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Medical suction equipment —

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

Appareils d'aspiration médicale —

Partie 3: Appareils d'aspiration alimentés par une source de vide ou de pression

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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).

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 10079-3:1999), 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 3:
Suction equipment powered from a vacuum or positive pressure gas source

1 Scope

This part of ISO 10079 specifies safety and performance requirements for medical suction equipment powered from a vacuum or positive pressure gas source generating venturi suction. It applies to equipment connected to medical gas pipeline systems or cylinders and venturi attachments. Annex D illustrates the three parts of ISO 10079 by providing a schematic for typical systems.

The equipment can be stand-alone or part of an integrated system.

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) central power supply (by vacuum/compressed air generation), piping systems of vehicles and buildings, and wall connectors;

b) end-piece such as suction catheters, Yankauer sucker and suction tips;

c) syringes;

d) dental suction equipment;

e) anaesthetic gas scavenging systems;

f) laboratory suction;

g) autotransfusion systems;

h) closed systems for wound drainage;

i) mucus extractors, including neonatal mucus extractors;

j) ventouse (obstetric) equipment;

k) breast pumps;

l) liposuction;

m) uterine aspiration;

n) plume evacuation systems.

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 3744, *Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound pressure — Engineering methods for an essentially free field over a reflecting plane*

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

ISO 5359, *Anaesthetic and respiratory equipment - Low-pressure hose assemblies for use with medical gases*

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 60601-1:2005+A1:2012, *Medical electrical equipment — Part 1: General requirements for safety*

IEC 60601-1-6, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance—Collateral standard: Usability*

IEC 61672-1, *Electroacoustics — Sound level meters — Part 1: Specifications*

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.

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

3.2
collection container assembly
collection container and its closure with connectors for suction

3.3
drainage
removal of liquid, solid particles or gas from body cavity or wound

3.4
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.

3.5
exhaust port
opening through which exhaust gas is discharged

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.

3.6
field use
use of suction equipment in situations outside of the health care facility at the site of accidents or other emergencies

3.7
filter
device for retention of particulate matter

3.8
free air flowrate
rate of unrestricted flow of air through a designated inlet

3.9
high flowrate
free air flowrate of 20 l/min or more

3.10
high vacuum
vacuum level of 60 kPa or more below atmospheric pressure

3.11
inlet port
opening through which liquids, solid particles or gas enter

3.12
intermediate tubing
tubing between the collection container and the vacuum source

3.13
intermittent vacuum
type of suction in which the negative pressure applied to the end piece is automatically and periodically returned to atmospheric pressure

3.14
low flowrate
free air flowrate less than 20 l/min

3.15
low vacuum
vacuum level of not more than 20 kPa below atmospheric pressure

3.16
medical gas pipeline system
complete system which comprises a supply system, a monitoring and alarm system and a distribution system with terminal units at the points where medical gases or vacuum are required

[SOURCE: ISO 7396-1:2007, definition 3.29]

3.17
medium vacuum
vacuum level of more than 20 kPa but less than 60 kPa below atmospheric pressure

3.18
outlet port
opening through which gas exits from the collection container

3.19
overfill protection device
device intended to prevent liquid or solid particles from entering the intermediate tubing

3.20
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.

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

3.22
suction tubing
tubing for conduction of liquid, solid particles or gas between the end-piece and the collection container

3.23
thoracic drainage
drainage of liquids and gas from the thoracic cavity by application of suction to the thoracic cavity of the patient

Note 1 to entry: For the purposes of this part of ISO 10079, all thoracic drainage is considered to be active.

3.24
transport use
use during patient transport outside of a health care facility (e.g. in an ambulance or airplane)

3.25
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.

3.26
vacuum level indicator
device for displaying the vacuum level

3.27
vacuum source
component of device for generating vacuum

3.28
vacuum regulator
device for controlling the applied vacuum level

4 General requirements

Suction equipment with components controlled by electrical means, e.g. electronic timing, shall meet the relevant requirements of IEC 60601-1:2005+A1:2012.

4.1 Risk management

4.1.1 This part of ISO 10079 specifies requirements that are generally applicable to risks associated with suction equipment powered from a vacuum or positive gas source. 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 Suction equipment powered from a vacuum or positive pressure gas source 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 60601-1-6 and 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 and the container shall be fitted with overflow protection.

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 tests given in A.3.