

INTERNATIONAL STANDARD

ISO
5366-2

Second edition
1993-07-15

Tracheostomy tubes —

Part 2:

Basic requirements for tubes for adults

Tubes de trachéostomie —

Partie 2: Prescriptions de base pour tubes destinés aux adultes



Reference number
ISO 5366-2:1993(E)

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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.

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 5366-2 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 5366-2:1985), of which it constitutes a technical revision.

ISO 5366 consists of the following parts, under the general title *Tracheostomy tubes*:

- Part 1: *Connectors for tubes for adults*
- Part 2: *Basic requirements for tubes for adults*
- Part 3: *Paediatric tracheostomy tubes*

Annexes A and B form an integral part of this part of ISO 5366. Annexes C and D are for information only.

Introduction

This part of ISO 5366 is one of a series dealing with anaesthetic equipment and lung ventilators, and is concerned with the basic requirements and method of size designation of tracheostomy tubes made of plastics materials and rubber. Specialized tubes, for example those without a connector at the machine end intended for spontaneously breathing patients, those with reinforced walls, self-inflating cuffs or tubes made of metal, have been excluded from the scope of ISO 5366.

The method of describing tube dimensions has been devised with the aim of assisting the clinician in the selection of a suitable tube. Size is designated by inside diameter, which is important because of its effect on resistance to gas flow. Because the stomal and tracheal diameters are important when selecting tubes, it is considered essential that the outside diameter should also be stated for each size of tube.

Cuffed tracheostomy tubes may be characterized by a combination of the tube inside and outside diameters and by the cuff resting diameter. 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 5366 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.

Tracheostomy tubes —

Part 2:

Basic requirements for tubes for adults

1 Scope

This part of ISO 5366 specifies basic requirements for tracheostomy tubes made of plastics materials and/or rubber, having inside diameters greater than 6 mm. Such tubes are primarily designed for adult patients who may require anaesthesia, artificial ventilation or other respiratory support, but need not be restricted to these uses. Specialized tubes (see the Introduction) are excluded from the scope of ISO 5366.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 5366. 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 5366 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 5356-1:1987, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets.*

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

ISO 5366-1:1986, *Tracheostomy tubes — Part 1: Connectors.*

3 Definitions

For the purposes of this part of ISO 5366, the following definitions apply.

3.1 tracheostomy (tracheotomy) tube: Tube designed for insertion into the trachea through a tracheostomy (tracheotomy).

3.2 machine end: That end of the tracheostomy tube which is intended to project from the patient.

3.3 patient end: That end of the tracheostomy tube which is intended to be inserted into the trachea.

3.4 centreline length: Distance from the patient side of the neck-plate to the patient end along the centreline (see figure 2).

NOTE 1 When the neck-plate is adjustable, the centreline length is variable.

3.5 outer tube: That part of the tracheostomy tube which is normally in contact with the tissues.

3.6 inner tube: Tube which fits closely to the inside contours of the outer tube (tracheostomy tube).

3.7 cuff: Inflatable balloon fitted near the patient end of the tracheostomy tube to provide an effective seal between the tube and the trachea.

3.8 inflating tube: Tube through which the cuff is inflated. [ISO 4135:—, definition 6.7.10]

3.9 pilot balloon: Balloon fitted to the inflating tube to indicate inflation of the cuff. [ISO 4135:—, definition 6.7.11]

3.10 neck-plate; shield: That part of the device which approximates to the contour of the patient's neck and is used to secure the tube in position.

3.11 introducer; obturator: Specially adapted stylet to facilitate the introduction of the outer tube into the trachea.

3.12 bevel: Slanted portion at the patient end of the tracheostomy tube. [adapted from ISO 4135:—, definition 6.7.5]

3.13 angle of bevel: Acute angle between the plane of the bevel and the longitudinal axis of the tracheostomy tube at the patient end. [adapted from ISO 4135:—, definition 6.7.6]

4 Size

4.1 Designation of inside diameter

The size of a tracheostomy tube (outer tube) shall be designated by the nominal inside diameter (ID) of the tube expressed in millimetres, as measured at the minimum diameter, in accordance with table 1, excluding any encroachment allowed by 6.5.1.

