Disclosure to Promote the Right To Information

Whereas the Parliament of India has set out to provide a practical regime of right to information for citizens to secure access to information under the control of public authorities, in order to promote transparency and accountability in the working of every public authority, and whereas the attached publication of the Bureau of Indian Standards is of particular interest to the public, particularly disadvantaged communities and those engaged in the pursuit of education and knowledge, the attached public safety standard is made available to promote the timely dissemination of this information in an accurate manner to the public.

Indian Standard

ANAESTHETIC AND RESPIRATORY EQUIPMENT — TRACHEAL TUBES AND CONNECTORS

ICS 11.040.10
NATIONAL FOREWORD

This Indian Standard which is identical with ISO 5361 : 1999 'Anaesthetic and respiratory equipment — Tracheal tubes and connectors' issued by the International Organization for Standardization (ISO) was adopted by the Bureau of Indian Standards on the recommendation of the Anaesthetic, Resuscitation and Allied Equipment Sectional Committee and approval of the Medical Equipment and Hospital Planning Division Council.

Indian Standards on tracheal tubes and connectors were earlier published separately as IS 12504 (Parts 1 to 5) and IS 11808 as follows:

b) IS 12504 (Part 2) : 1988 Specification for tracheal tubes: Part 2 Oro-tracheal and naso-tracheal tubes of the Magill type (Plain and cuffed) (Based on ISO 5361-2 : 1984)
f) IS 11808 : 1986 Tracheal tube connectors (Based on ISO 7228 : 1985)

The base ISOs of IS 12504 (Parts 1, 2, 3 and 5) and IS 11808 have been replaced by ISO 5361 : 1999. Indian Standards IS 12504 (Parts 3, 4 and 5) had already been withdrawn. This standard is therefore, now being published in a single number as IS/ISO, based on ISO 5361 : 1999 to align with the latest international practices. This standard will supersede IS 12504 (Parts 1 and 2) : 1988 and IS 11808 : 1986 and these shall be treated as withdrawn after the publication of this standard.

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

While the inside diameter has been specified for size reference, this standard requires that the outside diameter also be marked, since this information is of 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 therefore should be readily available. Provision has also been included for pre-cut tracheal tubes.

Cuffed tracheal tubes can be characterized by a combination of the tube inside and outside diameters 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 thereby the diameter, of the cuff.

The relationship between the cuff and tracheal diameters dictates the intracuff pressure required to provide a seal. Excessive pressure on the tracheal wall may obstruct capillary blood flow.
Tracheal tubes, when in position, are intended to conform as closely as possible to human anatomy.

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

Herniation in relation to cuffs is a term widely understood in clinical anaesthetic practice. It is used to describe a cuff which protrudes excessively at its patient end so that it partially or completely occludes the orifice at the bevel. Herniation may be due to a variety of causes, singly or in combination: these may include over-inflation of the cuff, traction of the tube when the cuff is inflated or deterioration of the material of the cuff.

It should be noted that although certain requirements for cuffs apply to tubes of sizes 2.0 to 4.5, cuffs are infrequently used on these smaller sizes of tube.

Flammability of tracheal tubes, for example, if flammable anaesthetics, electrosurgical units or lasers are used, is a well-recognized hazard, that is, addressed by appropriate clinical management, outside the scope of this standard.

It is a requirement that tracheal tubes include length mark(s) in centimetres, measured from the patient end. It is recognized, however, that additional marks, easier to see during intubation, may assist the clinician in positioning the tracheal tube within the trachea. There is currently, however, no clear consensus on the optimum style and positioning of these marks and whether the positioning should differ with size of tube. Further clinical data is required in order to support inclusion of recommendations for these marks in a future revision of this standard.

