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Medical suction equipment —

Part 2: Manually powered suction equipment

Appareils d'aspiration médicale —

Partie 2: Appareils d'aspiration manuelle

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Foreword

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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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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

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 8, *Suction devices for hospital and emergency care use*.

This third edition cancels and replaces the second edition (ISO 10079-2:1999), which has been technically revised.

ISO 10079 consists of the following parts, under the general title *Medical suction equipment*:

— *Part 1: Electrically powered suction equipment*

— *Part 2: Manually powered suction equipment*

— *Part 3: Suction equipment powered from a vacuum or positive pressure gas source*

Annex A forms a normative part of this part of ISO 10079 while Annexes B, C and D are for information only.

Annex B contains rationale statements for some of the requirements of this part of ISO 10079. The clauses and subclauses marked with an asterisk (*) after their number have corresponding rationale contained in Annex B, included to provide additional insight into the reasoning that led to the requirements and recommendations that have been incorporated in this part of ISO 10079. It is considered that knowledge of the reasons for the requirements will not only facilitate the proper application of this part of ISO 10079, but will expedite any subsequent revisions.

Medical suction equipment —

Part 2: Manually powered suction equipment

1 Scope

This part of ISO 10079 specifies safety and performance requirements for manually powered suction equipment intended for oro-pharyngeal suction. It applies to equipment operated by foot or by hand or both. Annex D illustrates the three parts of ISO 10079 by providing a schematic for typical systems.

The commonest use of manually powered suction is in situations outside of health care settings often described as field use or transport use. Use in these situations may involve extreme conditions of weather or terrain. Additional requirements for suction equipment intended for field and/or transport use are included in this part of ISO 10079.

This part of ISO 10079 does not apply to the following:

a) end pieces such as suction catheters, Yankauer sucker and suction tips;

b) dental suction equipment;

c) mucus extractors, including neonatal mucus extractors.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for 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 5356-1, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*

ISO 7000[1)], *Graphical symbols for use on equipment — Registered symbols*

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

ISO 80369 (all parts), *Small-bore connectors for liquids and gases in healthcare applications*

IEC 62366, *Medical devices — Application of usability engineering to medical devices*

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

3 Terms and definitions

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

1) The graphical symbol collections of ISO 7000, ISO 7001 and ISO 7010 are also available on the Online Browsing Platform http://www.iso.org/obp.

3.1
collection container
container in which liquids and solid particles are collected

3.2
end-piece
that part of the suction equipment applied to the patient which begins at the site where material is drawn in and ends at the first detachable connection

Note 1 to entry: Examples of commonly used end-pieces are a Yankauer sucker and a suction catheter.

3.3
exhaust port
opening through which exhaust gas is discharged

3.4
field use
use of suction equipment in situations outside of the health care facility at the site of accidents or other emergencies

3.5
filter
device for retention of particulate matter

3.6
free air flowrate
rate of unrestricted flow of air through a designated inlet

3.7
inlet port
opening through which liquid, solid particles or gas enter

3.8
intermediate tubing
tubing between the collection container and the vacuum source

3.9
manually powered suction
generation of vacuum by direct human effort

3.10
overfill protection device
device intended to prevent liquid or solid particles from entering the intermediate tubing

3.11
single fault condition
condition in which a single means for protection against a safety hazard in equipment is defective or a single external abnormal condition is present

Note 1 to entry: Maintenance of equipment is considered a normal condition.

3.12
suction
application of vacuum to remove liquid, solid particles or gas

3.13
suction tubing
tubing for conduction of liquid, solid particles or gas between the end-piece and the collection container

3.14
transport use
use during patient transport outside of a health care facility (e.g. in an ambulance or aeroplane)

3.15
vacuum level
pressure less than atmospheric pressure

Note 1 to entry: In this part of ISO 10079, vacuum level is expressed as a difference from atmospheric pressure.

3.16
vacuum level indicator
device for displaying the vacuum level

3.17
vacuum source
component of device for generating vacuum

4 General requirements

4.1 Risk management

4.1.1 This part of ISO 10079 specifies requirements that are generally applicable to risks associated with manually powered suction equipment. An established risk management process shall be applied to the design of the device. The risk management process shall include the following elements:

— risk analysis;

— risk evaluation;

— risk control;

— production and post-production information.

