
**Tracheobronchial tubes —
Recommendations for size designation
and labelling**

*Sondes trachéo-bronchiques — Recommandations pour la désignation
de grandeur et le marquage*

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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.

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

In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of normative document:

- an ISO Publicly Available Specification (ISO/PAS) represents an agreement between technical experts in an ISO working group and is accepted for publication if it is approved by more than 50 % of the members of the parent committee casting a vote;
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An ISO/PAS or ISO/TS is reviewed after three years in order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn. If the ISO/PAS or ISO/TS is confirmed, it is reviewed again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.

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.

ISO/TS 16628 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Tracheal tubes and other equipment*.

Introduction

This Technical Specification is intended to provide recommendations to assist manufacturers in establishing a standard method of size designation for tracheobronchial tubes and their parts. A tracheobronchial tube is a double-lumen tracheal tube that facilitates selective ventilation to one or both lungs. It is designed for either right or left mainstem bronchus placement, and has both a tracheal and a bronchial cuff.

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Tracheobronchial tubes — Recommendations for size designation and labelling

1 Scope

This Technical Specification provides recommendations for the size designation and labelling of tracheobronchial tubes, including colour coding of the bronchial cuff and its associated pilot balloon. Tracheobronchial tubes that include bronchus blockers are excluded from the scope of this Technical Specification.

2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

2.1

tracheobronchial tube

double-lumen tube designed for insertion through the larynx into the trachea and a main stem bronchus to separate right and left lung ventilation

3 General requirements

3.1 Size designation of bronchial segment

The size of the bronchial segment of the tube should be designated by the outside circumference measured at the mid-point of the bronchial cuff (see 1 in Figure 1), in millimetres $\pm 0,5$ mm, determined in accordance with Annex A.

3.2 Nominal maximum bronchoscope diameter

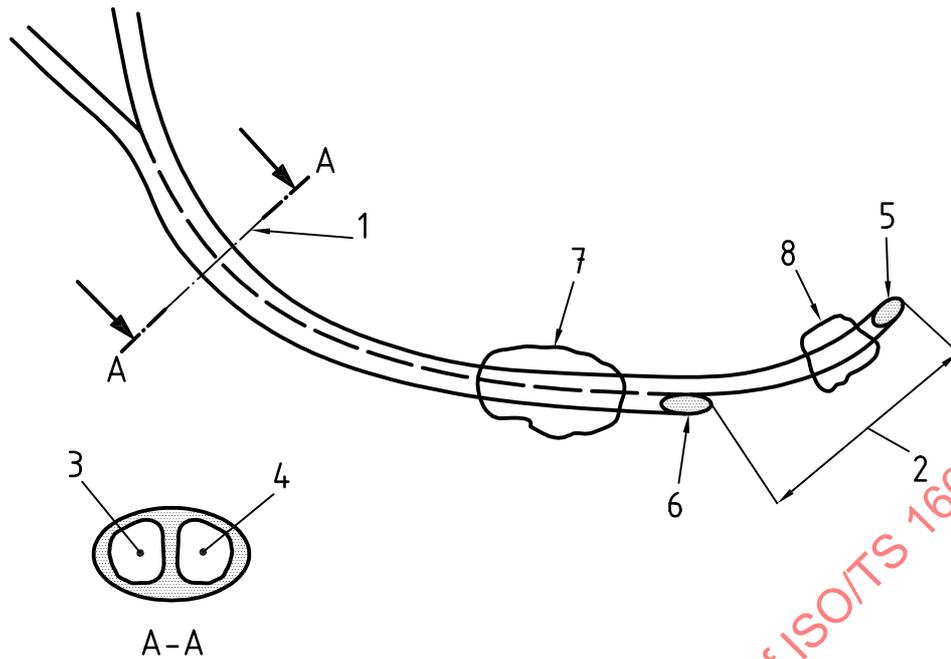
The nominal maximum bronchoscope diameter (representing the maximum size of bronchoscope that will pass through the lumina of the bronchial and tracheal segments of the tube) should be determined in accordance with Annex B.

3.3 Colour coding

The bronchial cuff and its associated pilot balloon should be entirely coloured blue.

3.4 Segment differentiation

The tracheal and bronchial segments should be clearly distinguishable from each other when viewed from the machine end.



Key

- 1 point of measurement of circumference of tracheobronchial tube
- 2 bronchial segment
- 3 cross-section of tracheal lumen (not necessarily circular)
- 4 cross-section of bronchial lumen (not necessarily circular)
- 5 patient end of bronchial segment
- 6 patient end of tracheal segment
- 7 tracheal cuff
- 8 bronchial cuff

Figure 1 — Typical example of a tracheobronchial tube

4 Marking

4.1 Use of symbols

4.1.1 The recommendations of 4.2 may be met by the appropriate symbols given in ISO 7000^[1] or ISO 15523^[2].

4.1.2 Marking of tracheobronchial tubes, packages and inserts and information to be supplied by the manufacturer should comply with EN 1041^[3].

