

INTERNATIONAL STANDARD

ISO
5361-2

Second edition
1993-06-15

Tracheal tubes —

Part 2:

Oro-tracheal and naso-tracheal tubes of Magill type (plain and cuffed)

Tubes trachéaux —

*Partie 2: Tubes orotrachéaux et nasotrachéaux (avec et sans ballonnets)
type Magill*



Reference number
ISO 5361-2:1993(E)

Contents

	Page
1 Scope	1
2 Normative references	1
3 General	1
4 Dimensions	1
5 Curvature of tube	1
6 Bevel	1
7 Cuff	2
8 Inflating tubes for cuffs	3
9 Marking	5

Annex

A Method for determining resting diameter of cuff	8
---	---

© ISO 1993

All rights reserved. No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from the publisher.

International Organization for Standardization

Case Postale 56 • CH-1211 Genève 20 • Switzerland

Printed in Switzerland

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.

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.

International Standard ISO 5361-2 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Sub-Committee SC 2, *Tracheal tubes and other equipment*.

This second edition cancels and replaces the first edition (ISO 5361-2:1984), of which it constitutes a technical revision, introducing a requirement for cuff resting diameter.

ISO 5361 consists of the following parts, under the general title *Tracheal tubes*:

- Part 1: *General requirements*
- Part 2: *Oro-tracheal and naso-tracheal tubes of Magill type (plain and cuffed)*
- Part 3: *Murphy type*
- Part 4: *Cole type*
- Part 5: *Requirements and methods of test for cuffs and tubes*

Annex A forms an integral part of this part of ISO 5361.

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.

Tracheal tubes —

Part 2:

Oro-tracheal and naso-tracheal tubes of Magill type (plain and cuffed)

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.

6 Bevel

All tubes shall have an angle of bevel of $38^\circ \pm 10^\circ$.

The bevel of the tube should have the opening facing to the left when the tube is viewed towards the concave aspect from the machine end [see figures 1a) and 1b)]. The end of the tube at the bevel should be

rounded and the orifice(s) should be free from sharp edges.

7 Cuff

7.1 The cuff, if provided, shall be permanently attached to the tube.

7.2 Cuffs of tracheal tubes shall comply with the requirements specified in ISO 5361-5.

7.3 For tracheal tubes of size 5,0 and larger, dimension *B* in figures 1a) and 1b) shall not exceed 15 mm.

7.4 The maximum distance from the patient end of the tube to the machine end of the inflatable length of the cuff [dimension *C* in figures 1a) and 1b)] shall be as given in table 1.

