000), which has been technically revised.

18 The following major changes were made:

- 19 - title and scope;
- 20 - additional normative references;
- 21 - additional terms and definitions;
- 22 - additional general requirements, including risk management, usability, clinical and biophysical research;
- 23 - requirements for coaxial tubing, revised leakage limits, and testing for flow resistance and compliance;
- 24 - revised limits for prevention of electrostatic charges;
- 25 - revised requirements for marking of packaging, including use of symbols, disclosure of intended patient
26 category, flow resistance, and compliance;
- 27 - added an annex for a rationale;
- 28 - added annex for hazard identification for risk assessment;
- 29 - revised test method annexes for resistance to flow, security of attachments, leakage, and compliance;
- 30 - added annex for compliance with the EU Directives.

Introduction

This International Standard contains requirements for **breathing sets, breathing tubes, and connectors** that are intended to function as accessories to anaesthetic and respiratory equipment. **Breathing sets and breathing tubes** are characterized by certain design requirements such as a means of connection and leakage limits. Disclosure requirements for **compliance** and flow resistance values and labelling allow the user to make an informed choice when connecting these accessories to a **breathing system**. These design requirements are intended to allow operation within the limits of system performance of the **anaesthetic breathing systems** and **ventilator breathing systems** with which the accessories are intended to operate.

This International Standard includes requirements for both single-use and reusable **breathing sets and breathing tubes**. Re-usable **breathing sets and breathing tubes** are intended to comply with the requirements of this International Standard for the recommended service life.

Certain tests are performed under constant pressure to simplify the test methodology. It is recognized that this does not reflect clinical use, where pressure is intermittent and peak pressures occur for short periods. The limits in the test methods take this into account. Whilst such test methods do not address product variability, the limits required also take this into account.

Terms defined in this document are set in **bold type**.

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

Throughout this standard, all pressures are denoted in SI units of hPa with corresponding cmH₂O equivalent values rounded to the nearest whole cmH₂O.

NOTE The unit cmH₂O is not in SI notation and is not allowed in ISO documents; rounded cmH₂O values are given for information only to allow comparison to medical literature and related **breathing system** standards.

Anaesthetic and respiratory equipment — Breathing sets and connectors

1 Scope

* This International Standard specifies basic requirements for **antistatic** and non-**antistatic breathing sets**, **breathing tubes**, and **breathing tubes** supplied to be cut to length, intended to be used with anaesthetic apparatus and ventilators, humidifiers and nebulizers. It also applies to **breathing sets** and **breathing tubes** and **patient end adaptors** supplied already assembled and to those supplied as components and assembled in accordance with the manufacturers' instructions.

This International Standard is applicable to **breathing sets** and **breathing tubes** having ends incorporating **adaptors** with conical connectors (**assembled ends**) or with **plain ends** (either cylindrical or tapered).

This International Standard is applicable to **breathing sets** which include special components (e.g. water traps) between the **patient end** and **machine end** which are supplied already assembled.

This International Standard is not applicable to **breathing sets** and **breathing tubes** for special purposes, such as those used with ventilators having special **compliance**, **pressure**, or breathing frequency requirements.

NOTE 1 Examples of these **breathing sets** may include High Frequency Oscillatory Ventilation, (HFOV), or High Frequency Jet Ventilation (HFJV).

Provision is made for coaxial and related bifurcated, double lumen, or multiple lumen **breathing sets** and **breathing tubes** suitable for use with **patient end adaptors**.

NOTE 2 Examples of various types of **breathing sets** with **patient end adaptors** are depicted in Annex A.

Requirements for exhalation valves, exhaust valves, and **adjustable pressure-limiting (APL) valves** and reservoir bags, if provided, are not covered by this standard.

NOTE 3 ISO 80601-2-12, ISO 80601-2-13 and ISO 5362 cover these.

NOTE 4 Certain aspects of heated wire **breathing tubes** are discussed in ISO 8185 ^[1].

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

ISO 7000, *Graphical symbols for use on equipment — Index and synopsis*

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

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

89 ISO 14971, *Medical devices – Application of risk management to medical devices.*

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

92 IEC 60417, *Graphical symbols for use on equipment*

93 IEC 60601-1, *Medical electrical equipment — Part 1: General requirements for safety.*

94 IEC 60601-1-6, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential*
 95 *performance – Collateral Standard: Usability*

96 IEC 62366, *Medical devices – Application of usability engineering to medical devices*

97 ISO 80601-2-12, *Medical Electrical Equipment — Part 2-12: Particular requirements for basic safety and*
 98 *essential performance of critical care ventilators*

99 ISO 80601-2-13, *Medical electrical equipment — Part 2-13: Particular requirements for basic safety and*
 100 *essential performance of an anaesthetic workstation*

