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Suction catheters for use in the respiratory tract

Sondes d'aspiration pour les voies respiratoires

Reference number
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Contents

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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 approval before their acceptance as International Standards by the ISO Council. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

International Standard ISO 8836 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*.

Annexes A, B and C of this International Standard are for information only.

Introduction

Suction catheters are commonly inserted through tracheal and tracheostomy tubes (see ISO 5361-1, ISO 5361-2, ISO 5361-3, ISO 5361-4, ISO 5366-2 and ISO 7228).

The need for this International Standard arises from the considerable international trade in suction catheters; at the same time there is a need to provide a range of sizes which will prove acceptable for clinical purposes.

Annex A gives recommendations for materials and annex B gives recommendations for the finish and design of catheters. A bibliography listing those International Standards referred to for information is given in annex C.

Suction catheters for use in the respiratory tract

1 Scope

This International Standard specifies requirements for suction catheters intended for use in suction of the respiratory tract. It covers suction catheters that are supplied either sterile or non-sterile and those that are intended either for single use or to be reused.

2 Normative reference

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

ISO 468 : 1982, *Surface roughness — Parameters, their values and general rules for specifying requirements.*

3 Definitions

For the purposes of this International Standard, the following definitions apply.

3.1 adaptor[1] : Specialized connector to establish functional continuity between otherwise disparate or incompatible components.

3.2 connector[1] : Fitting to join together two or more components.

3.3 effective length : Length of the shaft.

3.4 eye : Aperture in the patient end of the catheter.

3.5 machine end : That end of the catheter which is intended to be connected to a source of vacuum.

NOTE — It may either incorporate a connector or have a conical expansion to facilitate the insertion of a connector.

3.6 patient end : That end of the catheter which is intended to be inserted into the patient.

3.7 shaft : That part of a suction catheter between the connector or conical expansion at the machine end and the tip.

3.8 suction catheter : Flexible tube designed for introduction into the respiratory tract to remove material by suction.

3.9 tip : Extremity of the patient end.

3.10 vacuum control device : Means provided at the machine end of the catheter to control the flow of air and entrained material.

4 Dimensions and size designation

4.1 Dimensions

The outside diameter and the minimum inside diameter of suction catheters shall be as given in table 1 or table 2, as appropriate.

NOTE — For the purposes of this International Standard, the Charrière gauge system of size is based on the outside diameter of the shaft gauged in steps of thirds of a millimetre; the Charrière gauge size is not an SI unit. It is anticipated that the use of suction catheters manufactured in Charrière sizes will decline in the future and the use of metric size catheters will become prevalent. It is therefore intended to revise this International Standard five years after its publication to delete reference to the Charrière gauge sizes.

1) Definitions taken from ISO 4135.

Table 1 — Basic dimensions of suction catheters — Metric sizes

Dimensions in millimetres

Outside diameter			Charrière size equivalent[1]	Minimum inside diameter	
	tol.				
	Plastics materials	Rubber		Plastics materials	Rubber
1,5	± 0,1	± 0,15	4,5 *F*	0,8	0,4
2	± 0,1	± 0,15	6 *F*	1,05	0,8
2,5	± 0,1	± 0,25	7,5 *F*	1,45	1,1
3	± 0,15	± 0,25	9 *F*	1,75	1,4
4	± 0,15	± 0,25	12 *F*	2,45	2,1
5	± 0,2	± 0,25	15 *F*	3,2	2,7
6	± 0,2	± 0,25	18 *F*	3,9	3,4

1) The letters "*Ch*" may replace the letter "*F*" in the size designation (see 4.2); 1 *F* or 1 *Ch* is equal to one-third of a millimetre.

Table 2 — Basic dimensions of suction catheters — Charrière sizes

Dimensions in millimetres

Charrière size[1]		Outside diameter		Minimum inside diameter	
		tol.			
		Plastics materials	Rubber	Plastics materials	Rubber
4 *F*	1,32	± 0,1	—	0,55	—
5 *F*	1,67	± 0,1	± 0,15	0,8	0,4
6 *F*	2	± 0,1	± 0,15	1,05	0,8
8 *F*	2,67	± 0,1	± 0,25	1,5	1,2
10 *F*	3,33	± 0,15	± 0,25	2	1,7
12 *F*	4	± 0,15	± 0,25	2,45	2,1
14 *F*	4,7	± 0,2	± 0,25	2,95	2,5
16 *F*	5,33	± 0,2	± 0,25	3,4	3
18 *F*	6	± 0,2	± 0,25	3,9	3,4

1) The letters "*Ch*" may replace the letter "*F*" in the size designation (see 4.2); 1 *F* or 1 *Ch* is equal to one-third of a millimetre.

