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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

Reference number
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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.

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 6mm 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 if 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

Suction equipment with an operator-adjustable vacuum regulator, shall have a means of indicating the vacuum level below atmospheric pressure at the patient end when attached to a suction catheter or drainage tube.

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

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

NOTE Movement of a rotary analog vacuum level indicator should be anticlockwise for an increase in vacuum level.

6.4.3 Digital displays shall display vacuum level below atmospheric pressure at intervals of not greater than 5 % of the full-scale value.

6.4.4 Vacuum level indicators on suction equipment intended for thoracic drainage shall be accurate to within ± 5 % of the full-scale value in the middle three-fifths of the operating range.

6.4.5 Vacuum level indicators on suction equipment except as specified in 6.4.4 shall be accurate to within ± 5 % of the full-scale value.

6.4.6 Low vacuum equipment shall be fitted with a vacuum level indicator between the vacuum source and collection container.

Check compliance by inspection and functional testing.

6.5 Supply connections

Suction equipment powered by gas or vacuum shall:

— if connected directly to the terminal unit of a medical gas pipeline system, be fitted with a probe complying with the relevant national standard;

— if connected remotely to the terminal unit of a medical gas pipeline system or the outlet of a regulator via a low-pressure hose assembly, the hose assembly shall comply with ISO 5359.

Check compliance by inspection.

NOTE Medical gas pipeline systems complying with ISO 7396-1 supply vacuum level of 60 kPa (absolute pressure) at a flowrate of 25 l/min. Vacuum level of 60 kPa (absolute pressure) is the same as 40 kPa below atmospheric.

7 Operational requirements

7.1 Ease of operation

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

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

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

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 Protective devices

7.5.1 Contamination protection

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

Check compliance by inspection.

7.5.2 Overfill protection devices

When an overfill protection device is activated 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.2.1.

7.5.3 Pressure protection

7.5.3.1 Negative pressure protection

If a device to limit the maximum vacuum level is fitted, the vacuum shall not exceed the set vacuum level by more than 10 %.

Check compliance by functional testing.

7.5.3.2 Positive pressure protection

Thoracic drainage systems shall not develop a pressure in excess of 1 kPa.

Check compliance by the tests given in A.6.

A venturi-powered suction device shall not produce a positive pressure at the patient end of more than 1 kPa under normal or single fault condition.

Check compliance by the tests given in A.7.

7.6 Noise

7.6.1 Low vacuum/low flowrate equipment

In normal use the maximum A-weighted sound pressure level (peak or steady value) of low vacuum/low flowrate equipment, including equipment for thoracic drainage, shall not exceed 60 dB.

Check compliance by the test given in A.8.

7.6.2 Suction equipment other than that specified in 7.6.1

In normal use, the maximum A-weighted sound pressure level (steady or peak value) of suction equipment other than low vacuum/low flowrate equipment shall not exceed 70 dB.

Check compliance by the test given in A.8.

7.7 Air leakage

7.7.1 Collection containers for general use

The maximum leakage into the collection container assembly shall not exceed 200 ml/min. If the collection container is intended for use with suction equipment having a free air flowrate of more than 1 l/min, the pressure increase shall be less than 3,3 kPa/V in 10 s, where V is the total volume of the collection container in litres.

Collection 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.9.1.

7.7.2 Collection containers for thoracic drainage

The maximum leakage shall be no more than three bubbles in 10 s.

Collection 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.9.2.

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 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 lightweight as possible.

Check compliance by functional testing.

9 Performance requirements for vacuum level and flowrate

9.1 High vacuum/high flowrate equipment

Suction equipment marked “high vacuum/high flow” shall develop a vacuum of at least 60 kPa below atmospheric pressure within 10 s and a free air flow into the collection container (without suction tubing fitted) of not less than 20 l/min.

Check compliance by the test given in A.10, at the maximum and minimum supply pressures recommended by the manufacturer.