The text of ISO Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.
b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards which are to be substituted in their respective places are listed below along with their degree of equivalence for the editions indicated:

<table>
<thead>
<tr>
<th>International Standard</th>
<th>Corresponding Indian Standard</th>
<th>Degree of Equivalence</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO 594-1 : 1986 Conical fittings with a 6% (Luer) taper for syringes, needles and</td>
<td>IS 3234 (Part 1) : 1986 Conical fittings with a 6% (Luer) taper for syringes, needles and</td>
<td>Identical</td>
</tr>
<tr>
<td>certain other medical equipment — Part 1: General requirements</td>
<td>certain other medical equipment: Part 1 General requirements (second revision)</td>
<td></td>
</tr>
</tbody>
</table>
The technical committee has reviewed the provisions of the following International Standards referred in this adopted standard and has decided that they are acceptable for use in conjunction with this standard.

<table>
<thead>
<tr>
<th>International/Other Standard</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO 11607 : 2006</td>
<td>Packaging for terminally sterilized medical devices</td>
</tr>
<tr>
<td>EN 556 : 1994</td>
<td>Sterilization of medical devices — Requirements for medical devices to be labelled “sterile”</td>
</tr>
</tbody>
</table>

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test, shall be rounded off in accordance with IS 2 : 1960 ‘Rules for rounding off numerical values (revised)’. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.
1 Scope
This International Standard specifies requirements for the dimensions, basic properties and method of size designation of the most commonly used types of oro-tracheal and naso-tracheal tube made of plastics materials and/or rubber (plain and cuffed), and requirements for tracheal tube connectors.

Specialized tubes are excluded from the scope of this International Standard.

2 Normative references
The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

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

ISO 5356-1, Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets.


ISO 11607, Packaging for terminally sterilized medical devices.

EN 556:1994, Sterilization of medical devices — Requirements for medical devices to be labelled "Sterile".

3 Terms and definitions
For the purposes of this International Standard, the following terms and definitions apply.

3.1 angle of bevel
acute angle between the plane of the bevel and the longitudinal axis of the tracheal tube at the patient end

[ISO 4135:1995]
3.2
bevel
slanted portion at the patient end of the tracheal tube

[ISO 4135:1995]

3.3
cuff
inflatable balloon permanently attached around the tracheal tube near the patient end to provide an effective seal between the tube and the trachea

3.4
inflating tube
tube through which the cuff is inflated

[ISO 4135:1995]

3.5
inflation lumen
lumen within the wall of the tracheal tube for inflating the cuff

3.6
machine end
that end of a tracheal tube which is intended to project from a patient

[ISO 4135:1995]

3.7
machine end
that portion of the tracheal tube connector intended to mate with the breathing system of an anaesthetic machine or ventilator

3.8
Murphy eye
hole through the wall of a tracheal tube near the patient end and on the side opposite to the bevel

3.9
naso-tracheal tube
tracheal tube for insertion through the nose into the trachea

[ISO 4135:1995]

3.10
oro-tracheal tube
tracheal tube for insertion through the mouth into the trachea

[ISO 4135:1995]

3.11
patient end
that end of the tracheal tube which is intended to be inserted into the trachea

[ISO 4135:1995]

3.12
patient end
that end of the tracheal tube connector nearest to the patient, which is inserted into the tracheal tube.
3.13 pilot balloon 
balloon fitted to the inflating tube to indicate inflation of the cuff 

[ISO 4135:1995]

3.14 tracheal tube 
tube designed for insertion through the larynx into the trachea to convey gases and vapours to and from the trachea 

[ISO 4135:1995]

3.15 tracheal tube connector 
tubular component that fits directly into a tracheal tube 

[ISO 4135: 1995]

3.16 tracheal tube of the ‘Magill’ type 
tracheal tube with a radius of curvature (as specified in 4.7) 

4 General requirements for tracheal tubes and tracheal tube connectors 

4.1 Size designation 

The size of tracheal tubes and tracheal tube connectors shall be designated by the nominal inside diameter, expressed in millimetres, in accordance with Table 1 for tracheal tubes and Table 2 for tracheal tube connectors. 