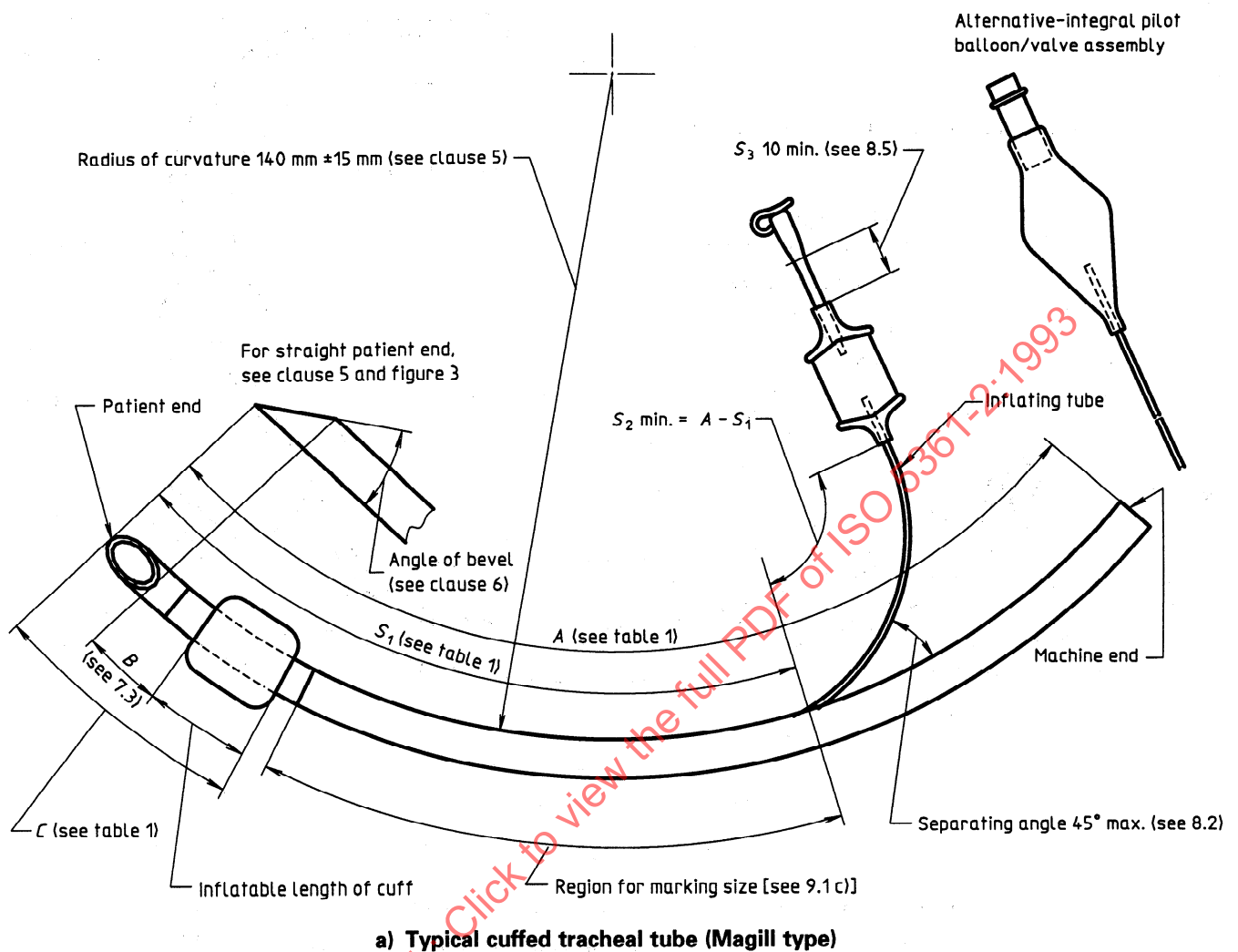
Table 1 — Basic dimensions of tracheal tubes

Dimensions in millimetres

Designated size (nominal inside diameter)	Minimum length of tube [see figures 1a) and 1b), dimension <i>A</i>]		Maximum distance <i>C</i> from patient end to machine end of inflatable length of cuff ¹⁾	Minimum distance of point of separation of inflating tube from patient end of tube [see figures 1a) and 1b), dimension <i>S₁</i> ¹⁾
	nasal or oral/nasal	oral ²⁾		
2,0	140	110	—	—
2,5	140	110	—	—
3,0	160	120	—	—
3,5	180	130	—	—
4,0	200	140	—	—
4,5	220	150	—	—
5,0	240	160	56	115
5,5	270	170	56	120
6,0	280	190	58	125
6,5	290	210	62	135
7,0	300	230	66	140
7,5	310	240	69	145
8,0	320	250	72	150
8,5	320	260	75	155
9,0	320	270	78	160
9,5	320	280	81	165
10,0	320	280	85	170
10,5	320	280	85	170
11,0	320	280	85	170

1) These values are not specified for cuffed tracheal tubes of sizes 4,5 or smaller because cuffed tubes of these sizes are infrequently used.

2) Manufacturers desiring to market packaged sterile oral "pre-cut" tubes with connectors inserted may be guided by the tube lengths shown. However, the user is cautioned that anatomical variations, conditions of use, length of tube inserted or other factors may well result in the use of a tracheal tube either too long or too short for a given patient. The necessity remains for expert clinical judgement in selecting the size and length of tracheal tubes.



a) Typical cuffed tracheal tube (Magill type)

Figure 1 — Typical cuffed tracheal tube (Magill type)

NOTE 1 Many cuffs have virtually no residual volume and are consequently easier to pass through the vocal cords than are some high volume cuffs. Small volume cuffs which generally need a relatively high pressure to inflate them are usually satisfactory for anaesthetic use, i.e. for a few hours, when correctly inflated.

Attention is drawn to the many reports of tracheal damage when tracheal (or tracheostomy) tubes with small volume cuffs have been used for extended periods as is commonly the case in respiratory care. In these circumstances, it would appear desirable that cuffs should be made of soft material of low extensibility and have a relatively large residual volume. These factors reduce both the required inflation pressure and the pressure exerted on the tracheal wall.