NOTE Pipelines conforming to ISO 7396-1 are required to have only a vacuum of -40 kPa and a free flow of 25 l/min.

9.2 Medium vacuum equipment

Suction equipment marked “medium vacuum” shall develop a vacuum of between 20 kPa and 60 kPa below atmospheric pressure, within 10 s.

Check compliance by the test given in A.10, at the maximum and minimum supply pressures recommended by the manufacturer.

9.3 Low vacuum/low flowrate equipment

Suction equipment marked “low vacuum/low flow” shall produce a vacuum of not more than 20 kPa below atmospheric pressure and a continuous free air flowrate of less than 20 l/min at the maximum vacuum level setting recommended by the manufacturer.

Check compliance by the test given in A.11, at the maximum and minimum supply pressures recommended by the manufacturer.

9.4 Low vacuum/high flowrate equipment

Suction equipment marked “low vacuum/high flow” shall produce a vacuum of not more than 20 kPa below atmospheric pressure and a free air flowrate of not less than 20 l/min at the maximum vacuum level setting recommended by the manufacturer.

Check compliance by the tests given in A.11, at the maximum and minimum supply pressures recommended by the manufacturer.

9.5 Thoracic drainage equipment for adults

Suction equipment marked “thoracic drainage” intended for use in adults shall produce a free air flowrate of not less than 15 l/min at the inlet of the collection container.

The vacuum level developed shall not exceed 10 kPa below atmospheric pressure.

It shall be possible to set the level of vacuum to between 0 kPa and 10 kPa below atmospheric pressure.

NOTE For most situations the vacuum level developed should not exceed 7 kPa below atmospheric pressure. However, in some situations, for example broncho-pleural fistula, a higher flowrate e.g. 25 l/min may be required and the ability to generate higher vacuum levels and higher flowrates is desirable.

Equipment marked “thoracic drainage” shall be adjustable to a static vacuum level of 7 kPa below atmospheric pressure. Such equipment shall produce a free air flowrate of at least 15 l/min, and shall be capable of developing, within 5 s, 95 % of the set vacuum level when connected to a closed system of 4,5 l total capacity.

Suction equipment intended for thoracic drainage shall not develop a pressure in excess of 1 kPa at the patient inlet with a free air flowrate of 10 l/min.

Check compliance by the tests in A.12.

9.6 Intermittent vacuum equipment

Suction equipment for intermittent vacuum shall produce a vacuum level ± 10 % of the vacuum level specified by the manufacturer or ± 10 % of the mid-range level if the vacuum level is adjustable. The cycling frequency shall be within 10 % of the specified frequency or 10 % of the middle frequency if the range is adjustable.

Check compliance by the test in A.13.

9.7 Vacuum regulators with fixed setting

The vacuum level indicated shall not deviate by more than ± 10 % from the fixed setting.

All vacuum levels shall be expressed as the occluded (no-flow) value.

Check compliance by the tests given in A.14.

9.8 Vacuum regulators with variable setting

The vacuum level indicated shall not deviate by more than ± 10 % when set within the middle three-fifths of its range.

Check compliance by the tests given in A.15.

9.9 Equipment intended for pharyngeal suction

Equipment intended for pharyngeal suction shall evacuate 200 ml of simulated vomitus in not more than 10 s.

Check compliance by the test in A.16.

10 (*)Resistance to environment of suction equipment for field and/or transport use

10.1 Operating conditions

Suction equipment intended for field and/or transport use shall meet the requirements given in Clauses 7 and 9, as appropriate, after being subjected to temperatures of -18 °C and +50 °C.

Check compliance by the tests given in A.17.2.1 and A.17.2.2.

10.2 Storage

Suction equipment intended for field and/or transport use shall meet the requirements given in Clauses 7 and 9, as appropriate, after being subjected to temperatures of -40 °C and +60 °C.

Check compliance by the tests given in A.17.2.3 and A.17.2.4.

