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Suction catheters for use in the respiratory tract

Sondes d'aspiration pour les voies respiratoires

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Contents

Page

Foreword ..... **v**

Introduction ..... **vi**

1 Scope **1**

2 Normative references **1**

3 Terms and definitions **2**

4 *General requirements for open and closed suction catheters **5**
4.1 Risk management 5
4.2 Safety 6

5 Specific requirements for open and closed suction catheters **6**
5.1 Size and length designations 6
5.2 *Dimensions 6

6 Materials **7**

7 *Design **8**
7.1 Lumen of the suction catheter 8
7.2 Suction catheter tip 8
7.3 *Suction catheter connector 8
7.4 Additional requirements for closed suction catheters 10

8 Performance requirements **12**
8.1 Security of construction 12
8.2 Shaft performance 12
8.3 *Vacuum control device performance 13
8.4 *Leakage 13
8.5 *Resistance to flow 13
8.6 *Radiopacity 13

9 Requirements for suction catheters supplied sterile **13**
9.1 Sterility assurance 13
9.2 Packaging of suction catheters supplied sterile 14

10 Marking **14**
10.1 Marking on suction catheters 14
10.2 Use of symbols 15
10.3 Labelling of individual packs 16
10.4 Labelling of shelf/multi-unit packs 16

Annex A (informative) **Rationale** **18**

Annex B (normative) **Test method for security of attachment** **21**

Annex C (normative) **Measurement of residual vacuum** **22**

Annex D (normative) **Method of testing leakage** **24**

Annex E (informative) **Hazard identification for risk assessment** **25**

Bibliography **27**

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. www.iso.org/directives

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Airways and related equipment*.

This fourth edition of ISO 8836 cancels and replaces the third edition (ISO 8836:2007), of which it constitutes a technical revision.

Introduction

This International Standard specifies dimensions and requirements for **suction catheters** for use in the respiratory tract. It 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. Size is designated by outside diameter which 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][4]

Revisions in this fourth edition are intended to harmonize this International Standard with recent amendments in the European Medical Device Directive.

Major technical revisions in this edition include requirements for **closed suction catheters**, new requirements to harmonize this International Standard with requirements for critical care **ventilators**, and **risk management**.

Terms defined in Clause 3 of this International Standard or in ISO 4135[1] appear in **bold** type.

Throughout this International Standard, text for which a rationale is provided in Annex A is indicated by an asterisk (*).

Suction catheters for use in the respiratory tract

1 Scope

This International Standard specifies requirements for **suction catheters**, including **closed suction catheters**, made of flexible materials and intended for use in suctioning of the respiratory tract.

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.

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

NOTE See ISO/TR 11991 for guidance on airway management during laser surgery of the upper airway.[6]

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable to its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

*ISO 594-1, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements*

*ISO 594-2, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*

ISO 5356-1, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*

ISO 5367:—1), *Anaesthetic and respiratory equipment — Breathing sets and connectors*

ISO 7000, *Graphical symbols for use on equipment — Registered symbols*2)

ISO 10079-1, *Medical suction equipment — Part 1: Electrically powered suction equipment*

ISO 10079-2, *Medical suction equipment — Part 2: Manually powered suction equipment*

ISO 10079-3, *Medical suction equipment — Part 3: Suction equipment powered from a vacuum or positive pressure gas source*

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

ISO 11135, *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 11137-1, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

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

1) To be published. (Revision of ISO 5367:2000)

2) The graphical symbols in ISO 7000 are also available on line in the ISO web store. For more information, consult http://www.iso.org/iso/publications_and_e-products/databases.htm?=.

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

ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 14971:2007, *Medical devices — Application of risk management to medical devices*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 15223-2, *Medical devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 2: Symbol development, selection and validation*

IEC 60601-1:2005, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 62366-1, *Medical devices — Part 1: Application of usability engineering to medical devices*

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 of medical devices*

EN 15986, *Symbol for use in the labelling of medical devices — Requirements for labelling of medical devices containing phthalates*

ASTM D3002:2007, *Standard Guide for Evaluation of Coatings Applied to Plastics*

ASTM F640, *Standard Test Methods for Determining Radiopacity for Medical Use*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4135[1] and ISO 14971 and the following apply.

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

[SOURCE: ISO 4135:2001, 4.2.3.1]

3.2
connector
fitting to join together two or more components

[SOURCE: ISO 4135:2001, 4.2.2.1]

3.3
***closed suction catheter**
suction catheter enclosed within a **protective sleeve** and **patient end adaptor** that allows its use within the airway without opening the **breathing system** directly to atmosphere

3.4
eye
side hole near the **patient end** of the **suction catheter**

[SOURCE: ISO 4135:2001, 8.3.6]

3.5
machine end
<suction catheter> that end of the catheter which is intended to be connected to a source of vacuum

[SOURCE: ISO 4135:2001, 8.3.2]

3.6
open suction catheter
suction catheter that is not enclosed within a **protective sleeve** and **patient end adaptor** or attached to a **VBS**

3.7
patient connection port
<closed suction catheter> opening at the **patient end** of a breathing system port of a **ventilator breathing system** intended for connection to an airway device

[SOURCE: ISO 4135:2001, 4.2.1.2]

3.8
patient end
<suction catheter> that end of the **suction catheter** which is intended to be inserted into a patient