4.2 Dimensions 

4.2.1 Tracheal tubes 

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

4.2.1.2 The actual inside diameter shall be the marked inside diameter subject to a tolerance of ±0.15 mm for sizes 6.0 and smaller, or subject to a tolerance of ±0.20 mm for sizes 6.5 and larger. 

4.2.1.3 The actual outside diameter (OD) shall be the marked outside diameter (OD) subject to a tolerance of ±0.15 mm for sizes 6.0 and smaller, or subject to a tolerance of ±0.20 mm for sizes 6.5 and larger [see 7.2.1.1 b)].
Table 1 — Basic dimensions of tracheal tubes

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

a Manufacturers desiring to market packaged sterile oral pre-cut tubes with connectors inserted may be guided by the tube lengths shown in the table. 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.

b These values are not specified for cuffed tracheal tubes of sizes 4.5 or smaller because cuffed tubes of these sizes are infrequently used.
Key
1 Patient end
2 Angle of bevel (see 4.4)
3 Radius of curvature (see 4.7)
4 Inflating tube
5 Machine end
6 Alternative integral pilot balloon/valve assembly
7 Separating angle (see 4.6.2)
8 Region for marking size [see 7.2.1.1 f]
9 Inflatable length of cuff

a) Typical cuffed tracheal tube (‘Magill’ type)

Figure 1 — Cuffed tracheal tubes
Key
1 Patient end
2 Angle of bevel (see 4.4)
3 Radius of curvature (see 4.7)
4 Inflating tube
5 Machine end
6 Pilot balloon
7 Separating angle (see 4.6.2)
8 Region for marking size [see 7.2.1.1 f]
9 Inflatable length of cuff

a See 4.6.6.
b See Table 1.
c Minimum value for $S_2 = A - S_1$.

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

Figure 1 — Cuffed tracheal tubes

4.2.2 Tracheal tube connectors

4.2.2.1 The basic dimensions of tracheal tube connectors shall be in accordance with Table 2.

4.2.2.2 When a tracheal tube is supplied with a tracheal tube connector, the designated size of the connector shall be not less than that of the tracheal tube with which it is provided.
4.2.2.3 The minimum inside diameter of a curved or angled connector shall be not less than 80 % of the designated size, and the corresponding cross-sectional area shall not be reduced by more than 10 %.

4.2.2.4 A suction port, if provided, shall be designed so that its closure does not obstruct or narrow the lumen of the connector.

NOTE The connector may be straight, curved or angled. If curved or angled, the connector may incorporate a suction port.

4.2.2.5 The machine end of a tracheal tube connector shall be a male 15 mm conical connector complying with ISO 5356-1. The inside diameter of the (conical) machine end shall be not less than that allowed by Table 2 for the patient end. Any transition in the inside diameter shall be tapered to permit an adequate lead-in for smooth passage of a suction catheter.

4.2.2.6 The basic dimensions of the patient end (see Figures 2 and 3) of the connector shall be in accordance with Table 2.

4.2.2.7 The opening at the patient end shall have a plane at \((90 \pm 5)°\) to the long axis of the patient end of the connector.