11 Marking

11.1 Use of symbols

Marking and information to be supplied by the manufacturer shall comply with EN 1041 and contain where appropriate symbols as specified in ISO 7000 or ISO 15223-1.

Check compliance by inspection.

11.2 Equipment

The following information shall be permanently and legibly marked on the suction equipment, or on parts of it, where applicable:

a) the name or trade name and address of the manufacturer and, in addition, the name and address of the authorized representative where applicable;

b) details necessary for the user to identify the device and the contents of the packaging;

c) the word “sterile”;

d) batch code preceded by the word “LOT”, or serial number;

e) an indication of the date by which the device, or parts thereof, can be used in safety, expressed as the year and month;

f) an indication that the device, or parts thereof, are for single use (manufacturer’s indication of single use shall be consistent);

g) words indicating “exhaust” on the exhaust port, if a single opening is provided. A single opening may allow a misconnection and should be labelled; a multiple hole exhaust system is unlikely to be misconnected;

h) words indicating “inlet” at the connection to the collection container, unless misconnection is prevented by a design feature;

i) for collection containers having a capacity of 500 ml or greater, the usable volume, expressed in millilitres, and graduations with intervals not less than 50 ml and not more than 250 ml;

j) all equipment generating suction shall be marked with words indicating suction. This marking shall be visible in the normal working position;

k) an indication that the equipment is intended for pharyngeal suction only;

l) if the suction equipment is intended for use in the field and/or transport, it shall be marked on the equipment case as not suitable for use at ambient temperatures below ...°C or above ...°C. If no case is provided, the statements shall be marked on the equipment;

m) for suction equipment intended for thoracic drainage, words indicating “thoracic drainage”;

n) the maximum vacuum level for which the equipment is designed shall be marked prominently on the display case or immediately adjacent to it;

o) suction equipment having a vacuum regulator with a variable control shall have a vacuum level indicator displaying the vacuum level on the inlet side of the vacuum regulator. The units of measurement shall be marked prominently on the display case or immediately adjacent to it;

p) all markings on the vacuum level indicator shall be legible to an operator having visual acuity, corrected if necessary, of at least 1,0, 1 m from the vacuum level indicator at an illuminance of 215 lx of white (simulated day-) light;

q) low vacuum equipment with a vacuum level which is not adjustable by the user shall be marked either with the vacuum level which can be attained or with words indicating “low vacuum level”;

r) intermittent suction equipment shall be marked with words indicating “intermittent suction”. Equipment which can provide both continuous and intermittent suction shall have the mode control clearly marked;

s) if a progressive variation in the degree of vacuum level is available, the direction of adjustment to increase vacuum shall be clearly and permanently marked;

t) for suction equipment powered from a positive pressure gas source, which can be detached from the power source, the recommended maximum and minimum supply pressures;

NOTE For medical gas pipeline systems complying with ISO 7396, the positive pressure gas supply is set between 270 kPa and 550 kPa.

u) for suction equipment powered from a vacuum source the recommended maximum and minimum supply vacuum level;

v) for suction equipment powered by gas or vacuum, the maximum vacuum level produced.

NOTE If the suction equipment is combined with a resuscitator, a single marking of items g), t), u) and v) is sufficient for the combination.

Check compliance by inspection.

11.3 Equipment or carrying case

The following information shall be permanently marked on the carrying case, or on the suction equipment when there is no carrying case.

The performance category (such as “high vacuum/high flow”, “medium vacuum”, “low vacuum/high flow”, “low vacuum/low flow”, “intermittent vacuum”, “pharyngeal suction”, or “thoracic drainage”, as appropriate) or the vacuum and flowrate ranges for patient use, with the marking visible in the normal operating position.

Check compliance by inspection.