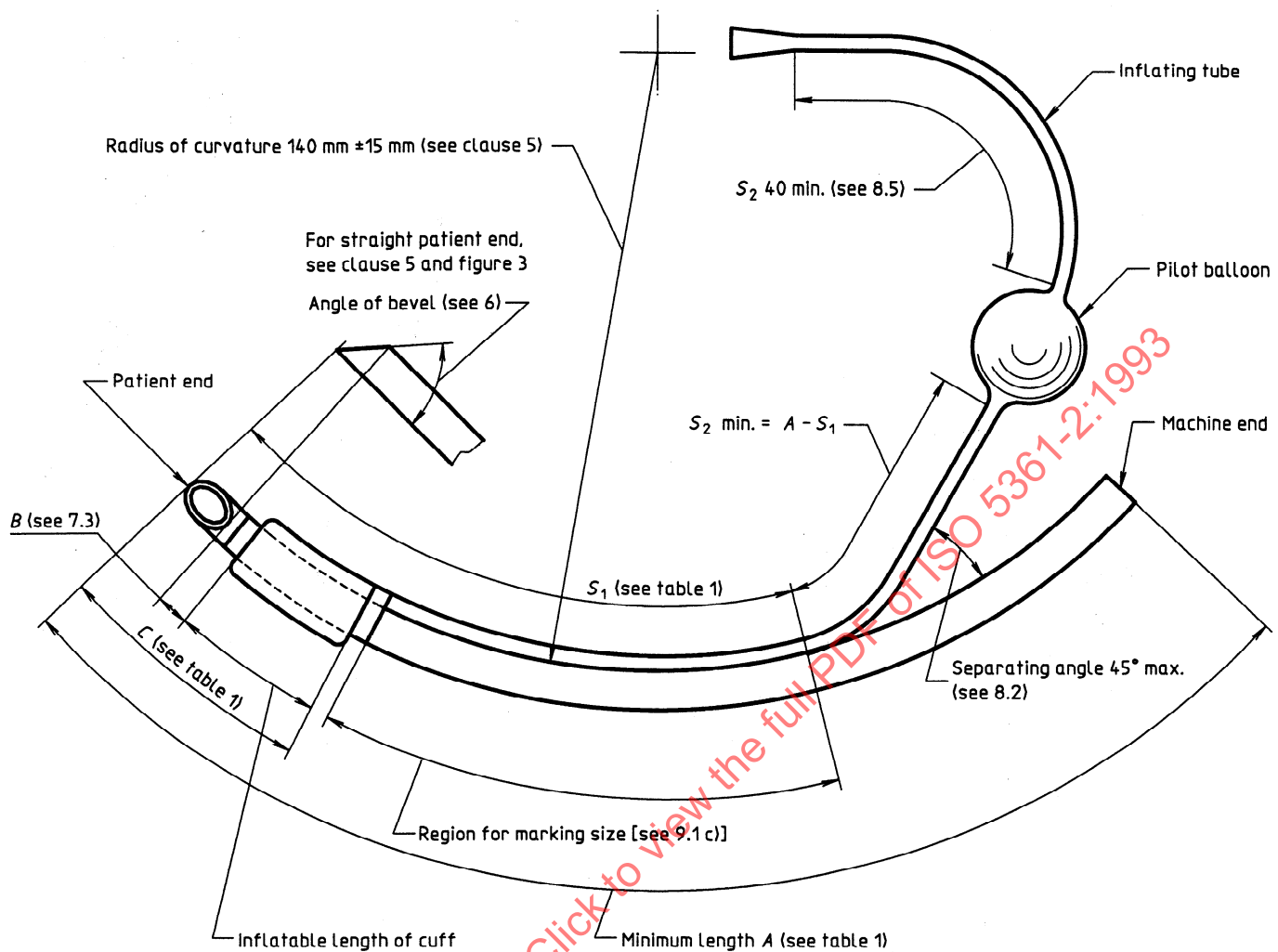
WARNING — Whatever type of cuff is used it is the responsibility of the user to ensure that it is inflated and maintained with no more than the minimum amount of air required to provide an effective seal at the desired lung inflation pressure.

7.5 The cuff resting diameter shall be within $\pm 15\%$ of the marked value when determined in accordance with annex A.

8 Inflating tubes for cuffs

8.1 The inflating tube, if fitted, shall have an outside diameter of not more than 3 mm and shall be situated on the concave aspect of the parent tube. The wall around the secondary (inflation) lumen shall not encroach on the lumen of the tracheal tube by more than 10 % of the inside diameter of the tracheal tube. The dimensions of the inflating tube shall be in accordance with table 1 and figures 1a) and 1b).