### Table 2 — Tracheal tube connectors — Size range and basic dimensions of patient end

<table>
<thead>
<tr>
<th>Designated size (nominal inside diameter)</th>
<th>Inside diameter (d (\pm 0.15))</th>
<th>Straight connectors — minimum dimension (l_1) (effective length)(^a) (Figure 2)</th>
<th>Curved connectors — minimum dimension (l_2) (effective length)(^a) (Figure 3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.0</td>
<td>2.0</td>
<td>9</td>
<td>—</td>
</tr>
<tr>
<td>2.5</td>
<td>2.5</td>
<td>9</td>
<td>—</td>
</tr>
<tr>
<td>3.0</td>
<td>3.0</td>
<td>9</td>
<td>—</td>
</tr>
<tr>
<td>3.5</td>
<td>3.5</td>
<td>11</td>
<td>—</td>
</tr>
<tr>
<td>4.0</td>
<td>4.0</td>
<td>11</td>
<td>—</td>
</tr>
<tr>
<td>4.5</td>
<td>4.5</td>
<td>12</td>
<td>—</td>
</tr>
<tr>
<td>5.0</td>
<td>5.0</td>
<td>12</td>
<td>—</td>
</tr>
<tr>
<td>5.5</td>
<td>5.5</td>
<td>13</td>
<td>10</td>
</tr>
<tr>
<td>6.0</td>
<td>6.0</td>
<td>13</td>
<td>10</td>
</tr>
<tr>
<td>6.5</td>
<td>6.5</td>
<td>16</td>
<td>10</td>
</tr>
<tr>
<td>7.0</td>
<td>7.0</td>
<td>16</td>
<td>10</td>
</tr>
<tr>
<td>7.5</td>
<td>7.5</td>
<td>16</td>
<td>10</td>
</tr>
<tr>
<td>8.0</td>
<td>8.0</td>
<td>16</td>
<td>10</td>
</tr>
<tr>
<td>8.5</td>
<td>8.5</td>
<td>16</td>
<td>10</td>
</tr>
<tr>
<td>9.0</td>
<td>9.0</td>
<td>16</td>
<td>10</td>
</tr>
<tr>
<td>9.5</td>
<td>9.5</td>
<td>16</td>
<td>10</td>
</tr>
<tr>
<td>10.0</td>
<td>10.0</td>
<td>16</td>
<td>10</td>
</tr>
<tr>
<td>10.5</td>
<td>10.5</td>
<td>16</td>
<td>10</td>
</tr>
<tr>
<td>11.0</td>
<td>11.0</td>
<td>16</td>
<td>10</td>
</tr>
</tbody>
</table>

\(^a\) The effective length of the patient end of a tracheal tube connector is that length available for insertion into the tracheal tube.
Key
1 Machine end (see 4.2.2.5)
2 Patient end

NOTE This figure illustrates a tracheal tube connector for the purpose of defining basic dimensions, and is intended as an example only.

Figure 2 — Straight tracheal tube connector
Key
1  Machine end (see 4.2.2.5)
2  Straight patient end

NOTE 1  Angle $\theta$ may be any angle greater than 45°.

NOTE 2  This figure illustrates a tracheal tube connector for the purpose of defining basic dimensions, and is intended as an example only.

Figure 3 — Example of a curved tracheal tube connector

4.3 Materials

Tracheal tubes, including cuffs, and tracheal tube connectors in their ready-for-use state after any preparation for use recommended by the manufacturer, shall satisfy appropriate biological safety testing, as indicated in ISO 10993-1.

NOTE  See annex D for guidance on materials and design.

4.4 Bevel

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

NOTE  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 Figure 1 a) and b)].
4.5 Cuff

4.5.1 A cuff, if provided, shall be integrally attached to the tube.

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

4.5.3 The cuff resting diameter shall be within ± 15 % of the marked value [see 7.2.2.1 k]), when determined in accordance with annex A.

4.5.4 When tested for tube collapse according to the method described in annex B, the steel ball shall pass freely through the tube.

4.5.5 When tested for cuff herniation according to the method described in annex C, no part of the inflated cuff shall reach beyond the nearest edge of the bevel (see Figure C.1).

4.6 Inflating tubes for cuffs

4.6.1 The inflating tube, if provided, shall have an outside diameter of not more than 3,0 mm and the point of separation shall be situated on the concave aspect of the tracheal tube. The wall around the 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 Figure 1 a) and b).

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

4.6.3 The inflating tube shall have a pilot balloon and/or other device to indicate inflation/deflation of the cuff.

NOTE This (these) device(s) may also serve as a pressure-indicating or -limiting device.

4.6.4 The intentional deflation of the cuff shall not be prevented by the inflating tube, inflating valve or any closure device acting as a non-return valve.

4.6.5 The free end of the inflating tube shall be either open or sealed with a closure device or inflation valve, but in all instances it shall be capable of accepting a male conical fitting with a 6% (Luer) taper, complying with ISO 594-1.