12 Information to be supplied by the manufacturer

The manufacturer shall provide the following information in the accompanying documents:

a) the name or trade name and address of the manufacturer and, in addition, the name and address of the authorized representative where applicable;

b) the intended purpose of the device, if not obvious;

c) a warning that the suction equipment should only be used by persons who have received adequate instructions in its use;

d) instructions on how to make the suction equipment operational in all intended modes of operation, and any limitations on the use of the equipment;

e) guidance on performance as either

1) the type of equipment, e.g. medical suction, high vacuum, high flow, or

2) the vacuum level and flowrate obtainable;

f) instructions for the dismantling and reassembly of components, if applicable (see 7.2), including an illustration of the component parts in their correct relationship;

g) instructions that the user should carry out the manufacturer’s recommended test procedure after dismantling and reassembly of the equipment [see 12 j)];

h) a specification detailing

1) operating environment limits,

2) storage environment limits;

i) the recommended methods for cleaning and disinfection or sterilization of all reusable parts and an estimated life in terms of use cycles (see Clause 5);

j) suction equipment function test(s) which must be performed by the user prior to use;

k) size and type of tubing and connection to the collection container, including any maximum length, if applicable;

l) useable volume of the collection container;

m) a list of parts that can be replaced by the user, including part numbers;

n) details of the operation of any overfill protection device fitted to the collection container assembly and the usable capacity of the collection container in all the recommended inclined planes of operation;

o) method of emptying the collection container and operation after overflow has occurred;

p) a statement advising removal and servicing of the equipment if liquid or solid has been drawn into the vacuum pump;

NOTE In some cases, this may require servicing by the manufacturer or his authorized agent.

q) if applicable, a statement that suction ceases when the overfill protection device operates, and the method of correcting this situation;

r) the method of controlling frothing in the collection container;

s) instructions for operating the vacuum level regulator, if supplied, and for setting the required vacuum level;

t) disclosure of any components containing natural rubber latex;

u) any special storage and/or handling conditions;

v) recommendations for maintenance, including a recommendation for frequency of approved or factory service;

w) fault-finding and correction procedures;

x) whether or not the suction equipment is suitable for use in an MRI environment;

y) any warnings and/or precautions to take;

z) the date of publication and/or revision of the manual.

Check compliance by inspection.

Annex A
(normative)

Test methods

A.1 General

The apparatus and test methods specified in this annex are not intended to exclude the use of other measuring devices or methods which yield results of an accuracy equal to or greater than those specified. In case of dispute, the methods given in this part of ISO 10079 shall be the reference methods.

A.2 Test for collection container usable volume, and overfill protection

A.2.1 Devices with overfill protection

Connect the overfill protection device in accordance with the manufacturer's instructions. Set the equipment to maximum free air flowrate. Suck water at room temperature into the collection container until the shut-off mechanism of the overfill protection device is activated. Note the water level. Remove the suction tubing from the water to allow free air flow. Run the equipment for a further 2 min. Measure the volume of water which has passed the shut-off mechanism of the overfill device. Measure the volume collected in the collection container at the time the overfill protection device is activated.

For re-usable suction equipment, perform the test after the equipment has been subjected to 30 cycles of cleaning and disinfection or sterilization as recommended by the manufacturer.

A.2.2 Devices with no overfill protection (field use)

Fill a graduated cylinder with 300 ml of water at room temperature. Operate the suction equipment until the collection container is full. Measure the volume of water remaining in the graduated cylinder. Without emptying the collection container, continue to operate the suction equipment until the graduated cylinder is emptied.

For re-usable suction equipment, perform the test after the equipment has been subjected to 30 cycles of cleaning and disinfection or sterilization as recommended by the manufacturer.

A.3 Test for collection container strength

Place the collection container and the filter assembly (if present) or the complete suction equipment (if the equipment has an integrated collection container) in a protective enclosure, at 20 °C to 25 °C. If an in-line filter is used or recommended, attach the filter for the test. Attach a vacuum source to the outlet port. Evacuate the collection container and accessories (if present) under test to 120 % of the manufacturer's recommended maximum vacuum level or to a vacuum level not exceeding 95 kPa below atmospheric pressure, whichever is less. Hold the vacuum level for 5 min, and then release. Repeat the procedure once.