4.2 Marking of tracheobronchial tubes

4.2.1 Marking of the tracheobronchial tube should include the following:

- a) the name and/or trademark of the manufacturer or supplier;
- b) the manufacturer’s stated size;
- c) the circumference of the bronchial segment, in accordance with 3.1 and prefixed “Br”;
- d) for tracheobronchial tubes for single use, the words “single-use” or equivalent;

- e) length marks at 20 mm intervals, measured from the tip of the bronchial segment and marked on the proximal end of the tracheal segment;
- f) the word “right” or “left”, as appropriate.

4.2.2 Marking should be of a colour that contrasts with the colour of the tube.

4.3 Marking on tracheobronchial tube individual pack and any insert

The following should be marked on, or visible through, the tracheobronchial tube individual pack and may additionally be given on an insert:

- a) a description of the contents;
- b) the word “right” or “left”, as appropriate;
- c) the manufacturer’s stated size;
- d) the circumference of the bronchial segment, in accordance with 3.1 and prefixed “Br”;
- e) the nominal maximum bronchoscope diameter, determined in accordance with 3.2;
- f) the name and/or trademark of the manufacturer;
- g) the batch number;

NOTE It is strongly recommended that the “use-by” date be given.

- h) the word “STERILE”, if appropriate;

NOTE It is recommended that the method of sterilization be given.

- i) for tubes not intended for re-use, the words “single-use” or equivalent;
- j) an indication of the presence of natural rubber (latex), if present in the device;
- k) instructions for cleaning and disinfecting or sterilizing, unless the tube is intended and marked as being for single use,
- l) recommendations for an appropriate sterilization method, if delivered non-sterile.

Annex A (informative)

Determination of circumference of bronchial segment of tracheobronchial tubes

A.1 Principle

The circumference of the bronchial segment of the tracheobronchial tube is measured by wrapping an inelastic wire or thread around the outside of the bronchial segment of the tube and subsequently measuring the length of the wire or thread.

A.2 Apparatus

A.2.1 Length of inelastic wire or thread, sufficiently long to be wrapped around the outside of the bronchial segment of the tube five times at the mid-point of the bronchial cuff (see 1 in Figure 1).

A.2.2 Means of measuring the length of the inelastic wire or thread (A.2.1) in millimetres.

A.3 Procedure

A.3.1 Wrap a piece of inelastic wire or thread (A.2.1) in a close spiral five times around the outside of the bronchial segment of the tube, at the mid-point of the bronchial cuff.

A.3.2 Measure the length of the inelastic wire or thread in millimetres.

A.3.3 Determine the circumference of the bronchial segment of the tracheobronchial tube by dividing the length by five.

A.4 Expression of results

Express the circumference of the bronchial segment of the tube in millimetres, as determined in A.3.3.

Annex B (informative)

Determination of nominal maximum bronchoscope diameter

B.1 Principle

The nominal maximum bronchoscope diameter (representing the maximum size of bronchoscope that can be passed through the tracheobronchial tube) is determined by passing a set of beads through the lumina of the bronchial and tracheal segments of the tube. The diameter of the beads is taken to represent the largest diameter of bronchoscope that can be passed down the tracheal and bronchial lumina of the tracheobronchial tube. This test is used because a bronchoscope is limited in its flexibility to pass around curves and because the cross-section of the inner lumina of the tubes may not be circular, thus precluding measurement (see Figure 1).

B.2 Apparatus

B.2.1 Set of three polished cylindrical beads (see Figure B.1), with rounded ends and of overall length 10 mm, all beads having the same diameter. The accuracy of the diameter should be $\pm 0,01$ mm, and the accuracy of the length should be $\pm 0,1$ mm. The end radius should be the nominal radius and the knot length between beads should be 1 mm to 2 mm. If the manufacturer has a designated maximum bronchoscope diameter, a single set of beads may be used to verify this. In order to establish the nominal maximum bronchoscope diameter, several sets of beads, with diameters increasing in 0,1 mm or 0,2 mm increments, should be used.

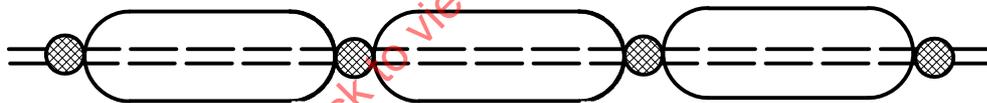


Figure B.1 — Example of a cylindrical bead set

B.2.2 Weight, of mass 100 g, to attach to the set of beads (B.2.1), with a length of thread at one end sufficiently long to draw the beads through the tubes.

B.3 Procedure

B.3.1 Holding the tracheobronchial tube vertically, feed the long end of the thread through the lumen of the bronchial segment of the tube.

B.3.2 Attach the weight to the end of the thread.

B.3.3 Feed the beads into the connector end of the lumen, allowing the weight to pull the beads through the tube. The lumen may be lubricated with water or water-soluble lubricant to assist the passage.

B.3.4 Repeat steps B.3.1 to B.3.3 for the lumen of the tracheal segment.