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Suction catheters for use in the respiratory tract

Sondes d'aspiration pour les voies respiratoires

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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 are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. 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.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

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

This third edition cancels and replaces the second edition (ISO 8836:1997) certain clauses of which have been technically revised. Suction catheters are now required to have more than one orifice, except when used in low vacuum systems or under direct vision. Material characteristics and requirements related to suction catheters were previously informative but are now normative to comply with the Essential Requirements of the Medical Device Directives. They have been moved from an informative annex to normative requirements in the body of the standard. Table 1 (colour identification) has been combined with Table 2 (metric dimensions).

This corrected version of ISO 8836 contains changes to the Normative references on page 1.

ISO 11607 has been replaced by ISO 11607-1 and ISO 11607-2. The reference in subclause 8.2.2 on page 6 has been altered.

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).

Flammability of suction catheters, for example if flammable anaesthetics, electrosurgical units or lasers are used, is a well-recognised 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 and suction catheters without a terminal orifice, are excluded from the scope of this International Standard.

Angled-tip suction catheters (e.g. Coudé catheters) and suction catheters with aspirator collectors are not considered to be specialized and are therefore included in the scope of this International Standard.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management system*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 11607-2, *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes*

EN 556-1:2001, *Sterilization of medical devices — Requirements for medical devices to be designated "STERILE" — Part 1: Requirements for terminally sterilized medical devices*

EN 1041, *Information supplied by the manufacturer with medical devices*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
adaptor
specialized connector to establish functional continuity between otherwise disparate or incompatible components

[ISO 4135, defintion 4.2.3.1]

3.2
connector
fitting to join together two or more components

[ISO 4135, defintion 4.2.2.1]

3.3
eye
side hole near the patient end of the catheter

[ISO 4135, definition 8.3.6]

3.4
machine end
⟨suction catheter⟩ that end of the catheter which is intended to be connected to a source of vacuum

[ISO 4135, definition 8.3.2]

3.5
patient end
⟨suction catheter⟩ that end of the catheter which is intended to be inserted into a patient

[ISO 4135, definition 8.3.3]

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 suction catheter which is of uniform outside diameter

3.8
suction catheter
flexible **shaft** (3.7) with a **machine end** (3.4) and **patient end** (3.5) for use in the respiratory tract to facilitate suction of tracheobronchial secretions

3.9
terminal orifice
central aperture at the patient end of the suction catheter

[ISO 4134, defintion 8.3.5]

3.10
tip
extremity of the patient end of a suction catheter

[ISO 4135, definition 8.3.4]

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

[ISO 4135, definition 8.3.9]

4 Size designation and dimension

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 (Charriere) gauge size (see Table 1);

b) the nominal shaft length, expressed in millimetres.

4.1.2 The size of the device shall be designated by use of colour identification at the machine end, in accordance with Table 1, for the designated sizes listed.

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

4.1.3 The 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		Outside diameter tolerance	Minimum inside diameter	Colour identification
French (Charriere) equivalent (F)	Nominal outside diameter (mm)	(mm)	(mm)	
4	1,33	± 0,10	0,55	Purple
4,5	1,5	± 0,10	0,70	Blue
5	1,67	± 0,10	0,80	Grey
6	2,0	± 0,10	1,0	Light green
6,5	2,1	± 0,10	1,1	Yellow green
7	2,33	± 0,10	1,25	Ivory
7,5	2,5	± 0,10	1,45	Pink
8	2,67	± 0,10	1,50	Light blue
9	3,0	± 0,15	1,75	Turquoise
10	3,33	± 0,15	2,00	Black
12	4,0	± 0,15	2,45	White
14	4,67	± 0,20	2,95	Green
15	5,0	± 0,20	3,20	Brown
16	5,33	± 0,20	3,40	Orange
18	6,0	± 0,20	3,90	Red
20	6,67	± 0,20	4,30	Yellow

4.2 Dimension designation

4.2.1 The outside diameter and the minimum inside diameter of suction catheters, excluding the tip, shall be in accordance with Table 1.

NOTE 1 For the purposes of this International Standard, the French gauge system of size (F) is based on the outside diameter of the shaft gauged in steps of thirds of a millimetre (1mm corresponds to 3F).

NOTE 2 The French gauge size is not an SI unit. Size designation in millimetres facilitates matching the 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 1.

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

5 Materials

5.1 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.