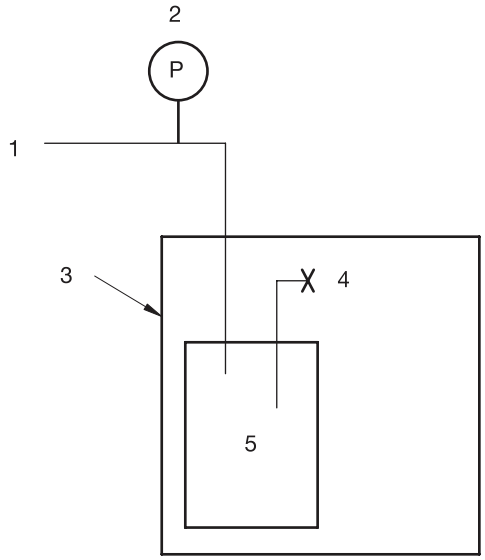
CAUTION — This test can be hazardous. Proper care should be taken to protect personnel from possible flying debris.

For re-usable collection containers or re-usable filter assemblies, perform the test after the equipment has been subjected to 30 cycles of cleaning and disinfection and/or sterilization as recommended by the manufacturer.

Inspect for implosion, cracking or permanent deformation of the collection container and the filter assembly.

Then test the suction equipment for compliance with the requirements given in Clauses 7 and 9, as appropriate.

A suitable test apparatus is shown in Figure A.1.



Key

1 vacuum source
2 vacuum level indicator
3 protective enclosure (loose fitting, not sealed)
4 closed to atmosphere
5 collection container under test

Figure A.1 — Typical apparatus for testing collection container strength

A.4 Test for degree of collapse for suction tubing

At 20 °C to 25 °C, uncoil the suction tubing to its full length and plug one end to prevent any air flow through it. Attach a vacuum source to the other end of the tubing and adjust the vacuum level to the maximum specified by the manufacturer. If there is no disclosed maximum, conduct the test at 60 kPa below atmospheric pressure. Hold the vacuum level for 5 min. Calculate the collapse of the tube *A* by measuring the outside diameter of the suction tubing along its length with callipers, as illustrated in Figure A.2.

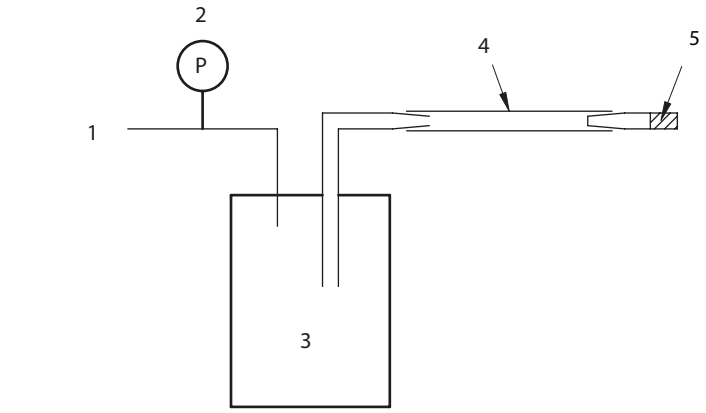
Repeat the test while the tube is loosely coiled around a 100 mm diameter cylinder.

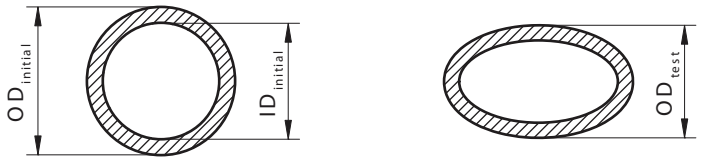
NOTE Narrow grooves may be cut in the cylinder to aid calliper measurement.