8.2 The angle between the inflating tube and the parent tube at the point of separation [see figures 1a) and 1b)] shall not exceed 45°.



b) Typical cuffed tracheal tube (Magill type) (showing alternative design features)

Figure 1 — Typical cuffed tracheal tubes (Magill type)

8.3 If the inflating tube is provided with a pilot balloon [see figures 1a) and 1b)], the pilot balloon shall be so constructed as to give an indication of inflation of the cuff. Neither the inflating tube nor any device shall act as a non-return valve to prevent the intentional evacuation of the cuff.

8.4 The free end of the inflating tube shall either be open or fitted with a valve or other insert. If the end is open, it shall be capable of accepting a male conical fitting having a 6 % taper (Luer) complying with the requirements specified in ISO 594-1. If the end is fitted with an insert, the insert shall have a female conical fitting having a 6 % taper (Luer) complying with the requirements specified in ISO 594-1.

8.5 Except where an inflation valve or closure device is provided, dimension S_3 [see figures 1a and 1b)] shall be at least 40 mm. If such a closure device is provided, except where the balloon and valve are built together, the distance between the pilot balloon and the female fitting which accepts a male Luer conical fitting shall be not less than 10 mm.

NOTE 2 This is to facilitate clamping of the inflating tube.

The lumen of the inflating tube should re-open after de-clamping to enable intentional deflation of the cuff.

8.6 If the unit pack is not transparent [see 9.2.1 a)], the distance of the point of separation of the inflating tube and the tracheal tube from the patient end shall be the marked value, subject to a tolerance of ± 10 mm.

