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Anaesthetic and respiratory equipment — Tracheostomy tubes —

Part : Tubes and connectors for use in adults

*Matériel d'anesthésie et de réanimation respiratoire — Tubes de trachéostomie —
Partie : Tubes et raccords pour utilisation chez les adultes*

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.

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101 **Foreword**

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

109 The procedures used to develop this document and those intended for its further maintenance are
 110 described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the
 111 different types of ISO documents should be noted. This document was drafted in accordance with the
 112 editorial rules of the ISO/IEC Directives, Part 2. www.iso.org/directives

113 Attention is drawn to the possibility that some of the elements of this document may be the subject of
 114 patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of
 115 any patent rights identified during the development of the document will be in the Introduction and/or
 116 on the ISO list of patent declarations received. www.iso.org/patents

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

119 For an explanation on the meaning of ISO specific terms and expressions related to conformity
 120 assessment, as well as information about ISO's adherence to the WTO principles in the Technical
 121 Barriers to Trade (TBT) see the following URL: [Foreword - Supplementary information](#)

122 The committee responsible for this document is ISO/TC 121, *Anaesthetic and respiratory equipment*,
 123 Subcommittee SC 2, *Airways and related equipment*.

124 This fifth edition cancels and replaces the fourth edition, ISO 5366-1:2000, which has been technically
 125 revised.

126 The requirements of ISO 5366-3:2001 and ISO 5366-3 Corr:2003, *Tracheostomy tubes – Part 3:*
 127 *Paediatric tracheostomy tubes*, have been included in this fifth edition.

128 Throughout this International Standard the following print types are used:

129 — Requirements and definitions: roman type;

130 — *Test specifications: italic type;*

131 — Informative material appearing outside of tables, such as notes, examples and references: smaller
 132 type. The Normative text of tables is also in smaller type;

133 — TERMS DEFINED IN CLAUSE 3: SMALL CAPS.

134 An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates
 135 that there is guidance or rationale related to that item in Annex A.

136 The attention of Member Bodies and National Committees is drawn to the fact that equipment
 137 manufacturers and testing organizations may need a transitional period following publication of a new,
 138 amended or revised ISO or IEC publication in which to make products in accordance with the new

139 requirements and to equip themselves for conducting new or revised tests. It is the recommendation of
140 the committee that the content of this publication be adopted for implementation nationally not earlier
141 than 3 years from the date of publication for equipment newly designed and not earlier than 5 years
142 from the date of publication for equipment already in production.

143

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144 Introduction

145 This standard provides the essential requirements for the design of cuffed and uncuffed TRACHEOSTOMY
146 TUBES and connectors. These devices are intended to be inserted through a stoma in the trachea to
147 convey gases and vapours to and from the trachea. Cuffed devices are designed to seal and protect the
148 trachea from aspiration and to provide an unobstructed airway in patients during spontaneous,
149 assisted, or controlled ventilation for short or prolonged durations. Specialized tubes with walls
150 reinforced with metal or nylon, tubes with shoulders, tapering tubes, tubes with provision for
151 suctioning or monitoring or delivery of drugs or other gases, and the many other types of TRACHEOSTOMY
152 TUBES devised for specialized applications are included in this specification, as many specialized
153 TRACHEOSTOMY TUBES are now commonly used, and all share similar essential requirements defined in
154 this International Standard.

155 The method of describing tube dimensions and configuration has been devised in order to assist
156 clinicians in the selection of the most suitable tube for a particular patient's anatomy. Size is designated
157 by the internal dimension, which is important because of its relationship to resistance to gas flow.
158 Because stoma and tracheal sizes are also an important factor when selecting a TRACHEOSTOMY TUBE it is
159 considered essential that the outside dimension for each size of tube is also made known to the user.

160 Cuffed TRACHEOSTOMY TUBES can be characterized by a combination of the tube inside and outside
161 dimensions and by the diameter of the CUFF to be marked.

162 A variety of CUFF designs are available to meet particular clinical requirements. CUFF performance
163 requirements with associated test methods, which are aligned with the requirements in ISO 5361,
164 *Tracheal tubes and connectors* have been added to this fifth edition.

165 Requirements for paediatric TRACHEOSTOMY TUBES have been included in this fifth edition because they
166 share many common requirements that can be standardized and which are important for patient safety.
167 An infant or child differs from an adult, not only in size but also with regard to airway anatomy and
168 respiratory physiology; thus airway equipment for paediatric patients differs from that for adults, both
169 in size and in basic design. It does not require the connector to be permanently attached to the tube, as
170 this can be impractical with infants and small children. Other acceptable methods of connecting these
171 components are available, and this standard makes provision for them. This standard does not limit the
172 range of tube designs needed to match the variations in paediatric anatomy, lesions and space
173 limitations encountered.

174 Kink resistance requirements with associated test methods have also been added to this fifth edition to
175 measure the ability of the shaft of the TRACHEOSTOMY TUBE to resist collapse and increased breathing
176 resistance when bent or curved. These new requirements are aligned with the requirements in ISO
177 5361, *Tracheal tubes and connectors* (under development).

178 Requirements for TRACHEOSTOMY TUBES that are common to other airway and related devices have been
179 removed from this fifth edition as these are now included in ISO 18190 *General requirements for*
180 *airways and related equipment*, which is cross referenced where appropriate.

181

182 Anaesthetic and respiratory equipment – Tracheostomy tubes

183 1 *Scope

184 This International standard specifies requirements for adult and paediatric TRACHEOSTOMY TUBES and
185 connectors. Such tubes are primarily designed for patients who require anaesthesia, artificial
186 ventilation or other respiratory support.

187 This International standard is also applicable to specialized TRACHEOSTOMY TUBES that share common
188 attributes , for example those without a connector at the MACHINE END intended for spontaneously
189 breathing patients and those with reinforced walls or tubes made of metal or tubes with shoulders,
190 tapering tubes, tubes with provision for suctioning or monitoring or delivery of drugs or other gases.

191 Flammability of TRACHEOSTOMY TUBES is a well-recognized hazard (for example when electrosurgical
192 units or lasers are used with flammable anaesthetic agents in oxidant-enriched atmospheres) that is
193 addressed by appropriate clinical management and is outside the scope of this International standard.

194 NOTE ISO/TR 11991 gives guidance on avoidance of airway fires.

195 2 Normative references

196 The following documents, in whole or in part, are normatively referenced in this document and are
197 indispensable for its application. For dated references, only the edition cited applies. For undated
198 references, the latest edition of the referenced document (including any amendments) applies.

199 ISO 4135, *Anaesthetic and respiratory equipment — Vocabulary*.

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

201 ISO/DIS 18190, *General requirements for airways and related equipment* (under development)

202 ISO/DIS 80369-7, *Small-bore connectors for liquids and gases in healthcare applications — Part 7:*
203 *Connectors with 6% (Luer) taper for intravascular or hypodermic applications* (under development)

204 ASTM F 640-12, *Standard Test Methods for Determining Radiopacity for Medical Use*

205 ASTM F 2052, *Standard Test Method for Measurement of Magnetically Induced Displacement Force on*
206 *Medical Devices in the Magnetic Resonance Environment*

207 ASTM F 2503, *Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance*
208 *Environment*

209 3 Terms and definitions

210 For the purposes of this document, the terms and definitions given in ISO 4135 and the following apply.

211 NOTE See Figure 1 for illustrations of typical TRACHEOSTOMY TUBES and associated nomenclature.

212 3.1

213 ANGLE OF BEVEL

214 angle between the plane of the BEVEL and the longitudinal axis of a TRACHEOSTOMY TUBE