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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Airways and related equipment*.

This fifth edition cancels and replaces the fourth edition (ISO 8836:2014), which has been technically revised. The main changes compared to the previous edition are as follows:

— it is no longer a requirement to have only male-type *suction catheter connector* on the *suction catheter*;

— the female-type suction catheter connector has been reinstated following removal in the fourth edition of this document;

— the terms and definitions have been revised;

— the conditions for the measurement of *residual vacuum* in *closed suction catheters* have been revised.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

This document is concerned with the basic requirements and method of size designation of both *open* and *closed suction catheters* made of flexible materials.

The method of describing tube dimensions and configuration has been devised in order to assist clinicians in the selection of the most suitable *suction catheter* for a particular patient. The size designation is important when selecting a catheter because of its relationship to the ease with which the catheter can be passed through a *tracheal or tracheostomy tube*[2][3].

Throughout this document the following print types are used:

— Requirements and definitions: roman type;

— *Conformance checks and test specifications: italic type;*

— Informative material appearing outside of tables, such as notes, examples and references: smaller type. The normative text of tables is also in smaller type;

— *defined terms: italics*.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex A.

Suction catheters for use in the respiratory tract

1 Scope

This document specifies dimensions and requirements for both *open* and *closed suction catheters* made of flexible materials and intended for use in suctioning of the respiratory tract.

Suction catheters intended for use with flammable anaesthetic gases or agents, lasers or electrosurgical equipment are not covered by this document.

NOTE For guidance on airway management during laser surgery of the upper airway, see ISO/TR 11991[4].

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 5356-1, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*

ISO 5367:2014, *Anaesthetic and respiratory equipment — Breathing sets and connectors*

ISO 18190:2016, *Anaesthetic and respiratory equipment — General requirements for airways and related equipment*

ISO 18562-1, *Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process*

ISO 80369-7, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
***closed suction catheter**
suction catheter (3.17) enclosed within a *protective sleeve* (3.8) that allows its use within the airway without opening the *breathing system* directly to atmosphere

3.2
***closed suction catheter manifold**
part of the *closed suction catheter* (3.1) that provides a connection to an airway device

3.3
connector
fitting to join together two or more components

[SOURCE: ISO 4135:2001, 4.2.2.1]

3.4
eye
side hole near the *patient end* (3.6) of the *suction catheter* (3.17)

3.5
machine end
that end of the catheter which is intended to be connected to suction tubing

3.6
patient end
that end of the *suction catheter* (3.17) which is intended to be inserted into a patient

[SOURCE: ISO 4135:2001, 8.3.3]

3.7
patient connection port
opening intended for connection to an airway device

3.8
protective sleeve
flexible barrier that encloses the *suction catheter* (3.17) *shaft* (3.15) to prevent contact with the user while connected to the *VBS* (3.23)

3.9
residual vacuum
negative pressure at the *tip* (3.21) of the *closed suction catheter* (3.1) when the *suction control device* (3.19) is in the relief position

3.10
risk
combination of the probability of occurrence of harm and the severity of that harm

[SOURCE: ISO 14971:2019, 3.18]

3.11
risk analysis
systematic use of available information to identify hazards and to estimate the *risk* (3.10)

[SOURCE: ISO 14971:2019, 3.19]

Note 1 to entry: *Risk analysis* includes examination of different sequences of events that can produce hazardous situations and harm (see ISO 14971:2019, 5.4).

3.12
risk assessment
overall process comprising a *risk analysis* (3.11) and a *risk evaluation*

[SOURCE: ISO 14971:2019, 3.20]

3.13
risk management
systematic application of management policies, procedures and practices to the tasks of analysing, evaluating, controlling and monitoring *risk* (3.10)

[SOURCE: ISO 14971:2019, 3.24]

3.14
risk management file
set of records and other documents that are produced by *risk management* (3.13)

[SOURCE: ISO 14971:2019, 3.25]

3.15
shaft
main part of the *suction catheter* (3.17) which is of uniform outside diameter

3.16
single-fault condition
condition in which a single means for reducing a *risk* (3.10) is defective or a single abnormal condition is present

3.17
suction catheter
flexible tube designed for introduction into the respiratory tract or an airway device to remove material by suction

3.18
***suction catheter connector**
connector (3.3) at the *machine end* (3.5) of the *suction catheter* (3.17) that allows a connection to suction tubing

3.19
suction control device
means provided at or near the *machine end* (3.5) of a *suction catheter* (3.17) to control the level of suction in the *suction catheter*

Note 1 to entry: *Suction control devices* can be integrated into the *suction catheter connector* or be a stand-alone device that attaches to the *suction catheter connector*.