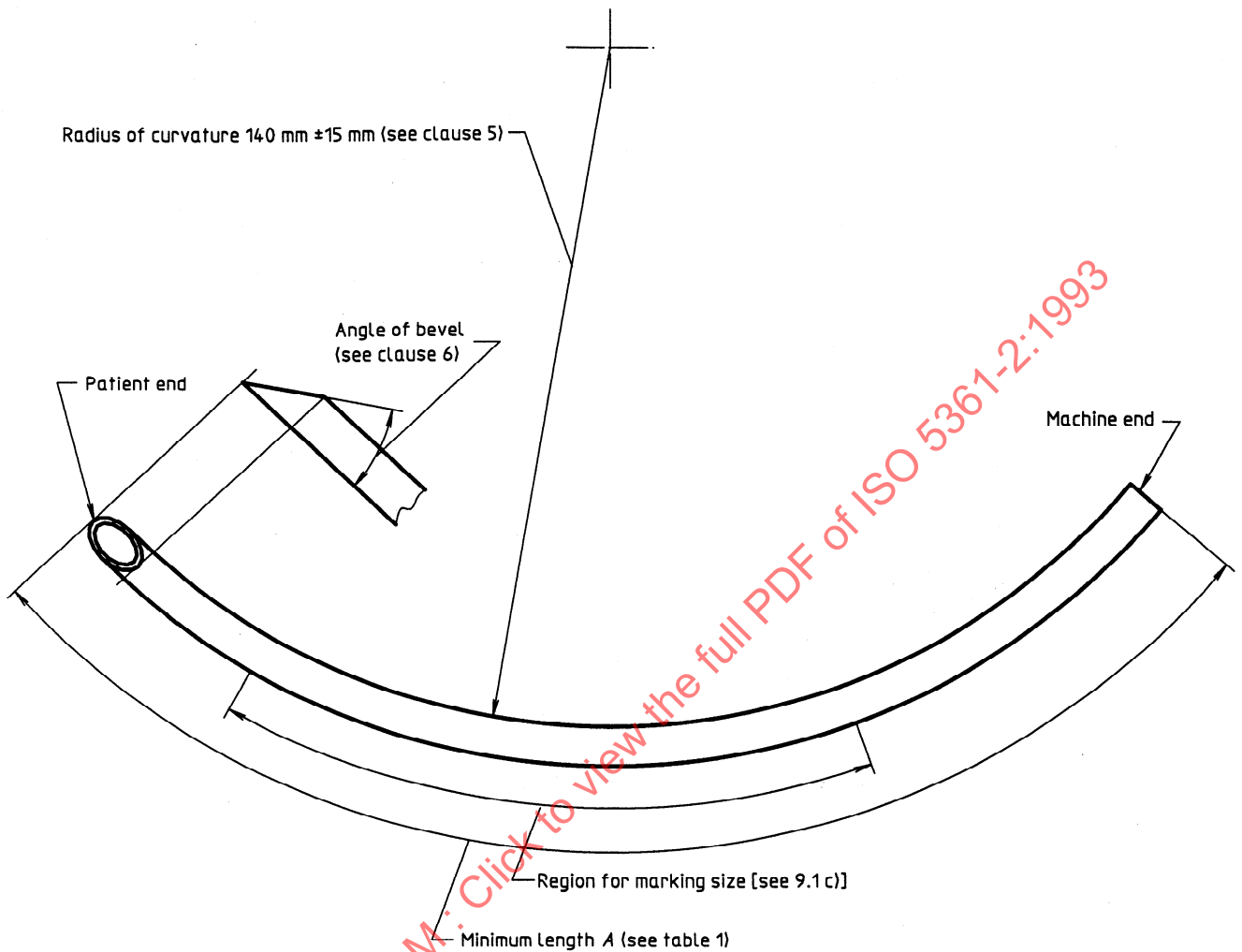


Figure 2 — Typical plain tracheal tube (Magill type)

9 Marking

9.1 Marking on tube

The marking of tracheal tubes of the Magill type shall comply with the general requirements for marking specified in ISO 5361-1 and with the following.

- The word "oral", "nasal" or "oral/nasal", as appropriate, shall be marked on tubes of sizes 5,0 and larger.
- For sizes 6,0 and smaller, the outside diameter shall be marked in millimetres.

If both the inside and the outside diameters are marked the marking shall be in accordance with either of the following examples:

4,0 Oral 5,7

ID 4,0 Oral 5,7 OD

NOTE 3 The figures preceding the word "Oral" denote the inside diameter and should be in larger and bolder type.

- The marking of the size of the tracheal tube shall be situated as shown in figures 1a), 1b) and 2, as appropriate, on the side of the tube reading from the patient end to the machine end. Plain tubes shall have the size marked in a region equivalent to cuffed tubes of similar size.