4.2 Size designation

The size of suction catheters shall be designated by the following characteristics :

a) the outside diameter of the shaft, expressed in millimetres;

b) the nominal effective length, expressed in millimetres, with a tolerance of ± 5 %.

The size shall be expressed according to the following designation example :

6 mm (18 *F*) × 500 mm

or

6 mm (18 *Ch*) × 500 mm

NOTE — For recommendations regarding the appropriate size of suction catheter, attention is drawn to the following article : ROSEN, M. and HILLARD, E.K., The use of suction in clinical medicine, *Br. J. Anaesth.*, **32**, 1960 : pp. 486-504.

5 Design

5.1 Lumen

The inside diameter of the shaft at any point between the machine end and the eye nearest to the machine end shall be not less than the inside diameter of the shaft at that eye.

5.2 Patient end

The catheter shall have a terminal orifice and one or more eyes.

NOTE — The dimensions of an eye or eyes should be such that they do not cause the suction catheter to kink or collapse in use.

5.3 Machine end

5.3.1 The machine end of the suction catheter shall be either

a) female (see 5.3.2) — designed to receive a male-to-male adaptor suitable for connection to a vacuum source that terminates in a female end; or

b) male (see 5.3.3) — designed for connection to a vacuum source that terminates in a female end.

5.3.2 Female ends shall be semi-rigid or elastomeric and shall be either conical or cylindrical over a length of not less than 25 mm (see figure 1). When tested in accordance with 7.1, the female end shall not part from the test connector.

NOTE — In the event of a female end to the suction catheter and a female end to the vacuum source, a male-to-male adaptor is needed (see figure 1). The minimum inside diameter should be not less than the minimum inside diameter of the suction catheter.

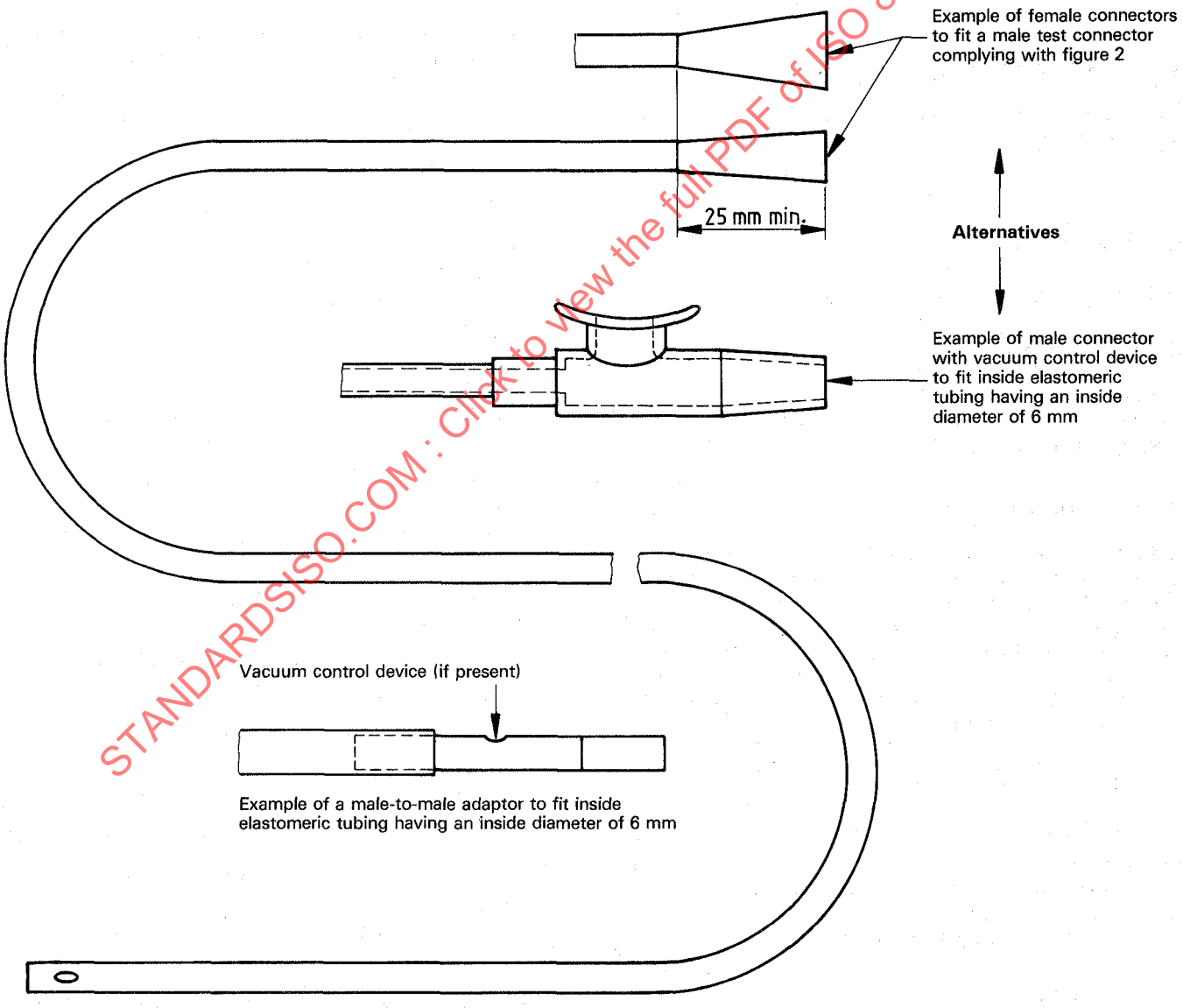
5.3.3 Male ends shall be rigid or semi-rigid and shall fit inside elastomeric tubing having an inside diameter of 6 mm (see figure 1).