Table 1 — Size range of tracheostomy tubes

Dimensions in millimetres

Designated size (nominal inside diameter, ID)	Inside diameter ± 0,2
6,5	6,5
7,0	7,0
7,5	7,5
8,0	8,0
8,5	8,5
9,0	9,0
9,5	9,5
10,0	10,0
11,0	11,0

4.2 Outside diameter

4.2.1 The outside diameter (OD) of sections A and C (see figure 2) of the tube, other than at the cuff, if provided, shall be expressed in millimetres.

NOTE 2 The marked outside diameter relates to that portion of the tube intended to be within the wall and lumen of the trachea.

4.2.2 The actual outside diameter of section A shall be the marked outside diameter, subject to a tolerance of ± 0,2 mm.

4.2.3 The actual outside diameter of section C shall be the marked outside diameter, subject to a tolerance of ± 0,5 mm.

4.3 Length

4.3.1 The centreline length (dimensions A + B + C in figure 2), shall be measured from the patient side of the neck-plate to the patient end including the bevel, if present (see figure 1), and expressed in millimetres.

4.3.2 The actual centreline length shall not vary by more than 2 mm from the marked length.

4.3.3 Dimensions A, B and C shall be expressed in millimetres.

NOTE 3 Dimensions A and/or B may be, or approach, zero.

4.3.4 For tubes with an adjustable neck-plate the range of centreline lengths shall be expressed in millimetres.

4.4 Angle θ

The angle θ (see figure 2) shall be expressed in degrees.

5 Materials

Tracheostomy tubes, including cuffs, in their ready-for-use state shall be compatible with the human tissues with which they are intended to be used. Compatibility shall be indicated by the implantation test given in annex A, a cell tissue culture test or other tests that give an equivalent indication of freedom from biological hazard.

See annex C for guidance on materials and design.

6 Design

6.1 Machine end

The machine end of tracheostomy tubes shall comply with the requirements specified in ISO 5366-1.

6.2 Neck-plate

6.2.1 Tracheostomy tubes shall have a neck-plate (see figure 2) which may be adjustable or permanently attached to the tube.