101 EN 556-1, *Sterilization of medical devices. Requirements for medical devices to be designated "STERILE".*
 102 *Requirements for terminally sterilized medical devices*

103 EN 980, *Symbols for use in the labelling of medical devices*

104 EN 1041, *Information supplied by the manufacturer with medical devices*

105 3 Terms and definitions

106 For the purposes of this International Standard, the following terms and definitions apply.

107 3.1

108 **accessory**

109 additional part for use with equipment in order to:

- 110 – achieve the INTENDED USE,
- 111 – adapt it to some special use,
- 112 – facilitate its use,
- 113 – enhance its performance, or
- 114 – enable its functions to be integrated with those of other equipment

115 [IEC 60601-1]

116 3.2

117 **adaptor**

118 specialized connector to establish functional continuity between otherwise disparate or incompatible components,
 119 one end of which is intended to be inserted into the end of a **breathing tube**, the other end having a conical
 120 connector complying with ISO 5356-1

121 [Adapted from ISO 4135 ^[2]]

122 3.3

123 **anaesthetic breathing system**

124 inspiratory and expiratory gas pathways through which anaesthetic gas flows at respiratory pressure between
 125 the fresh-gas inlet, the **patient connection port** and an exhaust valve or exhaust port

126 [ISO 80601-2-13]

127 3.4

128 antistatic

129 A property of material or a procedure that disperses or inhibits the accumulation of electrostatic charges

130 3.5

131 APL valve

132 adjustable pressure-limiting valve

133 pop-off valve

134 pressure-limiting valve which releases gas over an adjustable range of pressures

135 [Adapted from ISO 4135]

136 3.6

137 assembled end

138 end of a **breathing tube** incorporating an **adaptor**

139 3.7

140 breathing set

141 assembly of breathing tubes, connectors and components that form the inspiratory and expiratory limbs of the
142 gas pathways of an anaesthetic or ventilator **breathing system** between the ventilator and the patient's
143 airway device

144 NOTE 1 The exhaust valve is not included

145 NOTE 2 The **patient connection port** is included

146 [Adapted from ISO 4135:2001, definitions 3.1.6 and 4.1.1, ISO 80601-2-12, definition 201.3.221, and ISO
147 80601-2-13, definition 201.3.203]

148 3.8

149 breathing tube

150 non-rigid tube used to convey gases and/or vapours between components of a **breathing system**

151 [ISO 4135]

152 3.9

153 compliance

154 volume added per unit pressure increase when gas is added to an enclosed space, expressed at the temperature
155 and humidity of that enclosed space and at an ambient atmospheric pressure

156 [ISO 4135]

157 3.10

158 machine end

159 that end of the **breathing set** or **breathing tube** which is intended to be connected to the anaesthetic workstation,
160 ventilator or other **breathing system** accessory furthest from the patient

161 3.11

162 patient connection port

163 opening at the **patient end** of a **breathing system** intended for connection of an airway device such as a tracheal
164 or tracheostomy tube connector, a face mask, a supralaryngeal airway or a test apparatus

165 [Adapted from ISO 4135:2001, 4.2.1.2.]

166 **3.12**

167 **patient end**

168 that end of the **breathing set** or **breathing tube** which is intended to be connected to the **patient end**
 169 **adaptor**, **Y-piece** or other appropriate component near the patient

170 **3.13**

171 ***patient end adaptor**

172 tubular connector with multiple ports, one of which is a **patient connection port**

173 [ISO 4135]

174 NOTE Examples of **patient end adaptors** include a **Y-piece**, a **swivel adaptor**, and other specialized **adaptors** for
 175 coaxial, multiple tubes, and bifurcated tubes. See also Annex A Figures A.1 – A.5)

176 **3.14**

177 **plain end**

178 end of a **breathing tube** designed to fit directly over a male conical connector complying with ISO 5356-1

179 **3.15**

180 **swivel adaptor**

181 specialized connector which allows variation in the position of its ports relative to each other

182 [ISO 4135]

183 **3.16**

184 **Y-piece**

185 patient end adaptor as a 3-way connector with a **patient connection port** and two ports for connection to
 186 breathing tubes

187 [ISO 4135]

188 **3.17**

189 **VBS**

190 ventilator breathing system

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

193 [ISO 80601-2-12]

194 **4 General requirements**

195 **4.1 Risk management**

196 **4.1.1** This standard specifies requirements that are generally applicable to risks associated with **breathing**
 197 **sets** and **breathing tubes**. An established risk management process shall be applied to the design of the
 198 device.

199 NOTE An informative list of identified hazards is contained in Annex B – Hazard identification for Risk
 200 Assessment.

