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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ISO 11607 has been replaced by ISO 11607-1 and ISO 11607-2.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.