4.6.6 Dimension $S_3$ of the inflating tube [see $S_3$ in Figure 1 a) and b)] shall be at least 40 mm unless an inflation valve or closure device is provided. If such a closure device is provided, except if the pilot balloon and valve are integral, dimension $S_3$ shall be not less than 10 mm.

NOTE This is to facilitate clamping of the inflating tube.

4.6.7 If the distance of the point of separation of the inflating tube and the tracheal tube from the patient end is marked [see 7.2.2.1 a)], the actual distance shall be the marked value ± 10 mm.

4.7 Curvature of tube

4.7.1 Tracheal tubes may be straight or curved.

4.7.2 If tracheal tubes are described as being of the ‘Magill’ type, the radius of curvature shall be (140 ± 20) mm for tubes of sizes 6,5 and larger [see Figure 1 a) and b) and Figure 4], except that:

a) 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 Figure 5). If this curvature is so omitted, the straight portion shall be tangential to the curve of the tube.

b) this curvature may be omitted from uncuffed tubes of sizes 6,5 and larger over the same equivalent distance as for cuffed tubes in a).

4.7.3 Tracheal tubes of the ‘Magill’ type of sizes 6,0 and smaller may have a radius of curvature other than (140 ± 20) mm.
Figure 4 — Typical plain tracheal tube ('Magill' type)

Key
1 Patient end
2 Angle of bevel (see 4.4)
3 Radius of curvature (see 4.7)
4 Region for marking size [see 7.2.1.1 f)]
5 Machine end

\[ A \] Minimum length \( A \) (see Table 1).
5 Additional requirements for tracheal tubes with a Murphy eye

5.1 Size of the Murphy eye

The area of the Murphy eye shall be not less than 80 % of the cross-sectional area derived from the minimum inside diameter allowed by Table 1 for that size of tube.

5.2 Location of the Murphy eye

The location of the eye shall be on the side of the tube opposite the bevel (see Figure 6).

NOTE The size, shape and location of the eye should be such that the patient end of the tube is not unduly prone to kinking/collapse.
Key
1 Murphy eye

Figure 6 — Patient end of tracheal tube showing Murphy eye

6 Requirements for tracheal tubes with tracheal tube connector supplied sterile

6.1 Sterility assurance

Tracheal tubes with connectors supplied and marked as "STERILE" shall satisfy the requirements of 4.1 of EN 556:1994.

6.2 Packaging for tracheal tubes and tracheal tube connectors supplied sterile

Each tracheal tube with tracheal tube connector supplied and marked as "STERILE" shall be contained in an individual pack. The pack shall serve as an effective barrier to the penetration of microorganisms and particulate material, in accordance with ISO 11607. The pack shall permit the aseptic extraction of the contents and shall not be capable of re-closure without clearly revealing that it has been opened.

7 Marking

7.1 Use of symbols

The requirements of 7.2 may be met by the appropriate symbols as given in ISO 7000 or EN 980.

Marking of tracheal tubes, connectors, packages, inserts and information to be supplied by the manufacturer should comply with EN 1041.
7.2 Tracheal tubes

7.2.1 Marking of the tracheal tube

7.2.1.1 Marking of the tracheal tube shall include the following:

a) the name and/or trademark of the manufacturer or supplier;

b) the designated size (nominal inside diameter) in accordance with 4.1 and the outside diameter, expressed in millimetres, marked in accordance with one of the following formats:

<table>
<thead>
<tr>
<th>ID</th>
<th>4.0</th>
<th>5.7</th>
<th>OD</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>4.0</td>
</tr>
</tbody>
</table>

The figure denoting the inside diameter shall be larger and in bold type.

c) for tracheal tubes not intended for re-use, the words "single use" or equivalent;

d) length mark(s) in centimetres measured from the patient end;

e) the word "Oral", "Nasal" or "Oral/Nasal", as appropriate;

f) marking of the size of tracheal tubes situated as shown in Figure 1 a) and b) and Figure 4, 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.