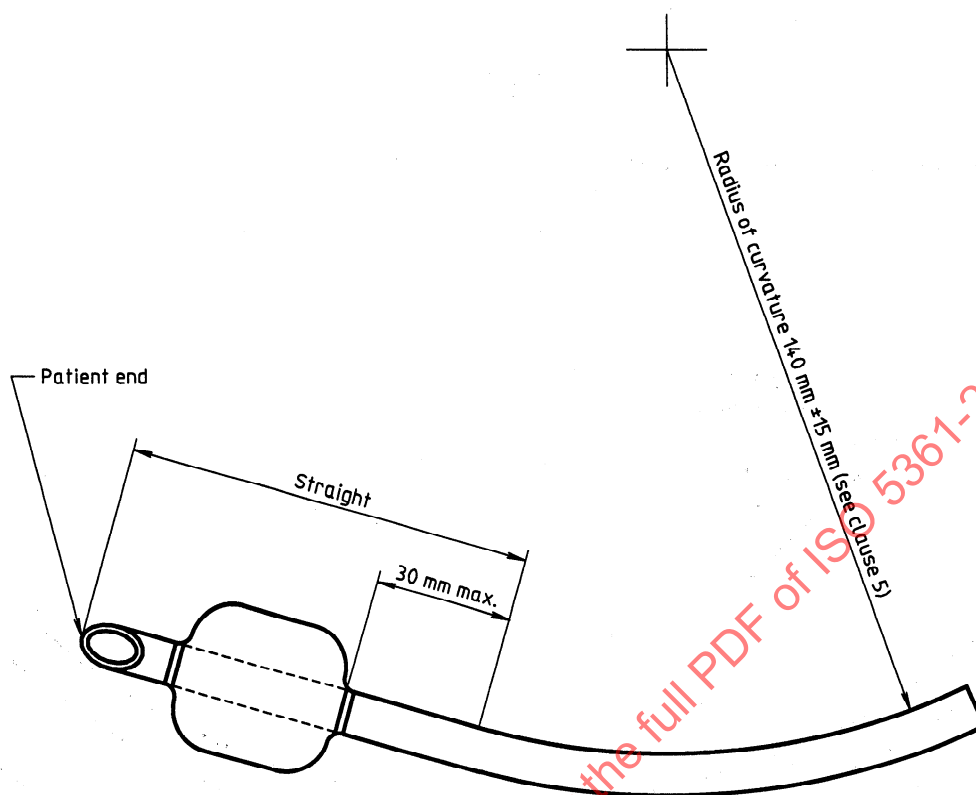


Figure 3 — Typical straight patient end

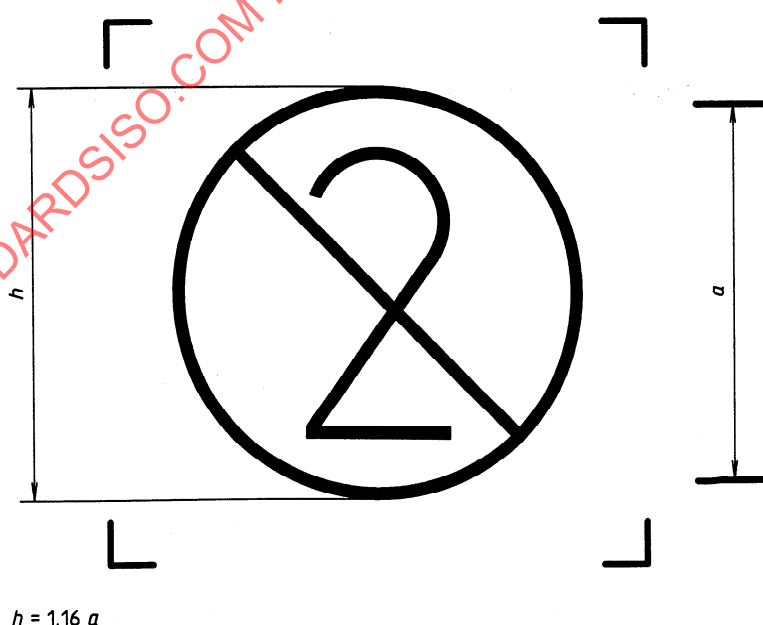


Figure 4 — ISO symbol 7000/1051 "Do not re-use"

9.2 Marking on package and any insert

9.2.1 The marking of packages containing tracheal tubes shall include the following:

- a) if the unit package is not transparent, the distance of the point of separation of the inflating tube and tracheal tube from the patient end;
- b) a description of contents;
- c) the word "oral", "nasal" or "oral/nasal", as appropriate;
- d) the designated size (nominal inside diameter) in accordance with ISO 5361-1;
- e) for tubes of sizes 6,0 and smaller, the outside diameter expressed in millimetres (see 4.3);
- f) the name and/or trademark of the manufacturer and/or supplier;
- g) the batch number;

NOTE 4 It is strongly recommended that the expiry date be given.

- h) the word "STERILE" or "NON-STERILE" as appropriate;
- i) for tubes not intended for re-use, the words "SINGLE USE" or equivalent;

NOTE 5 Symbol no. 1051 ("Do not re-use") given in ISO 7000 should additionally be used (see figure 4).

- j) If the straight portion of the tube extends beyond the machine end of the cuff (see clause 5), this shall be stated, for example by the words "Straight patient end".

9.2.2 The marking of packages or an insert shall include the following:

- a) if relevant, instructions for cleaning and disinfection or sterilization;
- b) for cuffed tubes, the resting diameter of the cuffs, determined in accordance with annex A and expressed in millimetres.

STANDARDSISO.COM : Click to view the full PDF of ISO 5361-2:1993

Annex A

(normative)

Method for determining resting diameter of cuff

A.1 Principle

The resting diameter of the cuff is measured when the cuff is inflated with a pressure which is intended to remove creases but minimize stretching of its walls.

A.2 Apparatus

Means to inflate the cuff with sufficient air to create an internal overpressure of 2 kPa ($20 \text{ cmH}_2\text{O}$) $\pm 5 \%$.

A.3 Procedure

A.3.1 Inflate the cuff with sufficient air to create an internal overpressure of 2 kPa ($20 \text{ cmH}_2\text{O}$) $\pm 5 \%$ and leave to stabilize for 5 min at $(23 \pm 2) ^\circ\text{C}$, maintaining that overpressure.

A.3.2 Measure the maximum cuff diameter in a plane perpendicular to the axis of the tube at intervals of 45° .

A.4 Expression of results

Calculate the arithmetic mean of the measurements obtained in A.3.2 and express the result in millimetres.