INTERNATIONAL STANDARD

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Suction catheters for use in the respiratory tract

Sondes d'aspiration pour les voies respiratoires

Reference number

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.

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 8836 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment,* Subcommittee SC 2, *Tracheal tubes and other equipment.*

This second edition cancels and replaces the first edition (ISO 8836:1988), of which it constitutes a technical revision.

It differs from ISO 8836:1988 in that it introduces a table of colour identification for use with suction catheters and it no longer includes requirements for suction catheters made of rubber.

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

Introduction

This International Standard specifies dimensions and requirements for suction catheters for use in the respiratory tract.

Size is designated by outside diameter which is important when selecting catheters, because of its relationship to the ease with which the catheter can be passed through a tracheal or tracheostomy tube (see ISO 5361 for details of requirements for tracheal tubes and tracheostomy tubes). Requirements for suction catheters made of rubber have been deleted because they are no longer in general use.

Table 1 has been introduced in order to standardize the (optional) use of colour identification for designating size of suction catheters. The sizes and colours listed in table 1 have been included as a result of a survey of current practice by manufacturers of suction catheters. No attempt has been made to standardize the colour identification of size designations not listed in table 1. Such tubes are permitted at the manufacturer's discretion.

Flammability of suction catheters, for example if flammable anaesthetics, electrosurgical units or lasers are used, is a well-recognized hazard[1)] that is addressed by appropriate clinical management, and is outside the scope of this International Standard.

1) See ISO/TR 11991

Suction catheters for use in the respiratory tract

1 Scope

This International Standard specifies requirements for suction catheters made of plastic materials and intended for use in suction of the respiratory tract.

Specialized suction catheters, e.g. those with more than one lumen, are excluded from the scope of this International Standard. Angled-tip suction catheters (e.g. Coudé catheters) are not considered to be specialized and are therefore included in the scope.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were 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 standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 10993-1: —[1], *Biological evaluation of medical devices - Part 1 : Guidance on selection of tests*

ISO 11607:1997, *Packaging for terminally sterilized medical devices*

EN 556 : 1994, *Sterilization of medical devices - Requirements for medical devices to be labelled 'STERILE'*

3 Definitions

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

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

3.2 connector: Fitting to join together two or more components. [ISO 4135]

3.3 eye: Lateral aperture near the patient end of the catheter. [ISO 4135]

3.4 machine end: That end of the catheter which is intended to be connected to a source of vacuum. [ISO 4135]

[1] To be published. (Revision of ISO 10993-1:1992)

3.5 patient end: That end of the catheter which is intended to be inserted into the patient. [ISO 4135]

3.6 residual vacuum: Negative pressure at the patient end of the suction catheter when the vacuum control device is in the relief position.

3.7 shaft: Main part of the catheter which is of uniform outside diameter.

3.8 suction catheter: Flexible tube designed for introduction into a respiratory tract to remove material by suction. [ISO 4135]

3.9 terminal orifice: Central opening of the patient end of the suction catheter.

3.10 tip: Extremity of the patient end of a catheter. [ISO 4135]

3.11 vacuum control device: Means provided at or near the machine end of a catheter to control the flow of air and entrained material.

4 Size designation and dimensions

4.1 Size designation

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

a) the nominal outside diameter of the shaft, expressed in millimetres. It may additionally be expressed in French (Charrière) gauge size;

b) the nominal shaft length, expressed in millimetres.

4.1.2 The size of the device may additionally be designated by use of colour identification at the machine end. If a colour code is used it shall be in accordance with table 1 for the designated sizes listed.

NOTE - Use and choice of colour identification for designated sizes not listed in table 1 are at the manufacturer's discretion.

Table 1 - Colour identification for designated size of suction catheter

Designated size		Colour identification
Nominal outside diameter mm	**French (Charrière) size equivalent**	
1,67	5	grey
2,0	6	light green
2,5	7,5	pink
2,67	8	light blue
3,0	9	turquoise
3,33	10	black
4,0	12	white
4,67	14	green
5,0	15	brown
5,33	16	orange
6,0	18	red
6,67	20	yellow

4.2 Dimensions

4.2.1 The outside diameter and the minimum inside diameter of suction catheters, excluding the tip, shall be in accordance with table 2.

NOTE - For the purposes of this International Standard, the French (Charrière) gauge system of size (F) is based on the outside diameter of the shaft gauged in steps of thirds of a millimetre (1 millimetre corresponds to 3F); the French (Charrière) gauge size is not an SI unit. Size designation in millimetres facilitates matching suction catheter outside diameter to the inside diameter of the tracheal or tracheostomy tube.