7.2.1.2 Additional marks may be provided to assist in positioning the tracheal tube within the trachea.

7.2.1.3 Marking materials shall be of a colour that contrasts with the colour of the tube.

7.2.2 Marking on the tracheal tube individual pack and any insert

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

a) if the unit package of a cuffed tube 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 4.1;

   NOTE   The figure denoting the inside diameter should be in larger and bolder type than that denoting the outside diameter.

 e) the outside diameter expressed in millimetres;

 f) the name and/or trademark of the manufacturer and/or supplier;

 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) if the straight portion of the tube extends beyond the machine end of the cuff (see 4.7.2), this shall be stated, for example by the words "straight patient end";

k) for cuffed tubes, the resting diameter of the cuff, determined in accordance with annex A and expressed in millimetres to two significant figures.

7.2.2.2 Unless the tracheal tube is intended and marked as being for single use, instructions for cleaning and disinfection or sterilization, and the maximum number or period of re-uses shall be marked on the tracheal tube package or on an insert.

7.3 Tracheal tube connectors

The tracheal tube connector shall be clearly marked with the designated size (nominal inside diameter) in accordance with 4.1.
Annex A
(normative)

Determination of cuff resting diameter

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

A.2.1 Means to inflate the cuff with sufficient air to create an internal overpressure of 2,0 kPa ± 5 %.

A.3 Procedure

A.3.1 Inflate the cuff with sufficient air (A.2.1) to create an internal overpressure of (2,0 ± 0,1) kPa and allow to stabilize for 5 min at (23 ± 2) °C, maintaining that overpressure.

A.3.2 Locate the plane of maximum cuff diameter perpendicular to the axis of the tube. Measure four cuff diameters at intervals of 45° in the located plane.

A.4 Expression of results

Calculate the arithmetic mean of the measurements obtained in A.3.2 and express the result in millimetres.
Annex B
(normative)

Test method for tube collapse

B.1 Principle

The resistance to tube collapse due to inward cuff pressure is tested by passing a steel ball through the tracheal tube lumen with the cuff inflated within a transparent tube.

B.2 Apparatus

B.2.1 Transparent tube made of glass or rigid plastics material, having a length of about twice the effective length of the cuff and an inside diameter of within 5 % of twice the marked outside diameter of the tracheal tube under test (see Figure B.1).

B.2.2 Water bath, thermostatically controlled at (40 ± 1) °C.

B.2.3 Air supply, capable of providing an air supply at the pressures given in Table B.1.

B.2.4 Air pressure indicating device, capable of indicating air pressure given in Table B.1 with an accuracy of ± 5 %.

B.2.5 Steel ball, of diameter 75 % of the designated size (nominal inside diameter) of the tracheal tube undergoing test.

<table>
<thead>
<tr>
<th>Reference inflation pressure</th>
<th>Test inflation pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 16,6 kPa</td>
<td>Twice the reference inflation pressure or 2,7 kPa, whichever is greater</td>
</tr>
<tr>
<td>16,6 kPa and &lt; 33,3 kPa</td>
<td>33,3 kPa</td>
</tr>
<tr>
<td>33,3 kPa</td>
<td>Reference inflation pressure</td>
</tr>
</tbody>
</table>

Table B.1 — Selection of test inflation pressures
B.3 Procedure

B.3.1 Set up the apparatus as illustrated in Figure B.1.

![Diagram of apparatus for tube collapse test]

**Key**

1. Machine end 7. Air supply
2. Tracheal tube 8. Inflating tube
4. T-piece with connector to fit inflating tube 10. Water bath at \((40 \pm 1) \, ^\circ\text{C}\)
5. Pressure-indicating device 11. Transparent tube

**Figure B.1 — Apparatus for tube collapse test**

B.3.2 Place the patient end of the tracheal tube into the transparent tube (B.2.1) so that the cuff is centrally located.