5.2 The inside surface of the suction catheter shall be smooth and free from irregularities. Test by visual inspection.

5.3 The outside surface of the suction catheter shall be free from characteristics which would hinder easy insertion through all types of plastic, rubber and metal oro- and naso-tracheal tubes, tracheostomy tubes and appropriate connectors. Test by visual inspection.

5.4 The outside surface of the shaft should be finished so as to reduce surface drag.

5.5 The materials used for the manufacture of suction catheters should allow construction of a suction catheter with the thinnest possible wall, which at the same time maintains resistance to collapse and kinking.

5.6 Suction catheters under normal conditions of use should be resistant to deterioration by anaesthetic vapours and gases.

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 Suction catheters, on which the terminal end cannot be observed during use or are for use with suction systems operating at a vacuum pressure $>$ 40 cm H_2O, (3,92 kPa) shall have a terminal orifice and at least one side hole within 2 cm of the terminal orifice.

6.2.2 Suction catheters that can be observed during use, or are for use with suction systems operated at vacuum from 0 cm H_2O to 40 cm H_2O (3,92 kPa), need not have a side hole.

6.2.3 The terminal orifice shall have an opening equal to at least 90 % of the inside diameter of the catheter.

6.2.4 The tip and side orifices shall be smooth. Test by visual inspection.

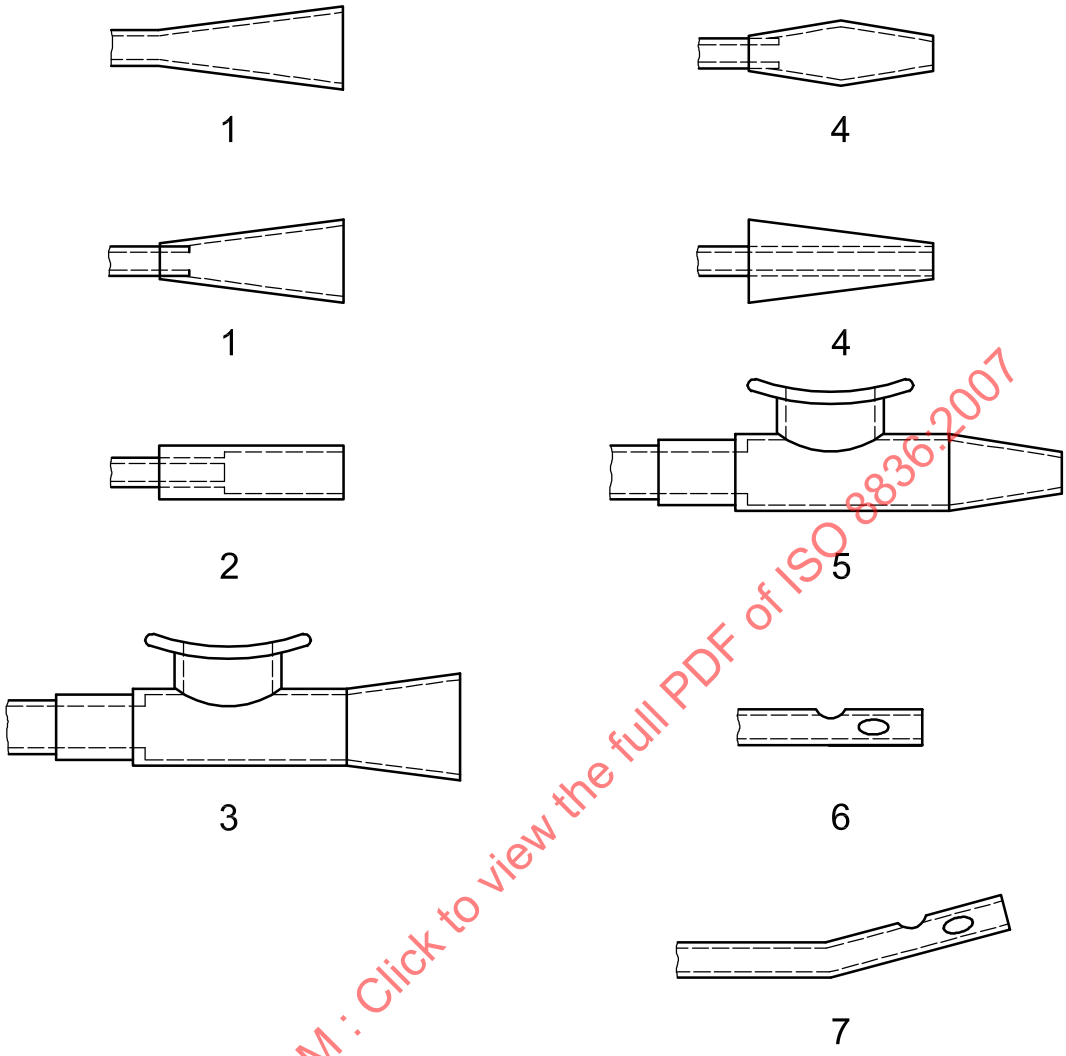
6.2.5 The side hole(s) should not cause the suction catheter to kink or collapse during use.