4.2.2 The minimum inside diameter at the tip shall be not less than 90 % of the inside diameter specified in table 2.

4.2.3 The actual shaft length shall be the marked shaft length subject to a tolerance of ± 5 %.

Table 2 - Basic dimensions of suction catheters - Metric sizes

Designated size		Outside diameter tolerance	Minimum inside diameter
Nominal outside diameter mm	French (Charrière) size equivalent F or Ch	mm	mm
1,33	4	±0,1	0,55
1,5	4,5	±0,1	0,7
1,67	5	±0,1	0,8
2	6	±0,1	1,05
2,5	7,5	±0,1	1,45
2,67	8	±0,1	1,5
3	9	±0,15	1,75
3,33	10	±0,15	2
4	12	±0,15	2,45
4,67	14	±0,2	2,95
5	15	±0,2	3,2
5,33	16	±0,2	3,4
6	18	±0,2	3,9
6,67	20	±0,2	4,3

5 Materials

Suction catheters for use in the respiratory tract, in their ready-to-use state after any preparation for use recommended by the manufacturer, shall satisfy appropriate biological safety testing, as indicated in ISO 10993-1.

NOTE - It is recommended that the shaft be colourless and either transparent or translucent.

6 Design

6.1 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.

6.2 Patient end

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

NOTE 1 - The use of a catheter with eye(s) may reduce the likelihood of trauma during suctioning.

NOTE 2 - The dimensions of the eye(s) should be such that they do not cause the suction catheter to kink or collapse in use.

6.2.2 The axis of the patient end may be at an angle to the long axis of the shaft (see Coudé catheter tip in figure 1).

6.3 Machine end

6.3.1 The machine end of the suction catheter shall be either:

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

b) male - designed for connection to a vacuum source that terminates in a female end; or

c) a permanently attached vacuum control device that terminates in either a male or female end.

6.3.2 Female ends shall be semi-rigid or elastomeric and shall be either conical or cylindrical (see figure 1) over a length of not less than 20 mm.

NOTE - Where a suction catheter with a female machine end is provided for use with a vacuum source with a female end, a male-to-male adaptor is needed. The minimum inside diameter of the adaptor should be not less than the minimum inside diameter of the suction catheter with which it is provided. The adaptor should fit inside elastomeric tubing having an inside diameter of 6 mm.

6.3.3 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 - It is advantageous if the male end fits inside elastomeric tubing with a larger inside diameter which may be used in emergency to clear the airway.

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

7 Performance requirements

7.1 Security of construction

When tested in accordance with annex A, the force required to detach any component permanently attached to the shaft shall be not less than that specified in table 4.

Table 4 - Minimum force needed to detach any component permanently attached to shaft

Designated size (outside diameter) mm	Minimum force N
1,33 to 2,67	5
3 to 4,67	15
⩾5	20

7.2 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 ± 2) °C with the patient end occluded and, if present, the vacuum control device occluded, the shaft shall not collapse.

7.3 Residual vacuum

When a suction catheter fitted with a permanently attached vacuum device is tested in accordance with annex B, the residual vacuum shall not exceed 0,33 kPa (2,5 mmHg).

8 Requirements for suction catheters supplied sterile

8.1 Sterility assurance

Suction catheters supplied and marked as "STERILE" shall satisfy the requirements in 4.1 of EN 556:1994.

8.2 Packaging of suction catheters supplied sterile

8.2.1 Each suction catheter supplied and marked as "STERILE" shall be contained in an individual pack.

8.2.2 The pack shall serve as an effective barrier to the penetration of microorganisms and particulate material in accordance with ISO 11607.

8.2.3 The pack shall permit the aseptic extraction of the contents and shall not be capable of reclosure without clearly revealing that it has been opened.

8.2.4 Individual packs shall be contained within a shelf or multi-unit pack.

9 Marking

NOTE - Marking of suction catheters, packages and inserts and information to be supplied by the manufacturer should comply with EN 1041.

9.1 Marking of suction catheters

9.1.1 Suction catheters that are not individually packaged shall be marked with the nominal outside diameter in accordance with 4.1.

9.1.2 Suction catheters that are individually packaged may be marked with the nominal outside diameter, expressed as millimetres or French (Charrière) gauge (see 4.1).

NOTE - Manufacturers of the smaller sizes of suction catheters for paediatric use are encouraged to also mark the distance, in centimetres or parts thereof, from the patient end.

9.2 Use of symbols

The requirements of 9.3 and 9.4 may be met by the use of appropriate symbols as given in ISO 7000 or EN 980.