
International Standard



5361/4

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● **Tracheal tubes —
Part 4: Cole type**

Tubes trachéaux — Partie 4: Type Cole

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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 developing International Standards is carried out through ISO technical committees. Every member body interested in a subject for which a technical committee has been authorized 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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council.

International Standard ISO 5361/4 was developed by Technical Committee ISO/TC 121, *Anaesthetic equipment and medical breathing machines*, and was circulated to the member bodies in December 1981.

It has been approved by the member bodies of the following countries:

Australia	Germany, F.R.	South Africa, Rep. of
Canada	Japan	Sweden
China	Mexico	Switzerland
Czechoslovakia	Netherlands	United Kingdom
Egypt, Arab Rep. of	New Zealand	USA
France	Romania	USSR

No member body expressed disapproval of the document.

Tracheal tubes — Part 4: Cole type

0 Introduction

This International Standard is one of a series dealing with anaesthetic equipment and medical breathing machines. It makes provision for tracheal tubes of the Cole type, i.e. the type with a small patient end for use with infants. The narrowest part of the infant airway is the non-distensible cricoid cartilage ring which is the main controlling factor during tracheal intubation. Consequently, the size of the tracheal portion is the limiting factor which determines the choice of size of tube to be used.

Provision is made for a large number of sizes of tubes at close intervals so that the laryngo-tracheal portion of the Cole tube may easily fit the cricoid ring without causing trauma or undue resistance to gas flow.

WARNING NOTE — Users are cautioned that in clinical practice the shoulder must not exert pressure on the laryngeal tissues.

The larger lumen in the oral portion of the Cole type is provided mainly to enable the use of a tracheal tube connector of larger size than would otherwise be possible, to minimize resistance to gaseous flow and to facilitate the introduction of a suction catheter.

1 Scope and field of application

This part of ISO 5361 specifies general requirements for Cole tubes for use in infants.

2 Reference

ISO 5361/1, *Tracheal tubes — Part 1: General requirements.*

3 Definitions

In addition to the definitions given in ISO 5361/1 the following definitions apply for the purpose of this International Standard.

3.1 Cole tube: Specialized tracheal tube combining a short laryngo-tracheal portion of a small diameter and a longer oral portion of larger diameter with transition from one to the other resulting in a shoulder.

3.2 laryngo-tracheal portion: That portion of a Cole tube of small diameter extending from the bevel tip to the point at which there is an increase in the outside diameter.

3.3 oral portion: That portion of a Cole tube of a larger diameter extending from the machine end to the point at which there is a decrease in the outside diameter.

3.4 shoulder: That portion of a Cole tube at which transition from the oral portion to the laryngo-tracheal portion occurs.

4 General

Cole tubes shall, unless otherwise specified, comply with the general requirements for tracheal tubes specified in ISO 5361/1.

5 Size designation

The size of Cole tubes shall be designated by the nominal inside diameter of the tracheal portion of the tube (see the figure, dimension d_1) expressed in millimetres.

6 Size range

The size range of Cole tubes shall be in accordance with the table.

7 Dimensions

7.1 The dimensions of Cole tubes shall be in accordance with the table and the figure.

7.2 The inside diameter (ID) shall be the nominal diameter subject to a tolerance of $\begin{matrix} +0,15 \\ -0,1 \end{matrix}$ mm.

8 Bevel

8.1 Cole tubes shall have a bevel of $45^\circ \pm 5^\circ$ in relation to the axis of the tube.

8.2 The end of the tube at the bevel shall be rounded and the orifice(s) shall be free from sharp edges.

8.3 The bevel shall have the opening facing to the left when the tube is viewed towards the concave aspect from the machine end.

9 Shoulder

9.1 There shall be smooth transitional blending at the inside and outside surfaces between the tracheal and oral portions of the tube.

9.2 The combination of the inside and outside profiles shall be such as to minimize kinking in the region of the shoulder.

9.3 The axial length of the outside surface of the shouldered region (see the figure, dimension S_1, S_2) shall not exceed 4 mm for sizes up to and including 3,0 mm.

10 Curvature of the tube

Cole tubes shall be smoothly curved to a radius of about 60 mm so that the machine end makes an angle of $45^\circ \pm 15^\circ$ to the patient end as illustrated in the figure.

The curvature shall start within 20 mm of the beginning of the taper (see the figure, dimension S_1) on the outside surface.

11 Marking

11.1 In addition to the general requirements for marking given in ISO 5361/1, Cole tubes shall be marked as follows:

- the size in accordance with clause 5 and the table, together with the maximum outside diameter of the tracheal portion in millimetres (see d_2 in the figure), and denoted as in the following examples:

TRACHEAL END ID 3,5/5,0 OD or ID 3,5/5,0 OD

11.2 The marking of the size of the Cole tube shall be situated on the bevelled side of the oral portion within the minimum length of the tube reading from the patient end to the machine end (see the figure).