6.2.2 The neck-plate shall be provided with holes or other means to permit attachment to the patient.

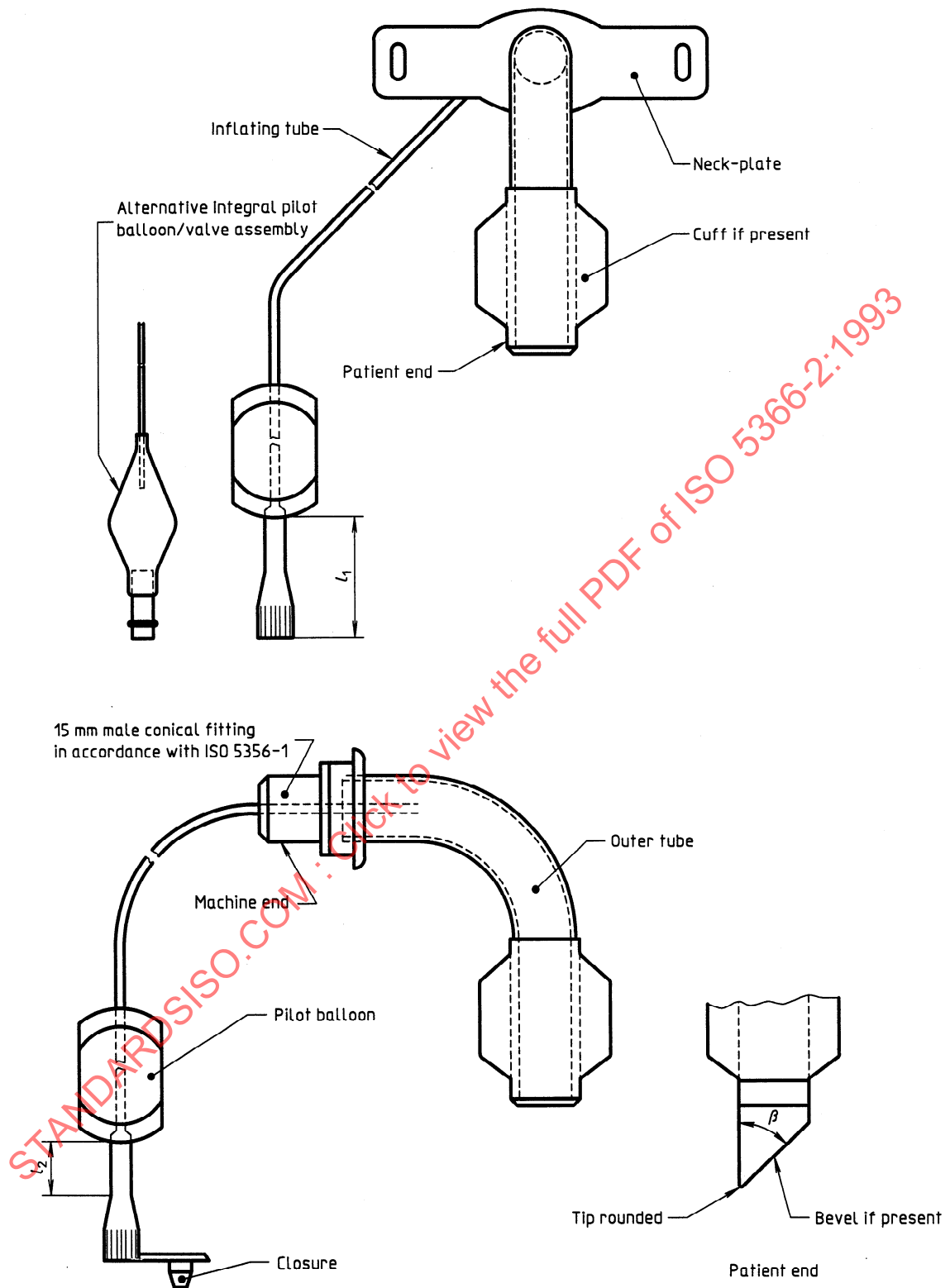


Figure 1 — Typical tracheostomy tube

6.2.3 If a tracheostomy tube has an adjustable neck-plate, it shall be securable to the tube.

6.3 Inner tube

The inner tube shall extend to within 1 mm of the patient end and not more than 1 mm beyond the patient end of the tracheostomy tube with which it is provided.

6.4 Cuff

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

6.4.2 Cuffs of tracheostomy tubes shall comply with the requirements specified in ISO 5361-5.

6.4.3 The cuff resting diameter shall be within $\pm 15\%$ of the marked value when determined as in annex B.

6.5 Inflating tubes for cuffs

6.5.1 Inflating tube

The inflating tube, if fitted, shall have an outside diameter of not more than 2,5 mm. The wall around the secondary (inflation) lumen shall not encroach on the lumen of the tracheostomy tube by more than 10 % of the inside diameter of the tracheostomy tube.

The wall around the secondary (inflation) lumen should not project substantially on the outside surface.

6.5.2 Pilot balloon

6.5.2.1 The inflating tube shall have a pilot balloon and/or other means to indicate inflation of the cuff.

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

6.5.2.2 Neither the inflating tube nor any device shall act as a non-return valve to prevent the intentional evacuation of the cuff.

6.5.3 Free end of inflating tubes for cuffs

The end of the inflating tube may be 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 % taper (Luer), complying with the requirements specified in ISO 594-1. The length (see figure 1, dimension l_1) of the free end of the inflating tube shall be not less than 40 mm unless an inflation valve or closure device is provided.

If an inflation valve or closure device is provided, the length (see figure 1, dimension l_2) between the pilot balloon (or other device) and the 6 % conical fitting shall be not less than 10 mm (for clamping) unless the pilot balloon and valve or closure device are integral.

6.6 Patient end

If a bevel is present, the angle of bevel β shall be not less than 50° (see figure 1 inset).

6.7 Introducer (obturator)

If provided, the introducer when correctly seated shall not fall out of the tracheostomy tube under its own mass when the tube is held by the neck-plate with the patient end uppermost.

The introducer should be freely removable in use.

7 Packaging for tracheostomy tubes supplied sterile

7.1 The following information shall be apparent on visual examination of the intact unit container:

- the size and preformed shape of the tube;
- whether a cuff is provided.

For example, the unit container may be transparent and the tube visible, or a drawing to scale, preferably full scale, may be used.