3.20
terminal orifice
central aperture at the *tip* (3.21) of the *suction catheter* (3.17)

3.21
tip
extremity of the *patient end* (3.6) of a *suction catheter* (3.17)

[SOURCE: ISO 4135:2001, 8.3.4]

3.22
vacuum
pressure less than atmospheric pressure

Note 1 to entry: It is usually expressed as a difference from atmospheric pressure.

[SOURCE: ISO 4135:2001, 8.1.1]

3.23
ventilator breathing system
VBS
inspiratory or expiratory pathways through which gas flows at respiratory pressures and bounded by the port through which fresh gas enters, the *patient connection port* (3.7) and the exhaust port

[SOURCE: ISO 80601-2-12:2011, 201.3.221]

4 *General requirements

The requirements of ISO 18190:2016, Clause 4 apply.

NOTE Annex E covers hazard identification for *risk assessment of suction catheters*.

5 Materials

5.1 The requirements of ISO 18190:2016, Clause 5 and the following apply.

5.2 The shaft of the suction catheter shall be constructed from materials which facilitate passage through an airway device.

NOTE Examples of airway devices are tracheal tubes, tracheostomy tubes, tracheobronchial tubes and supralaryngeal airways.

Check conformance by inspection of the technical file.

5.3 The *shaft* shall be transparent.

Check conformance by visual inspection.

5.4 *Suction catheters* shall also be evaluated for biocompatibility in accordance with ISO 18562-1.

Check conformance by inspection of the technical file.

6 Design requirements

6.1 General

The requirements of ISO 18190:2016, Clause 6 and the following apply:

6.2 Size designations and dimensions

6.2.1 Designated sizes of *suction catheters* shall be within the tolerances of the nominal outside diameters specified in Table 1 and expressed in millimetres. The designated size can additionally be expressed in French (Charrière) gauge size.

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

NOTE 2 The French gauge size is not an SI unit. Size designation in millimetres facilitates matching the outside diameter of the *suction catheter* to the inside diameter of the tracheal or tracheostomy tube.

Check conformance by measurement.

6.2.2 *Suction catheters* shall have a colour identification at the *machine end*, to denote the designated size in accordance with Table 1.

NOTE The use and choice of colour identification for designated sizes not listed in Table 1 are at the manufacturer's discretion.

Check conformance by visual inspection.

6.2.3 The minimum inside diameter of the *shaft*, shall be in accordance with Table 1 and shall not, at any point between the *suction catheter connector* and the *eye* nearest to the *machine end*, be less than the inside diameter of the *shaft* at that *eye*.

Check conformance by measurement.

6.2.4 The inside diameter of the *terminal orifice* shall be not less than 90 % of the minimum inside diameter of the *shaft*.

Check conformance by measurement.

6.2.5 The *shaft* length shall be within ±5 % of the marked length.

Check conformance by measurement.

Table 1 — Designated size and colour identification

Designated size		Outside diameter tolerance	Minimum inside diameter	Colour identification
French (Charrière) 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

6.3 *Suction catheter tip*

6.3.1 *Suction catheters* for use with suction systems operating at a *vacuum* >4,0 kPa, shall have a *terminal orifice* and at least two *eyes* within 2 cm of the *terminal orifice*.

NOTE The availability of one or more *eye(s)* reduces the *risk* and likelihood of injury.

Check conformance by visual inspection.

6.3.2 *Suction catheters* for use with suction systems operated at *vacuum* ≤4,0 kPa shall have a *terminal orifice* but need not have an *eye*.

Check conformance by visual inspection.

6.3.3 The edges of the *tip*, *terminal orifice* and *eye(s)* shall be smooth.

NOTE This is to minimize injuries of the tracheal epithelium.

Check conformance by inspection.