6.2.6 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 permanently attached to the shaft and shall meet the requirements of 7.1.

6.3.2 The machine end shall have an internal diameter equal to or greater than the internal diameter of the shaft to which it is attached.



Key

1 female conical
2 female cylindrical
3 female connector with vacuum control device
4 male
5 male connector with vacuum control device
6 catheter tip with eyes
7 Coudé catheter tip with eyes

Figure 1 — Examples of different designs for machine ends and patient ends of suction catheters for use in the respiratory tract

6.3.3 Any machine end adaptor shall have an internal diameter equal to or greater than the internal diameter of the catheter with which it is provided.

6.3.4 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.

6.3.5 The adaptor should fit inside elastomeric tubing having an inside diameter of 6 mm.

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

6.3.7 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.

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 2.

Table 2 — Minimum force needed to detach any component permanently attached to the 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 (408 cmH_2O) 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 Vacuum control device

When a suction catheter fitted with a permanently attached vacuum control device is tested in accordance with Annex B, the residual vacuum shall not exceed 0,33 kPa (3,4 cmH_2O).

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 556-1:2001.

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 11607-1 and ISO 11607-2.

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

9.1 Marking of suction catheters

9.1.1 Marking of suction catheters shall comply with EN 1041.

9.1.2 Suction catheters shall be marked with the outside diameter in accordance with 4.1. Suction catheters may, in addition, be marked with the French gauge [see 4.1.1 a)].

9.1.3 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.

9.1.4 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.

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.

9.3 Labelling of individual packs

9.3.1 Labelling of individual packs shall comply with EN 1041.

9.3.2 The labelling of individual packs shall include the following:

a) a description of the contents;

b) the designated size in accordance with 4.1.1, expressed in accordance with one or both of the following examples: 6 mm × 500 mm, or 6 mm (18F) × 500 mm;

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

d) the batch number;

e) where appropriate, an indication of the date by which the catheter should be used, expressed as the year and month;

f) where appropriate, the word “STERILE” and the method of sterilization;

g) for suction catheters not intended for re-use, the words “single use” or equivalent.

9.4 Labelling of shelf/multi-unit packs

9.4.1 Labelling of shelf/multi-unit packs shall comply with EN 1041.

9.4.2 The labelling of shelf/multi-unit packs shall include the following:

a) a description of the contents;

b) the designated size in accordance with 4.1.1, expressed in accordance with one or both of the following examples: 6 mm × 500 mm, or 6 mm (18F) × 500 mm;

c) the name and/or trademark and address of the manufacturer and/or supplier;

d) the batch number;

e) where appropriate, an indication of the date by which the catheter should be used, expressed as the year and month;

f) appropriate instructions on preparation for use;

g) where appropriate, the word “STERILE” and the method of sterilization;

h) for suction catheters intended for re-use, instructions for cleaning and disinfection or sterilization;

i) for suction catheters not intended for re-use, the words “single use” or equivalent.

Annex A
(normative)

Test methods

A.1 Principle

The security of attachment of any component permanently attached to the shaft is tested by applying an axial separation force to the component relative to the shaft of the suction catheter.

A.2 Apparatus

A.2.1 Means of conditioning the suction catheter at (23 ± 2) °C at (50 ± 20) % relative humidity and carrying out the test under the same conditions.

A.2.2 Means of separately securing the component under test and the shaft of the suction catheter and separating the two at a rate of (200 ± 20) mm/min and measuring and recording the axial separation force applied.

A.3 Procedure

A.3.1 Condition the suction catheter at (23 ± 2) °C and at (50 ± 20) % relative humidity for 1 h and carry out the test under the same conditions.

A.3.2 Separate the component under test and the shaft of the catheter at a rate of (200 ± 20) mm/min and observe whether the component becomes detached from the shaft before the appropriate minimum force, given in Table 2, has been reached.

A.4 Expression of results

Record whether the component becomes detached from the shaft before the appropriate minimum force, given in Table 2, has been reached.