7.2 Each tracheostomy tube supplied and marked as sterile shall be contained in an individual pack. The pack shall serve as a microbiological barrier. 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.

8 Marking

8.1 Marking of tracheostomy tubes

The neck-plate and/or tracheostomy tube shall be marked with the following:

- the designated size (nominal inside diameter) expressed in millimetres in accordance with 4.1;
- the nominal outside diameter expressed in millimetres in accordance with 4.2;
- the name and/or trademark of the manufacturer.

All markings shall be visible from the machine end.

8.2 Labelling of unit packs

Individual packs or a package insert shall be clearly labelled to indicate the following information:

- a) a description of the contents;
- b) dimensions in accordance with clause 4;
- c) the name and/or trademark of the manufacturer and/or supplier;
- d) the batch number;

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

- e) if relevant, instructions for cleaning and disinfection or sterilization;
- f) the word "STERILE" or "NON-STERILE" as appropriate;
- g) 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^[2] should additionally be used (see figure 3).

- h) for cuffed tubes, the resting diameter of the cuff, determined in accordance with annex B and expressed in millimetres.

8.3 Labelling of inner tube unit packs

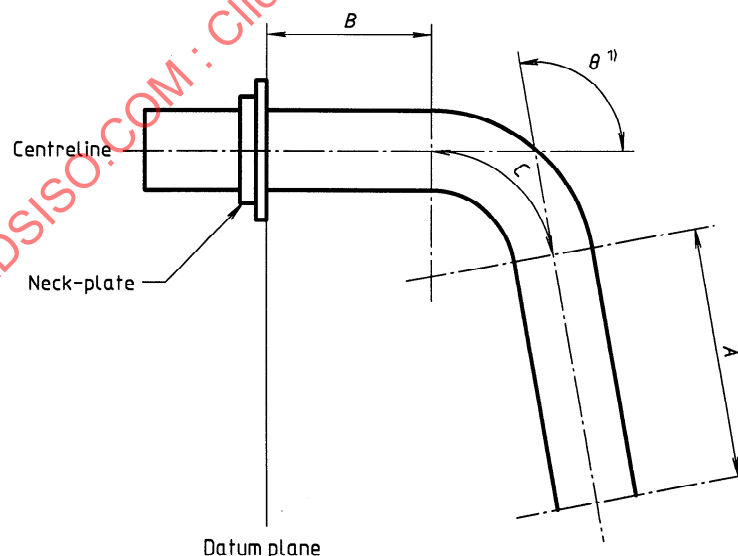
Individual packs shall be clearly labelled to indicate the following:

- a) the size designation of the tracheostomy tube (outer tube) into which it is designed to fit;
- b) the inside diameter (ID) of the inner tube;
- c) a description of the contents;
- d) the name and/or trademark of the manufacturer and/or supplier;
- e) the batch number;

NOTE 6 It is strongly recommended that the expiry date be given.

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

NOTE 7 Symbol No. 1051 ("Do not re-use") given in ISO 7000^[2] should additionally be used (see figure 3).



1) The angle θ is the obtuse angle formed between the long axes of the tube at the machine and patient ends.