EXAMPLE ISO 14971.

Check compliance by inspection of the risk management file.

4.1.2 Manually powered suction equipment 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 associated 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.

Check compliance by inspection of the risk management file.

4.1.3 Where requirements of this part of ISO 10079 refer to freedom from unacceptable risk, the acceptability or unacceptability of this risk shall be determined by the manufacturer in accordance with their policy for determining acceptable risk.

Check compliance by inspection of the risk management file.

4.1.4 The manufacturer may use type tests different from those detailed within this part of ISO 10079, if an equivalent degree of safety is obtained. Alternative test methods shall be validated against the test methods specified in Annex A of this part of ISO 10079.

Check compliance by inspection of the technical file.

4.2 Usability

The manufacturer shall address, in accordance with IEC 62366, the usability engineering process, and the risk resulting from poor usability.

Check compliance by inspection of the usability engineering file.

4.3 Clinical investigation

Where appropriate, clinical investigation shall be performed under the conditions for which performance is claimed, and documented in the risk management file. The clinical investigation shall comply with the requirements of ISO 14155.

NOTE 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 of either the device in question or a similar device for which equivalence to the device in question can be demonstrated.

Check compliance by inspection of the risk management file.

4.4 Biophysical or modelling research

Where appropriate, validated biophysical or modelling research shall be performed under the conditions for which performance is claimed and documented in the risk management file.

Check compliance by inspection of the technical file.

5 Cleaning, disinfection and sterilization

Parts of the suction equipment which may be subject to contamination shall either be for single use or capable of being cleaned and disinfected or sterilized as appropriate. This includes filters, suction tubing and collection containers.

Parts intended for re-use shall meet the requirements of Clauses 7 and 9, as appropriate, after those components have been submitted to 30 cycles of cleaning and disinfection or sterilization as recommended by the manufacturer.

Check compliance by functional testing.

6 Design requirements

6.1 Collection container

6.1.1 General

The collection container shall clearly show the level of contents in normal use.

Check compliance by inspection.

6.1.2 Container capacity and usable volume

6.1.2.1(*)For suction equipment intended for field use with overfill protection, the usable volume of the collection container shall be not less than 300 ml.

6.1.2.2(*)For suction equipment intended for field use and which is intended to continue operating when the collection container is full, the volume of the collection container shall be not less than 200 ml. Check compliance by functional testing and inspection.

6.1.2.3 For all other suction equipment, including suction equipment intended for transport use, the usable volume of the collection container shall be not less than 500 ml.

Check compliance by inspection and the tests given in A.2.

6.1.3 Container strength

The collection container shall not implode, crack or permanently deform and shall meet the requirements of Clauses 7 and 9, as appropriate, after being subjected to a pressure of either 120 % of the manufacturer's recommended maximum vacuum level or 95 kPa below atmospheric, whichever is less, for 5 min.

Containers intended for re-use shall be tested after 30 cycles of cleaning and disinfection or sterilization as recommended by the manufacturer.

Check compliance by the test given in A.3.

6.2 Connections

6.2.1 Tubing connectors for collection containers

The connectors for the suction tubing and the intermediate tubing shall be designed to facilitate correct assembly or clearly marked to indicate correct assembly when all parts are mated.

Check compliance by functional testing and inspection.

NOTE Incorrect connections have frequently been a cause of spill over into the vacuum source and a loss of suction.

6.2.2 Inlet port

The inside diameter of the suction tubing connector (inlet port of the collection container) shall be at least 6 mm and the inside diameter of the suction tubing connection (inlet port) shall be equal to or larger than the inside diameter of the largest tubing size as specified by the manufacturer.

The inlet shall not be compatible with any conical connector specified in ISO 5356-1 or small-bore connectors specified in ISO 80369 (all parts).

Check compliance by functional testing and inspection.

NOTE Because of the risk of misconnection, the internal diameter of the inlet port of the collection container should not be greater than 14 mm.

6.2.3 Exhaust port

It shall not be possible to connect suction tubing to the exhaust port.