Degree of collapse, *A*: $A = \frac{OD_{initial} - OD_{test}}{ID_{initial}}$

Pass $A < 0{,}5$

Fail $A > 0{,}5$





a) Before test b) During test

Key

1 vacuum source
2 vacuum level indicator
3 collection container
4 suction tubing
5 plug

Figure A.2 — Test apparatus for degree of collapse for suction tubing

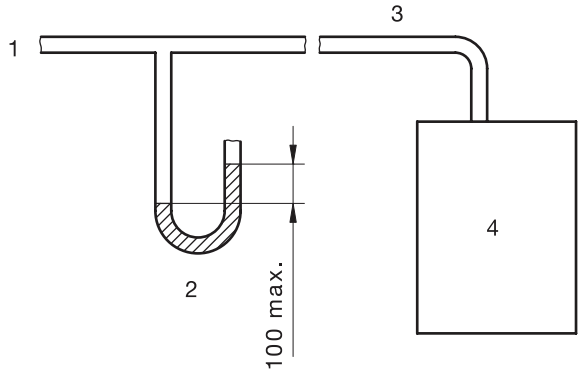
A.5 Drop test

Drop the suction equipment from a height of 1 m onto a concrete floor in the worst-case mode, then test the suction equipment for compliance with the requirements given in Clauses 7 and 9 as appropriate.

A.6 Test for positive-pressure protection in thoracic drainage

Attach the patient end of the thoracic drainage system setup for normal use in accordance with the manufacturer's instructions (see Figure A.3) to a positive pressure source adjusted to produce a flowrate of 10 l/min, and measure the pressure at that point.

Dimensions in millimetres



Key

1 positive pressure source with a flowrate of 10 l/min
2 water manometer
3 suction tube
4 thoracic drainage system

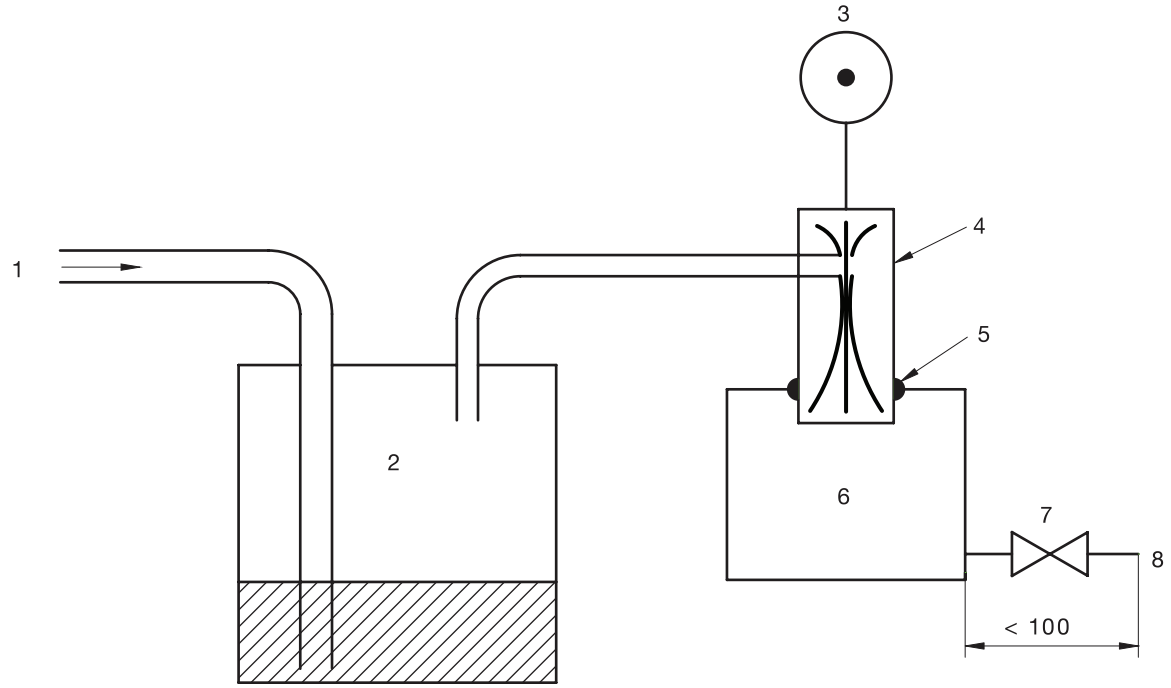
Figure A.3 — Typical apparatus for testing positive-pressure protection in thoracic drainage