NOTE — A means may be provided near the machine end to facilitate control of the vacuum by the operator.

5.3.4 The machine end of a suction catheter having an angulated patient end shall, by a mark or other means, indicate the direction in which the tip points.

5.4 Shaft

When the machine end of the suction catheter is connected to a vacuum source at 40 kPa (300 mmHg) below ambient pressure for 15 s at a temperature of 23 °C ± 2 °C with the patient end occluded and, if present, the vacuum control device occluded, the shaft shall not collapse.



NOTE — The figure is intended to illustrate essential features of a suction catheter but does not otherwise form part of the requirements specified in this International Standard.

Figure 1 — Example of a suction catheter for use in the respiratory tract

6 Performance requirements

6.1 Security of construction

When tested in accordance with 7.2, the force required to detach any component bonded to the shaft shall be not less than that specified in table 3.

Table 3 — Minimum force needed to detach any component bonded to shaft

Designated size (outside diameter) mm	Minimum force N
1,32 to 2,67	5
3 to 4,7	15
5 and greater	20

6.2 Residual vacuum

When tested in accordance with 7.3, the residual vacuum shall not exceed 0,33 kPa.

7 Test methods

7.1 Security of fit of female ends

7.1.1 Principle

Fitting of a specified test connector to the female end of the suction catheter and application of an axial extensional force to test the security of the connection.

7.1.2 Apparatus

7.1.2.1 Test connector, made from metal, with the dimensions as shown in figure 2 and having a surface roughness of 0,8 µm (roughness number N6) when determined as specified in ISO 468. For testing suction catheters with outside diameters of up to and including 3 mm, diameter A shall be either 4 mm ± 0,1 mm or 6 mm ± 0,1 mm. For testing suction catheters with outside diameters greater than 3 mm, diameter A shall be 6 mm ± 0,1 mm.

7.1.2.2 Clamp for suspending the suction catheter.

7.1.2.3 Device for attaching a weight to the test connector and a weight, the combined mass of connector, device and weight being 0,75 kg for testing catheters with outside diameters of up to and including 3 mm and 1 kg for testing those with outside diameters greater than 3 mm.

7.1.2.4 Stopwatch.

7.1.3 Test conditions

7.1.3.1 The test shall be carried out at a temperature of 23 °C ± 2 °C.

7.1.3.2 Ensure that the female end of the catheter and the test connector are clean and dry.

7.1.4 Test procedure

7.1.4.1 Fit the appropriate test connector (7.1.2.1) into the female end to a depth of engagement of, or exceeding, 10 mm (i.e. up to, or beyond, the mark circumscribed on the connector).

7.1.4.2 Suspend the catheter by clamping it between 30 mm and 60 mm from the female end.

7.1.4.3 Manually support the weight. Attach the weight to the test connector and gently lower the weight until it is freely suspended from the connector. Allow it to remain in this position for 1 min, and observe.

