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# Anaesthetic and respiratory equipment — Tracheobronchial tubes

*Matériel d'anesthésie et de réanimation respiratoire — Sondes trachéobronchiques*

Reference number
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# Contents

Page

**Foreword** ... **iv**

**Introduction** ... **v**

**1 Scope** ... **1**

**2 Normative references** ... **1**

**3 Terms and definitions** ... **1**

**4 General requirements** ... **2**
4.1 General ... 2
4.2 Safety ... 2

**5 Materials** ... **2**
5.1 General ... 2
5.2 Biological safety testing ... 2

**6 Design requirements** ... **3**
6.1 General ... 3
6.2 *Designated size* ... 3
6.3 Dimensions ... 3
6.4 Connectors ... 3
6.5 *Cuffs* ... 3
6.6 *Cuff* inflation system ... 4
6.7 Bronchial segment ... 4

**7 Requirements for *tracheobronchial tubes* supplied sterile** ... **5**

**8 Packaging** ... **5**

**9 Information supplied by the manufacturer** ... **6**
9.1 General ... 6
9.2 Marking ... 6
9.2.1 Durability and legibility ... 6
9.2.2 Marking on the *tracheobronchial tube* ... 6
9.3 Colour coding ... 7
9.4 Marking on the individual packaging or insert ... 7

**Annex A** (informative) **Rationale** ... **8**

**Annex B** (normative) **Test method to determine the outside diameter of the bronchial segment** ... **10**

**Annex C** (normative) **Test method to determine the *effective inside diameters*** ... **11**

**Bibliography** ... **13**

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# Foreword

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

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

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

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Airways and related equipment,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 16628:2008), which has been technically revised.

The main changes are as follows:

— alignment with the general standard for airway devices, ISO 18190;

— inclusion of requirements in addition to marking and sizing;

— updating of references.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.


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# Introduction

*Tracheobronchial tubes* are double lumen *tracheal tubes* that enable isolation of the airways of one lung from the other. This allows protection of one lung if there is bleeding or a leak in the airways of the other. They facilitate selective ventilation of each lung. One lumen ends in the trachea, with a tracheal *cuff* above the opening. The other lumen is designed to lie either in the right or the left main bronchus with a *cuff* sealing that bronchus. The *cuff* of a right-sided tube is usually shaped to permit ventilation of the right upper lobe.

The first edition of ISO 16628 only specified requirements for the marking and sizing of *tracheobronchial tubes*.

Throughout this document the following print types are used:

— requirements and definitions: roman type;

— informative material appearing outside of tables, such as notes, examples and references: smaller type. The normative text of tables is also in smaller type;

— *terms defined in Clause 3: italics.*

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# Anaesthetic and respiratory equipment — Tracheobronchial tubes

## 1 Scope

This document specifies requirements for safety, materials, design and information supplied with *tracheobronchial tubes.* These devices are used when isolation of the airways of one or both lungs is required.

*Tracheal tubes* that include bronchus blockers are excluded from the scope of this document

## 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 4135, *Anaesthetic and respiratory equipment — Vocabulary*

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

ISO 5361:2016, *Anaesthetic and respiratory equipment — Tracheal tubes and connectors*

ISO 18190:2016, *Anaesthetic and respiratory equipment — General requirements for airways and related equipment*

ISO 18562-1, *Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process*

ISO 80369-7, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4135, ISO 18190 and the following apply:

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

**3.1**
**cuff**
inflatable balloon permanently attached around the *tracheobronchial tube* (3.8) near the patient end of the tracheal segment and patient end of the bronchial segment, that is used to provide a seal between the tube and the trachea or bronchus

Note 1 to entry: See Figure 1.

**3.2**
**designated size**
circumference of the tracheal segment of the *tracheobronchial tube* (3.8)

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**3.3**
**effective inside diameter**
diameter of the maximum size of cylindrical object that will pass through the tube

**3.4**
**risk**
combination of the probability of occurrence of harm and the severity of that harm

[SOURCE: ISO 14971:2019, 3.18]

**3.5**
**risk management**
systematic application of management policies, procedures and practices to the tasks of analysing, evaluating, controlling and monitoring *risk* (3.4)

[SOURCE: ISO 14971:2019, 3.24]

**3.6**
**risk management file**
set of records and other documents that are produced by *risk management* (3.5)

[SOURCE: ISO 14971:2019, 3.25]

**3.7**
**tracheal tube**
tube designed for insertion through the larynx into the trachea to convey gases and vapours to and from the trachea

[SOURCE: ISO 4135:2022, 3.8.3.1]

**3.8**
**tracheobronchial tube**
double-lumen tube designed for insertion into the trachea and a main bronchus to enable isolation of the airways of one lung from the other

# 4 General requirements

## 4.1 General

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

## 4.2 Safety

Manufacturers may use type tests different from those detailed within this document, if an equivalent degree of safety is obtained. Alternative test methods shall be validated against the test methods specified in this document.

# 5 Materials

## 5.1 General

The applicable requirements of ISO 18190:2016, Clause 5 shall apply.

## 5.2 Biological safety testing

*Tracheobronchial tubes* shall also be evaluated and tested in conformance with ISO 18562-1.


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