B.3.3 Attach the inflating tube to the air supply (B.2.3).

B.3.4 Inflate the cuff with air until it just makes circumferential contact with the internal surface of the transparent tube.

**NOTE** For transparent cuffs, the addition of a small quantity of colouring, for example ink, may assist in determining the point of circumferential contact.

B.3.5 Immerse the tracheal tube and the transparent tube in the water bath (B.2.2) at \((40 \pm 1) \, ^\circ\text{C}\).
B.3.6 Adjust the volume of air in the cuff so that circumferential contact is only just maintained with the internal wall of the transparent tube.

B.3.7 After 30 min in the water bath and with the inflation volume of air in the cuff adjusted so that circumferential contact is only just maintained, record (B.2.4) the inflation pressure of the cuff (reference inflation pressure). Select the test inflation pressure appropriate for the reference inflation pressure obtained as given in Table B.1.

B.3.8 With the tracheal tube in the transparent tube, inflate the cuff with air to the test inflation pressure determined in B.3.1 to B.3.7 and maintain the pressure for 24 h in the water bath at \((40 \pm 1)\) °C.

B.3.9 At the end of the 24 h conditioning period, check the cuff inflation pressure and adjust if necessary. Check the patency of the lumen by dropping a steel ball (B.2.5) through the lumen of the tube.

B.4 Expression of results

Record whether or not the steel ball passes freely through the tube.
Annex C
(normative)

Test method for cuff herniation

C.1 Principle

The tendency of the cuff to herniate beyond the plane perpendicular to the long axis of the tube at the nearest edge of the bevel is tested by applying an axial force with the cuff inflated within a transparent tube.

C.2 Apparatus

C.2.1 Apparatus as specified in B.2.1, B.2.2, B.2.3 and B.2.4.

C.2.2 Weight, of mass 100 g.

C.3 Procedure

C.3.1 With the tracheal tube in the transparent tube (C.2.1), inflate the cuff with air (C.2.1) at the test inflation pressure determined in annex B, but using a minimum of 5.4 kPa and maintain the pressure for 24 h in the water bath (C.2.1) at (40 ± 1) °C.

C.3.2 At the end of the 24 h conditioning period, remove the tracheal tube and transparent tube from the water bath. Check the cuff inflation pressure and adjust if necessary.

C.3.3 Invert the tracheal tube and the transparent tube and, holding the transparent tube in a fixed position, gently suspend a 100 g weight (C.2.2) from the tracheal tube as shown in Figure C.1, for not less than 60 s.

C.3.4 Observe whether any part of the inflated cuff reaches beyond the nearest edge of the bevel, as shown in Figure C.1. Continue the test by progressively deflating the cuff over a period of not less than 10 s while continuously observing the configuration of the cuff.
C.4 Expression of results

Record whether or not any part of the inflated cuff reaches beyond the nearest edge of the bevel, as shown in Figure C.1.

Key
1 Nearest edge of bevel
2 Limit of cuff distortion (see 4.5.5)
3 Transparent tube
4 Inflated cuff
5 Clamping device
6 100 g weight

Figure C.1 — Apparatus for cuff herniation test
Annex D
(informative)

Guidance on materials and design

D.1 Materials

D.1.1 The materials used for the manufacture of the tubes should have sufficient rigidity to allow the construction of a tube with the thinnest possible wall which, at the same time, maintains the resistance to collapse and kinking. When in place, it should be flexible and soft enough to conform to the patient's anatomy without exerting undue pressure on the body tissues.

D.1.2 The marking of tracheal tubes should be durable and legible.

D.1.3 Unless intended and marked for single use, tracheal tubes and connectors and marking materials used on tracheal tubes should be reasonably resistant to deterioration by the methods of cleaning, disinfection and sterilization recommended by the manufacturer. Such tubes should withstand accepted methods of steam sterilization.

The recommended method or methods of sterilization should not produce changes in the materials which will compromise the biological safety of the tracheal tube and connector (see 4.3).