Check compliance by functional testing.

6.3 Suction tubing

6.3.1 Suction tubing shall have an inside diameter of not less than 6 mm.

The degree of collapse of the suction tubing shall be less than 0,5 throughout its entire length.

Check compliance by the tests given in A.4 using the tubing specified by the manufacturer of the suction equipment.

6.3.2(*)Suction tubing supplied or recommended by the manufacturer shall have a minimum length of 1,3 m.

NOTE Suction performance may be markedly affected by the length and diameter of the tubing between the collection container and end-piece. See Annex C.

6.4 Vacuum level indicators

Vacuum level indicators, if present, shall have the following specifications.

a) The full-scale of analog vacuum level indicators shall not be more than 200 % of the maximum vacuum level below atmospheric pressure as specified by the manufacturer.

b) Analog displays shall have graduations not less than 2 mm apart, each graduation representing not more than 5 % of the full-scale value.

c) Vacuum level indicators shall be accurate to within ± 5 % of the full-scale value.

Check compliance by inspection and functional testing.

7 Operational requirements

7.1 Ease of operation

The suction equipment shall be designed to be operated by one person unaided.

Foot-operated suction equipment should require a force of less than 350 N (approximately 35 kg), and hand-operated suction equipment should require a force of less than 45 N (approximately 4 kg).

Check compliance by functional testing.

7.2 Dismantling and reassembly

Suction equipment intended to be dismantled by the user (e.g. for cleaning) shall be designed to facilitate correct reassembly or marked to indicate correct reassembly. After dismantling and reassembling, in accordance with the manufacturer's instructions, the suction equipment shall meet the requirements of Clause 9 as appropriate.

7.3 Mechanical shock

Suction equipment intended for field and/or transport use shall meet the requirements of Clause 9 after being dropped from a height of 1 m onto a concrete floor in the worst-case mode.

If the suction equipment can be operated outside its carrying case, individual parts of the suction equipment shall be drop-tested as above and reassembled. The reassembled suction equipment shall meet the requirements given in Clause 9, as appropriate.

Check compliance by the tests given in A.5.

7.4 Stability

7.4.1 Foot-operated suction equipment intended for field use and/or transport use shall meet the requirements of Clause 9, as appropriate, when placed on a surface of (20 ± 2)° slope from the horizontal.

7.4.2 Foot-operated suction equipment not intended for field use and/or transport use shall meet the requirements of Clause 9, as appropriate, when placed in any position on a surface of (10 ± 1)° slope from the horizontal, unless excluded by the manufacturer.

Check compliance by functional testing.

7.5 Protection devices

7.5.1 Contamination protection device

There shall be a means to prevent contamination of the vacuum pump e.g. microbial filter.

Check compliance by inspection.

7.5.2 Overfill protection device

When an overfill protection device is operated suction shall cease and no more than 5 ml of fluid shall pass downstream of the overfill protection device.

If the overfill protection device is integral with the collection container, it shall not activate until at least 90 % of the stated capacity of the collection container has been reached.

Means to prevent foam passing downstream into the vacuum source shall be provided.

Check compliance by the tests given in A.2.

7.6 Immersion in water

Suction equipment intended for field use shall meet the requirements of Clause 9 as appropriate after being dropped into water from a height of 1 m and immersed for 10 s.

Check compliance by the test given in A.6.

8 Physical requirements for field and transport use suction equipment

8.1 (*)Dimensions

Suction equipment intended for field use, including any carrying case or frame, shall pass through a rectangular opening having dimensions of 600 mm × 300 mm.

NOTE Suction equipment is often combined with resuscitation equipment which may make it impossible to define the mass or dimensions for suction equipment alone. In these circumstances this subclause may not apply, but the mass and dimensions of all equipment intended for field use should be as small as possible.

Check compliance by functional testing.

8.2 Mass

The mass of suction equipment intended for field use, complete with its carrying case or frame and accessories, shall not exceed 6 kg.

NOTE Suction equipment is often combined with resuscitation equipment, which may make it impossible to define a mass for suction equipment alone. In these circumstances this item may not apply, but all equipment intended for field use should be as light as possible.

Check compliance by functional testing.