[SOURCE: ISO 4135:2001, 8.3.3]

3.9
patient end
<closed suction catheter> the **patient connection port** of the **closed suction catheter patient end adaptor** intended to be connected to the conical **connector** of an artificial airway (e.g. tracheostomy or tracheal tube)

3.10
***patient end adaptor**
tubular **connector** with multiple ports, one of which is a **patient connection port**

3.11
protective sleeve
flexible barrier that encloses the **suction catheter** shaft to prevent contact with the user while connected to the **VBS**

3.12
residual vacuum
negative pressure at the **patient end** of the **suction catheter** when the **vacuum control device** is in the relief position

3.13
risk
combination of the probability of occurrence of harm and the severity of that harm

[SOURCE: ISO 14971:2007]

3.14
risk analysis
systematic use of available information to identify hazards and to estimate the **risk**

Note 1 to entry: **Risk analysis** includes examination of different sequences of events that can produce hazardous situations and harm (see ISO 14971:2007, Annex F).

[SOURCE: ISO 14971:2007]

3.15
risk assessment
overall process comprising a **risk analysis** and a **risk evaluation**

[SOURCE: SO 14971:2007]

3.16
risk evaluation
process of comparing the estimated **risk** against given **risk** criteria to determine the acceptability of the **risk**

[SOURCE: ISO 14971:2007]

3.17
risk management
systematic application of management policies, procedures and practices to the tasks of analysing, evaluating, controlling and monitoring **risk**

[SOURCE: ISO 14971:2007]

3.18
risk management file
set of records and other documents that are produced by **risk management**

[SOURCE: ISO 14971:2007, 2.23]

3.19
shaft
main part of the **suction catheter** which is of uniform outside diameter

3.20
single-fault condition
condition in which a single means for reducing a **risk** is defective or a single abnormal condition is present

3.21
suction
application of vacuum to remove gas, liquids or solid particles

[SOURCE: ISO 4135, 8.1.2]

3.22
suction catheter
flexible tube designed for introduction into the respiratory tract or an airway device to remove material by suction

[SOURCE: ISO 4135]

3.23
***suction catheter connector**
connector at the **machine end** of the **suction catheter** that allows a connection to a vacuum source

3.24
terminal orifice
central aperture at the **tip** of the **suction catheter**

[SOURCE: ISO 4135:2001, 8.3.5]

3.25
tip
extremity of the **patient end** of a **suction catheter**

[SOURCE: ISO 4135:2001, 8.3.4]

3.26
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]

3.27
vacuum control device
means provided at or near the **machine end** of a **suction catheter** to control the flow of air and entrained material

[SOURCE: ISO 4135:2001, 8.3.9]

3.28
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** and the **exhaust port**[ISO 80601-2-12:2011,[8] 201.3.221, and ISO 4135:2001, 4.1.1, modified]

3.29
wiper
means for removing secretion residues from the surface of the **suction catheter**

4 *General requirements for open and closed suction catheters

4.1 Risk management

4.1.1 An established **risk management** process in accordance with ISO 14971 shall be applied to the design of the device.

Check compliance by inspection of the **risk management file**.

NOTE See Annex E.

4.1.2 The manufacturer shall apply a usability engineering process to assess and mitigate risks caused by usability problems associated with correct use and use errors.

EXAMPLES IEC 60601–1 and IEC 62366–1.

Check compliance by inspection of the usability engineering file.

4.1.3 Clinical evaluation shall be performed. Clinical evaluation is the assessment and analysis of clinical data pertaining to a medical device in order to verify the clinical safety and performance of the device.

Clinical data may be sourced from

— clinical investigation(s) of the device concerned, or

— clinical investigation(s) or other studies reported in the scientific literature, of a similar device for which equivalence to the device in question can be demonstrated, or

— published and/or unpublished reports on other clinical experience with either the device in question or a similar device for which equivalence to the device in question can be demonstrated.

If required, clinical investigations shall be performed under the conditions for which performance is claimed and documented in the **risk management file**. The clinical studies shall comply with the requirements of ISO 14155.

Check compliance by inspection of the **risk management file**.

4.2 Safety

The manufacturer may use type tests different from those detailed within this International Standard, if an equivalent degree of safety is obtained. Alternative test methods shall be validated against the test methods specified in this International Standard.

5 Specific requirements for open and closed suction catheters

5.1 Size and length designations

5.1.1 The size of **suction catheters** shall be designated by the nominal outside diameter of the **shaft**, expressed in millimetres; it may additionally be expressed in French (Charriere) gauge size (see 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 (1 mm 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.

5.1.2 The size of the **suction catheter** shall also be designated by use of colour identification at the **machine end** in accordance with Table 1, for the designated sizes listed.

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

5.1.4 The length of the **suction catheter** shall be designated by the nominal **shaft** length, expressed in millimetres.

5.2 *Dimensions

5.2.1 The outside diameter of the **shaft** shall be the designated nominal outside diameter, subject to a tolerance in accordance with Table 1.

5.2.2 The minimum inside diameter of the **shaft**, excluding the **tip**, shall be in accordance with Table 1.

5.2.3 The minimum inside diameter of the **terminal orifice** at the **tip** shall be not less than 90 % of the minimum inside diameter in accordance with Table 1.

5.2.4 The **shaft** length shall be the designated nominal **shaft** length subject to a tolerance of ±5 %.