D.1.4 Tracheal tubes and connectors and marking materials used on tracheal tubes under normal conditions of use should be reasonably resistant to deterioration by clinically used concentrations of anaesthetic vapours and gases.

D.1.5 Tracheal tubes should be readily detectable by X-ray, either by the nature of the material of which they are made or by the provision of a marker at the patient end.

D.1.6 The tracheal tube should maintain its intended shape when stored in its original packaging in accordance with the manufacturer's instructions.

D.2 Design

D.2.1 Tracheal tubes should have smooth outside and inside surfaces. The cuff should have a smooth surface. There should be a smooth transition between the outside surface of the main tube and the cuff at the points of attachment.

D.2.2 The patient end of the tracheal tube at the bevel and the Murphy eye, if present, should be free from sharp edges.

D.2.3 The lumen of the tracheal tube should be essentially circular in a plane at right angles to the long axis.

D.2.4 Tracheal tube connectors should be light in weight but should be of sufficient strength to resist deformation under normal conditions of use.

D.2.5 Tracheal tube connectors should be designed to have minimal dead space and to offer minimal resistance to gas flow. The lumen should be smooth and free from ridges.

D.2.6 Tracheal tube connectors may be provided with lugs, flats or other means to facilitate connection and disconnection, provided that any protrusions are well-rounded.

D.2.7 A retaining or latching device may be incorporated in the design to provide added security of attachment of the conical connectors.

Any projections (for example hooks, lugs or studs) should be designed so as to minimize the risk of catching on surgical dressings or other equipment.
Bibliography


Bureau of Indian Standards

BIS is a statutory institution established under the Bureau of Indian Standards Act, 1986 to promote harmonious development of the activities of standardization, marking and quality certification of goods and attending to connected matters in the country.

Copyright

BIS has the copyright of all its publications. No part of these publications may be reproduced in any form without the prior permission in writing of BIS. This does not preclude the free use, in course of implementing the standard, of necessary details, such as symbols and sizes, type or grade designations. Enquiries relating to copyright be addressed to the Director (Publications), BIS.

Review of Indian Standards

Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the latest issue of ‘BIS Catalogue’ and ‘Standards: Monthly Additions’.

This Indian Standard has been developed from Doc No.: MHD 11 (0095).

Amendments Issued Since Publication

<table>
<thead>
<tr>
<th>Amendment No.</th>
<th>Date of Issue</th>
<th>Text Affected</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

BUREAU OF INDIAN STANDARDS

Headquarters:
Manak Bhavan, 9 Bahadur Shah Zafar Marg, New Delhi 110002
Telephones: 2323 0131, 2323 3375, 2323 9402  Website: www.bis.org.in

Regional Offices:  
Central : Manak Bhavan, 9 Bahadur Shah Zafar Marg  
NEW DELHI 110002  { 2323 7617  
                    { 2323 3841
Eastern : 1/14, C.I.T. Scheme VII M, V.I.P. Road, Kankurgachi  
KOLKATA 700054  { 2337 8499, 2337 8561  
                    { 2337 8626, 2337 9120
Northern : SCO 335-336, Sector 34-A, CHANDIGARH 160022  { 260 3843  
                    { 260 9285
Southern : C.I.T. Campus, IV Cross Road, CHENNAI 600113  { 2254 1216, 2254 1442  
                    { 2254 2519, 2254 2315
Western : Manakalaya, E9 MIDC, Marol, Andheri (East)  
MUMBAI 400093  { 2832 9295, 2832 7858  
                    { 2832 7891, 2832 7892

Branches: AHMEDABAD. BANGALORE. BHOPAL. BHBANESHWAR. COIMBATORE. DEHRADUN. FARIDABAD. GHAZIABAD. GUWAHATI. HYDERABAD. JAIPUR. KANPUR. LUCKNOW. NAGPUR. PARWANOO. PATNA. PUNE. RAJKOT. THIRUVANATHAPURAM. VISAKHAPATNAM.

Published by BIS, New Delhi