201 **4.1.2 Breathing tubes** shall, when transported, stored, installed, operated in normal use and maintained
 202 according to the instructions of the manufacturer, present no risks that are not reduced to an acceptable level
 203 using risk management procedures in accordance with ISO 14971 and which are connected with their
 204 intended application, in normal and in single fault condition.

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

209 **4.1.3** It is recognized that the manufacturer may not be able to follow all of the processes identified in this
 210 standard for each constituent component of the breathing tube, such as proprietary components, subsystems
 211 of non-medical origin, and legacy devices. In this case, the manufacturer should take special account of the
 212 need for additional risk control measures.

213 **4.1.4** Where requirements of this standard refer to freedom from unacceptable risk, acceptability or
 214 unacceptability is determined by the manufacturer in accordance with the manufacturer's policy for
 215 determining acceptable risk.

216 **4.2 Usability**

217 If required by a competent authority, the manufacturer shall address in a usability engineering process the risk
 218 resulting from poor usability (see IEC 60601-1-6 and IEC 62366).

219 *Check compliance by inspection of the usability engineering file.*

220 **4.3 Clinical evaluation**

221 If required by a competent authority, a clinical evaluation shall be performed and documented in the technical
 222 documentation of the device.

223 *Check compliance by inspection of the technical documentation of the device*

224 **4.4 Biophysical or modelling research**

225 If required by a competent authority, and where appropriate, validated biophysical or modelling research shall
 226 be carried out.

227 *Check compliance by inspection of the technical file.*

228 **4.5 Test Methods**

229 The manufacturer may use type tests different from those detailed within this International Standard, if an
 230 equivalent degree of safety is obtained. However, in the event of dispute, the methods specified herein shall
 231 be used as the reference methods.

232 **4.6 Recommended service life**

233 Re-usable **breathing sets** and **breathing tubes** shall comply with the requirements of this International Standard
 234 throughout the recommended service life as specified in 8.4.2.

235 **5 Specific requirements**

236 **5.1 Materials**

237 **5.1.1 Breathing sets and breathing tubes**, in their ready-for-use state after any preparation recommended by
 238 the manufacturer, shall satisfy appropriate biological safety testing, in accordance with ISO 10993-1.

239 NOTE A test for Volatile Organic Compounds may replace some or all of ISO 10993-1 tests for materials in the gas
 240 path only.

241 **5.1.2 Breathing sets and breathing tubes** shall be made of materials suitable for their intended use and, if
 242 applicable, shall function in the presence of commonly used concentrations of anaesthetic agents and gases
 243 in accordance with their intended use. Tubes shall not emit harmful substances.

244 **5.1.3** If required by a competent authority and if phthalates are incorporated in parts of the medical devices
 245 coming directly or indirectly into contact with the patient the medical device shall be labelled accordingly.

246 NOTE Attention is drawn to substances which are carcinogenic, mutagenic or toxic to reproduction

247 **5.2 Length**

248 **5.2.1** The length of a **breathing tube** shall be designated by its nominal overall length, expressed in
 249 metres, when measured in the resting condition (without extension), lying on a horizontal surface. **Breathing**
 250 **tubes** intended to be extended when used shall be designated by both the unextended and extended lengths.

251 **5.2.2** The designated length of **breathing tubes** provided integrally attached to a **Y-piece** or **patient end**
 252 **adaptor** shall include the length of the **Y-piece** or **patient end adaptor** and any **assembled ends**.

253 **5.2.3** The actual length shall be within $\pm 10\%$ of the designated length.

254 **5.3 Means of connection**

255 **5.3.1 Breathing tubes**, whether of corrugated construction or otherwise, shall have **plain ends** (cylindrical
 256 or tapered) and/or **assembled ends** with **adaptors** incorporating 22 mm or 15 mm conical connectors
 257 complying with ISO 5356-1.

258 **5.3.2 Plain ends of breathing tubes**

259 **5.3.2.1** The axial length (l_1) of **plain ends of breathing tubes** [see Figure 1 a)], excluding those specified
 260 in 5.3.2.2, shall be not less than 21 mm for **breathing tubes** intended to engage with 22 mm male conical
 261 connectors or not less than 14 mm for **breathing tubes** intended to engage with 15 mm male conical
 262 connectors.

263 **5.3.2.2** The axial length (l_2) of **plain ends of breathing tubes** that incorporate an internal ridge [see
 264 Figure 1 b)], intended to engage with the recess at the base of a 22 mm male conical connector as specified
 265 in ISO 5356-1, shall be not less than 26,5 mm.

266 **5.3.2.3** When tested as described in Annex C, the **plain ends of breathing tubes** shall not become
 267 detached from the appropriate male conical connector at a force of less than 40 N.

