

Tracheal tubes —

Part 2: Oro-tracheal and naso-tracheal tubes of the Magill type (plain and cuffed)

UDC 615.471:616.231-089.5:621.643.2.02

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The preparation of this British Standard was entrusted by the Health Care Standards Policy Committee (HCC/-) to Technical Committee HCC/45, upon which the following bodies were represented:

- Association of Anaesthetists of Great Britain and Ireland
- Association of British Health-care Industries
- Association of Veterinary Anaesthetists of Great Britain and Ireland
- British Anaesthetic and Respiratory Equipment Manufacturers' Association
- British Association of Otolaryngologists
- British Paediatric Association
- British Surgical Trades Association
- Department of Health
- Intensive Care Society
- Medical Sterile Products Association
- National Association of Theatre Nurses

This British Standard, having been prepared under the direction of the Health Care Standards Policy Committee, was published under the authority of the Standards Board and comes into effect on 15 December 1993

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First published as BS 3487 April 1962
Second edition as BS 3487-2 February 1986
Third edition December 1993

The following BSI references relate to the work on this standard:
Committee reference HCC/45
Draft for comment 91/51388 DC

ISBN 0 580 22666 2

Amendments issued since publication

Amd. No.	Date	Comments

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National foreword

This Part of BS 3487 has been prepared under the direction of the Health Care Standards Policy Committee. It is identical with ISO 5361-2:1993 *Tracheal tubes — Part 2: Oro-tracheal and naso-tracheal tubes of the Magill type (plain and cuffed)*, which was prepared by Technical Committee ISO/TC 121, Anaesthetic and respiratory equipment, and published by the International Organization for Standardization (ISO). It supersedes BS 3487-2:1986, which is withdrawn.

The major change from the 1986 edition of BS 3487-2 is that this revision introduces a requirement for cuff resting diameter.

Cross-references

International Standard	Corresponding British Standard
ISO 594-1:1986	BS 3930 <i>Conical fittings with a 6 % (Luer) taper for syringes, needles and other medical equipment</i> Part 1:1987 <i>Specification for general requirements</i> (Identical) BS 3487 <i>Tracheal tubes</i>
ISO 5361-1:1988	Part 1:1989 <i>Specification for all types of tubes</i> (Identical)
ISO 5361-5:1984	Part 5:1986 <i>Specification and methods of test for tube collapse and cuff herniation</i> (Identical)

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Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, pages 1 to 8, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

Introduction

ISO 5361-2 specifies the dimensions and basic properties of the most commonly used types of tracheal tubes made of plastics materials and/or rubber. Tubes with walls reinforced with metal or nylon, tubes with shoulders, tapering tubes or the many other types of tubes devised for specialized applications are not specifically covered, although most may be classified by their inside diameter as required by this specification.

While the inside diameter has been specified for size reference, this part of ISO 5361 requires that the outside diameter be marked on the smaller sizes of tubes since for these sizes this information is of greater clinical importance.

Clinical considerations have also dictated the apparently excessive specified length of tubes because long tubes, sometimes of relatively narrow diameter, may be urgently required and must therefore be readily available. Provision has also been included for pre-cut tracheal tubes.

Cuffed tracheal tubes may be characterized by a combination of the tube inside diameter (and outside diameter for the smaller sizes) and by the cuff resting diameter. For tubes intended for re-use, information on the cuff resting diameter is required to be marked on the package or insert but not on the tube itself. This is because re-use may alter the elastic properties and so the diameter of the cuff.

The relationship of cuff and tracheal diameters dictates the intra-cuff pressures required to provide a seal. Excessive pressure on the tracheal wall may obstruct capillary blood flow.

A range of cuff designs is available to meet particular clinical requirements. This part of ISO 5361 requires that the resting diameter of the cuff is marked on the unit package, as this information allows the clinician to match the product to the application.

1 Scope

This part of ISO 5361 specifies requirements for oro-tracheal and naso-tracheal tubes of the Magill type (plain and cuffed) made of plastics materials and/or rubber. Specialized tubes (see the Introduction) are excluded from the scope of this part of ISO 5361.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 5361. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 5361 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 594-1:1986, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements*.

ISO 5361-1:1988, *Tracheal tubes — Part 1: General requirements*.

ISO 5361-5:1984, *Tracheal tubes — Part 5: Requirements and methods of test for cuffs and tubes*.

3 General

Oro-tracheal and naso-tracheal tubes of the Magill type (plain and cuffed) shall comply with the requirements specified in ISO 5361-1.

4 Dimensions

4.1 The basic dimensions of tracheal tubes shall be in accordance with Table 1.

4.2 The actual inside diameter shall be the nominal inside diameter subject to a tolerance of $\pm 0,15$ mm for size 6,0 and smaller, and subject to a tolerance of $\pm 0,2$ mm for size 6,5 and larger.

4.3 For size 6,0 and smaller the actual outside diameter (OD) shall be the marked outside diameter (OD) subject to a tolerance of $\pm 0,15$ mm [see **9.1 b**].

5 Curvature of tube

The radius of curvature for both oral and nasal tubes shall be $140 \text{ mm} \pm 15 \text{ mm}$ for tubes of size 6,5 and larger, except that this curvature may be omitted from the tip of the bevel to not more than 30 mm beyond the machine end of the cuff (see Table 1). If this curvature (see Figure 3) is so omitted, the straight portion shall be tangential to the curve of the tube.

The curvature may also be omitted from uncuffed tubes of size 6,5 and larger over the same equivalent distances as for cuffed tubes.