7.1.4.4 Record whether the test connector becomes detached from the female end of the suction catheter.

Dimensions in millimetres

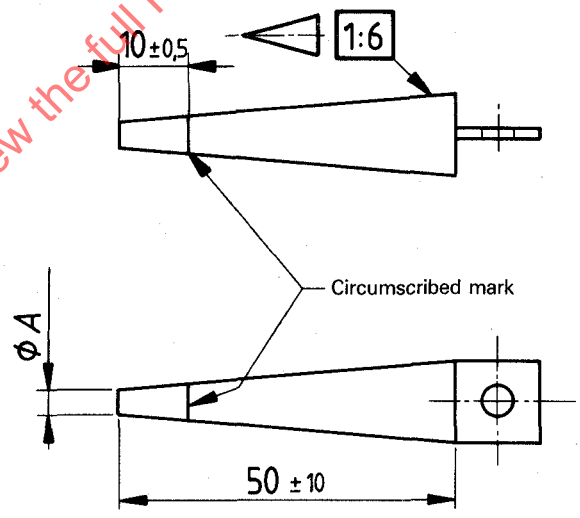


Figure 2 — Test connector for testing security of fit of female ends

7.2 Security of construction

7.2.1 Test conditions

The test shall be carried out at an ambient temperature of 23 °C ± 2 °C.

7.2.2 Procedure

Clamp the component under test into a vice and attach the shaft of the suction catheter to a spring force gauge or tensometer. Separate the two ends of the catheter at a rate of 200 mm/min and observe whether the component becomes detached from the shaft before the appropriate minimum force given in table 3 has been reached.

7.3 Residual vacuum

7.3.1 Principle

Assessment of the effectiveness of the suction control device as a means of relieving vacuum at the patient end. Measurement of the residual vacuum at the tip of the catheter with the suction control device in the relief position and with suction being applied to the machine end of the catheter.

7.3.2 Apparatus

7.3.2.1 Pneumotachograph or **gas meter,** capable of measuring a flow rate of 30 l/min with an accuracy of within 5 %.

7.3.2.2 Adjustable vacuum pump.

7.3.2.3 Water manometer.

7.3.3 Procedure

7.3.3.1 Assemble the apparatus, as shown in figure 3, with the pneumotachograph or gas meter (7.3.2.1) fitted to the exit of the vacuum pump (7.3.2.2), ensuring an airtight fit between the catheter and the manometer.

7.3.3.2 Open the suction control device to the relief position.

7.3.3.3 Switch on the vacuum pump and adjust the applied vacuum until a flow rate of 30 l/min is indicated on the pneumotachograph or gas meter.

7.3.3.4 Observe and record the residual vacuum as indicated by the reading on the water manometer (7.3.2.3).

8 Packaging

8.1 Suction catheters supplied sterile

8.1.1 Unit container

Each catheter shall be sealed in a unit container which permits subsequent sterilization of the contents.

NOTE — It is essential that the material and design of this container

a) maintain sterility of the contents under dry, clean and adequately ventilated storage conditions and protect the contents from contamination;

b) do not cause deformation or physical damage, including kinking, during normal handling, transit and storage;

c) ensure that, once opened, it cannot be resealed easily and that it is obvious that the container has been opened.

8.1.2 Outer packaging

Unit containers shall be packed into a shelf or multi-unit container.

NOTES

1 The shelf container should protect the contents from physical damage, deformation, contamination and light until time for use.

2 In addition, shelf or multi-unit containers may be packed into a transit container which provides protection from physical damage and contamination during distribution and storage.

8.2 Suction catheters supplied non-sterile

Suction catheters supplied non-sterile shall not be packed in unit containers.

NOTES

1 Non-sterile catheters should be packed into a container which provides protection during storage from contamination, deformation or physical damage, including kinking, during normal handling, transit and storage.

2 An additional outer or transit container may be used to provide protection from physical damage and contamination during distribution and storage.

9 Marking

NOTE — The nominal outside diameter, expressed in millimetres or Charrière gauge, may be marked on the suction catheter.

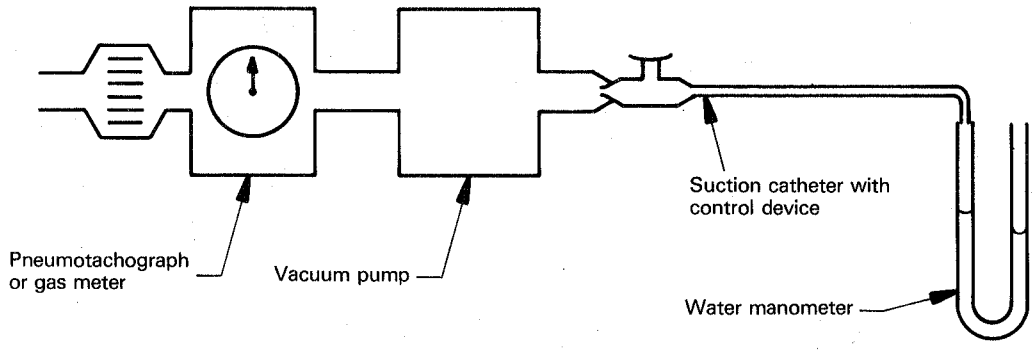


Figure 3 — Apparatus for residual vacuum test