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Second edition  
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## **Anaesthetic and respiratory equipment — Tracheostomy tubes —**

### **Part 3: Paediatric tracheostomy tubes**

*Matériel respiratoire et d'anesthésie — Tubes de trachéostomie —  
Partie 3: Tubes de trachéostomie pédiatriques*



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## Contents

	Page
1 Scope .....	1
2 Normative references .....	1
3 Terms and definitions .....	1
4 Size designation and dimensions .....	2
5 Materials .....	4
6 Design and finish .....	4
7 Requirements for tracheostomy tubes supplied sterile .....	6
8 Marking .....	6

## Annexes

<b>A</b> Test for security of attachment of permanently attached connector, if provided, and neck-plate to tracheostomy tube .....	<b>9</b>
<b>B</b> Test method for determining the resting diameter of the cuff .....	<b>10</b>
<b>C</b> Guidance on materials and design .....	<b>11</b>
Bibliography .....	<b>12</b>

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

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.

Attention is drawn to the possibility that some of the elements of this part of ISO 5366 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 5366-3 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Tracheal tubes and other equipment*.

This second edition cancels and replaces the first edition (ISO 5366-3:1994), which has been technically revised.

ISO 5366 consists of the following parts, under the general title *Anaesthetic and respiratory equipment — Tracheostomy tubes*:

- *Part 1: Tubes and connectors for use in adults*
- *Part 3: Paediatric tracheostomy tubes*

Annexes A and B form a normative part of this part of ISO 5366. Annex C is for information only.

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## Introduction

ISO 5366 is concerned with the basic requirements and method of size designation of tracheostomy tubes made of plastics materials and/or rubber.

ISO 5366-1 gives requirements for adult tracheostomy tubes made of plastics materials and/or rubber.

This part of ISO 5366 gives requirements for paediatric tracheostomy tubes with an inside diameter from 2,0 mm to 6,0 mm.

Paediatric tracheotomy tubes are primarily intended for use with infants and children who may require anaesthesia, artificial ventilation, relief of upper airway obstruction or other respiratory therapy.

An infant or child differs from an adult, not only in size but especially with regard to airway anatomy and respiratory physiology; thus airway equipment for paediatric patients differs from that for adults in size and also in basic design. It should be noted that, although this part of ISO 5366 gives some requirements for cuffs, cuffs are seldom provided on the smaller sizes of paediatric tubes.

This part of ISO 5366 gives requirements for those characteristics of tracheostomy tubes that can be standardized and which are important for patient safety. It does not require the connector to be permanently attached to the tube, as this may be impractical with infants and small children. Other acceptable methods of connecting these components are available, and this part of ISO 5366 makes provision for them. This part of ISO 5366 does not limit the range of tube designs needed to match the variety of paediatric anatomy, lesions and space limitations encountered.

The method of describing tube dimensions and configuration has been devised with the aim of assisting the clinician in the selection of a suitable tube to conform as far as possible to a particular patient's anatomy. Size is designated by inside diameter, which is important because of its relation to resistance to gas flow. Because the stomal and tracheal diameters are important when selecting tubes, it is considered essential that the outside diameter be stated for each size of tube.

A tracheostomy tube can increase resistance to gas flow. For tubes with a given outside diameter, differences in wall thickness have a major influence on the resistance to gas flow, especially in the smaller sizes of paediatric tracheostomy tubes.

Flammability of tracheostomy tubes, for example if flammable anaesthetics, electrosurgical units or lasers are used in oxidant-enriched atmospheres, is a well-recognized hazard<sup>1)</sup> addressed by appropriate clinical management, which is outside the scope of this part of ISO 5366.

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1) See ISO/TR 11991.