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Suction catheters for use in the respiratory tract

Sondes d'aspiration pour les voies respiratoires

[Revision of third edition (ISO 8836:2007)]

ICS 11.040.10; 11.040.25

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO-lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five-month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.

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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, *Airways and related equipment*.

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**.

Throughout this Particular Standard, terms defined in Clause 3 or in ISO 4135[1] appear in **bold** type.

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

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 plastics 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 catheters because of its relationship to the ease with which the catheter can be passed through a **tracheal** or **tracheostomy tube** [2],[3],[4].

Suction catheters for use in the respiratory tract

1 Scope

This International Standard specifies requirements for **suction catheters**, including **closed suction catheters**, made of plastic materials and intended for use in suction 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 standard.

NOTE See ISO/TR 11991-95 for guidance on airway management during laser surgery of the upper airway. [5]

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 594-1, *Luer conical fittings with a 6 % (Luer) taper for syringes, needles and certain other 1146 medical equipment – Part 1: General requirements*

ISO 594-2, *Luer conical fittings with a 6 % (Luer) taper for syringes, needles and certain other 1148 medical equipment – Part 1: Luer lock fittings*

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

ISO 5367:2013, *Breathing sets and connectors (under development*)

ISO 7000, *Graphical symbols for use on equipment -- Index and synopsis*.[1)]

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 from vacuum or pressure source*

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

ISO 11135-1, *Sterilization of health care products -- Ethylene oxide -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

1) 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 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*

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, *Medical Devices - Application of risk management to medical devices*

ISO 15223-1, *Medical device – 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 62366*, Medical devices — 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 980, *Symbols for use in the labelling of medical devices*

EN 1041:2008, *Terminology, symbols and information provided with medical devices: Information supplied by the manufacturer with medical devices*

ASTM D3002-2007, *Standard guide for evaluation of coatings applied to plastics*

ASTM F640-2007*, Standard test methods for radiopacity of plastics 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

[ISO 4135:2001, definition 4.2.3.1]

3.2
connector
fitting to join together two or more components

[ISO 4135:2001, definition 4.2.2.1]

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

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

[ISO 4135:2001, definition 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

[ISO 4135:2001, definition 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

[ISO 4135:2001, definition 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

[ISO 4135:2001, definition 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 (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

[ISO 14971:2007]

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

NOTE **Risk analysis** includes examination of different sequences of events that can produce hazardous situations and harm. (See ISO 14971:2007, Annex F)

[ISO 14971:2007]

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

[SO 14971:2007]

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

[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**

[ISO 14971:2007]

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

[ISO 14971:2007, definition 2.23]

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

3.20
single-fault condition
a 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

[ISO 4135, definition 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.

[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**

[ISO 4135:2001, definition 8.3.5]

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

[ISO 4135:2001, definition 8.3.4]

3.26
vacuum
pressure less than atmospheric pressure

NOTE It is usually expressed as a difference from atmospheric pressure.

[ISO 4135:2001, definition 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

[ISO 4135:2001, definition 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[6], definition 201.3.221, and ISO 4135:2001, definition 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 assessment

4.1.1 An established **risk assessment** process shall be applied to the design of the device.

EXAMPLE ISO 14971

Check compliance by inspection of the **risk management file**. If clinical studies are performed, these studies shall document measurements taken during the conditions for which performance is claimed. The clinical studies shall comply with the requirements of ISO 14155.

NOTE See Annex E

4.1.2 Open and closed suction catheters shall, when transported, stored, installed, operated in normal use and maintained according to the instructions of the manufacturer, present no **risks** that are not reduced to an acceptable level using **risk management** procedures in accordance with ISO 14971 and which are connected with their intended application, in normal and in **single fault condition**.

NOTE A situation in which a fault is not detected is considered a normal condition. Fault conditions/hazardous situations might remain undetected over a period of time and, as a consequence, might lead to an unacceptable **risk**. In that case, a subsequent detected fault condition needs to be considered as a **single fault condition**. Specific **risk** control measures need to be determined within the **risk management** process to deal with such situations.