Figure 2 — Basic dimensions of tracheostomy tubes

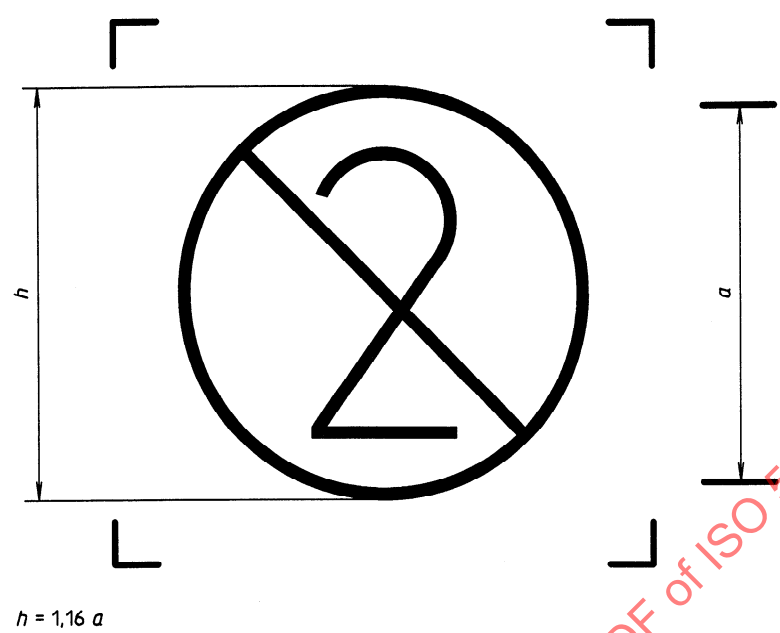


Figure 3 — ISO symbol 7000/1051 “Do not re-use”

Annex A (normative)

Implantation test¹⁾

A.1 General

The implantation test is designed for the evaluation of a plastics material in direct contact with living tissue. Care shall be taken in the preparation of the implant strips and their proper implantation under aseptic conditions.

A.2 Preparation of test samples

Prepare for implantation eight strips of the sample and four strips of USP Negative Control Plastic RS²⁾. Each strip shall measure not less than 10 mm × 1 mm. The edges of the strips should be as smooth as possible to avoid additional mechanical trauma upon implantation. Strips of the specified minimum size shall be implanted by means of a hypodermic needle such as a 15 gauge needle with intravenous point and of 19 mm (0,75 in) cannula length, and a sterile trocar. Use either presterilized needles into which the sterile plastics strips are aseptically inserted, or insert each clean strip into a needle, the cannula and hub of which are protected with an appropriate cover, and then subjected to the appropriate sterilization procedure.

Allowance should be made for proper de-gassing if agents such as ethylene oxide are used.

A.3 Test animal

Select healthy, adult rabbits weighing not less than 2,5 kg, and whose paravertebral muscles are sufficiently large in size to allow for implantation of the test strips. Do not use any muscular tissue other than the paravertebral site. The animals may be anaesthetized with a commonly used anaesthetic

agent to a degree deep enough to prevent muscular movements, such as twitching.

A.4 Procedure

Perform the test in a clean area. On the day of the test or up to 20 h before testing, clip the fur of the animals on both sides of the spinal column. Remove loose hair by means of vacuum.

Implant four strips of the sample into the paravertebral muscle on one side of the spine of each of two rabbits, 2,5 cm to 5 cm from the mid-line and parallel to the spinal column, and about 2,5 cm apart from each other. In a similar fashion implant two strips of USP Negative Control Plastic RS in the opposite muscle of each animal. Insert a sterile stylet into the needle to hold the plastics strips in the tissue while withdrawing the needle. If excessive bleeding is observed after implantation of a strip, place a duplicate strip at another site. Close the incision after implantation is complete.

Keep the animals for a period of not less than 72 h and sacrifice them at the end of the observation period by administering an overdose of an anaesthetic agent. Allow sufficient time to elapse for the tissue to be cut without bleeding. Examine macroscopically the area of the tissue surrounding the centre portion of each implant strip. Use a magnifying lens if necessary. The tissue immediately surrounding the USP Negative Control Plastic RS strips appears normal and entirely free from haemorrhage, film or encapsulation. The requirements of the test are met if, in each rabbit, the reaction to not more than one of the four sample strips is significantly greater than that to the strips of USP Negative Control Plastics RS.

1) Taken from the US Pharmacopeia.

2) USP Negative Control Plastic RS is a tradename for a commercial product available from the US Pharmacopeial Convention Inc., 12601 Twinbrook Parkway, Rockville, Maryland 20852, USA. At present no other products intended for this purpose are known to be available commercially. This information is given for the convenience of the users of this part of ISO 5366 and does not constitute an endorsement of this product by ISO.

Annex B

(normative)

Method for determining resting diameter of cuff

B.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.

B.2 Apparatus

Means to inflate the cuff with sufficient air to create an internal overpressure of 2 kPa (20 cmH₂O) $\pm$ 5 %.

B.3 Procedure

B.3.1 Inflate the cuff with sufficient air to create an internal overpressure of 2 kPa (20 cmH₂O) $\pm$ 5 % and leave to stabilize for 5 min at (23 $\pm$ 2)°C, maintaining that overpressure.

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

B.4 Expression of results

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