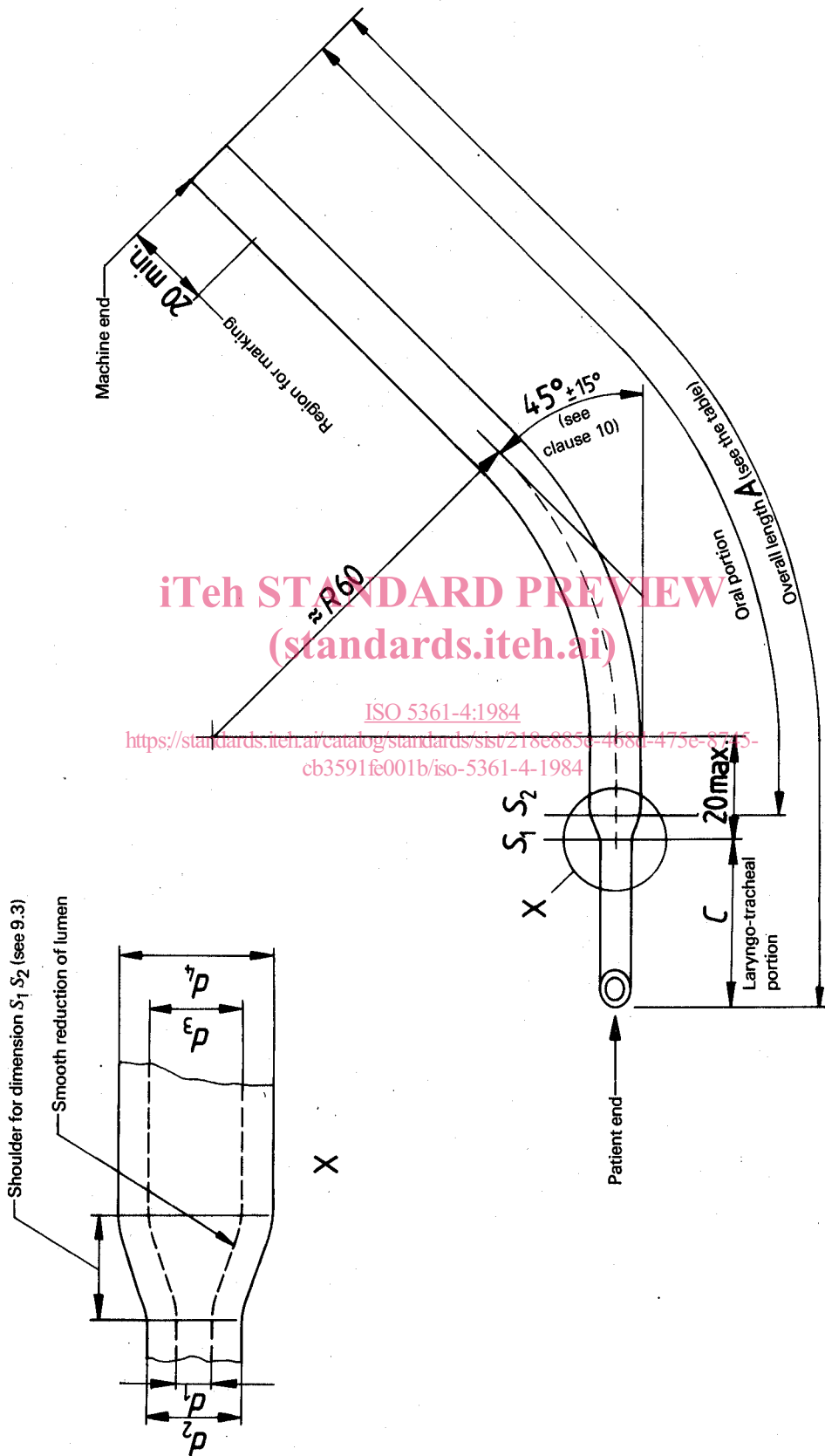
Table — Dimensions of Cole tubes

iTeh STANDARD PREVIEW Dimensions in millimetres

Designated size (nominal inside diameter of tracheal portion, see the figure, dimension d_1)	Length of laryngo-tracheal portion (see the figure, dimension C)		Oral portion			Overall length (see the figure, dimension A)	
			Inside diameter (see the figure, dimension d_3)		Outside diameter (see the figure, dimension d_4)		
	min.	max.	min.	max.	max.	min.	max.
1,5	20	24	3,9	5,0	7,0	110	140
1,75	20	24	4,1	5,0	7,0	110	140
2,0	20	25	4,2	5,0	7,0	120	140
2,25	25	30	4,3	5,0	7,0	120	140
2,5	25	30	4,3	5,0	7,5	125	140
3,0	25	30	4,3	5,0	7,5	125	140
3,5	25	35	5,0	6,0	9,5	130	150
4,0	25	35	5,5	6,5	9,5	140	160
4,5	28	38	6,5	7,0	10,5	150	170

* For convenience in size designation, the second decimal place may be omitted.

Dimensions in millimetres



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Figure — Cole type tube

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