A.7 Test for positive-pressure protection in venturi-powered suction systems

Set up the venturi with the maximum driving pressure and flow as recommended by the manufacturer. Occlude the outlet port of the venturi exhaust and measure the static water column back-pressure in the inlet tube (see Figure A.4).

NOTE A high-pressure relief valve may be fitted to the test apparatus.

Dimensions in millimetres



Key

1 inlet
2 container (capacity 1 l to 2 l)
3 driving gas at manufacturer's recommended pressure
4 device under test
5 seal above exhaust port
6 exhaust enclosure, at least 100 mm clear of venturi
7 on/off valve
8 outlet (at least 100 % venturi exhaust cross-sectional area)

Figure A.4 — Typical apparatus for testing positive-pressure protection in venture-powered suction systems

A.8 Noise test

Place the microphone of a sound-level meter complying with the requirements for a type I instrument specified in IEC 61672-1 at the position of maximum sound pressure level in the horizontal plane passing through the geometric centre of the suction equipment at a radius of 1 m. The measured sound pressure level shall not exceed the specified value.

For this test, the suction equipment shall be operated with the inlet port open to atmosphere and with the inlet port occluded and over its normal working range of flowrate, including the maximum flowrate recommended by the manufacturer. Measurements shall be taken using the frequency-weighting characteristic A and the time-weighting characteristic S on the sound-level meter. The measurements shall be taken in a free field over a reflecting plane as specified in ISO 3744.

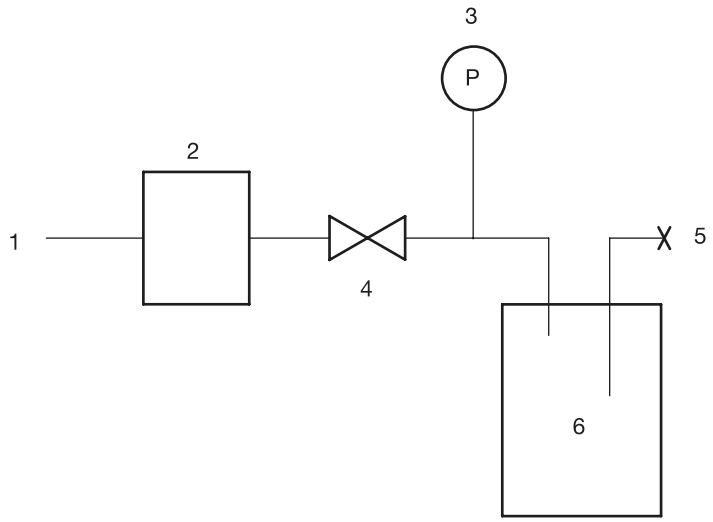
The A-weighted background level of extraneous noise shall be at least 10 dB below that measured during the test.

A.9 Test for air leakage from the collection container

A.9.1 Collection containers for general use

Evacuate the collection container to 40 kPa below atmospheric pressure. Close off the suction tubing to the vacuum level indicator (P shown in Figure A.5) and observe the pressure increase within 10 s.

NOTE Collection containers will usually have a pneumatic compliance of approximately 10 ml/kPa per litre volume.



Key

1 vacuum source
2 vacuum regulator
3 vacuum level indicator (P), accurate to 0,5 kPa between 30 kPa and 50 kPa below atmospheric pressure
4 on/off valve
5 closed to atmosphere
6 test collection container

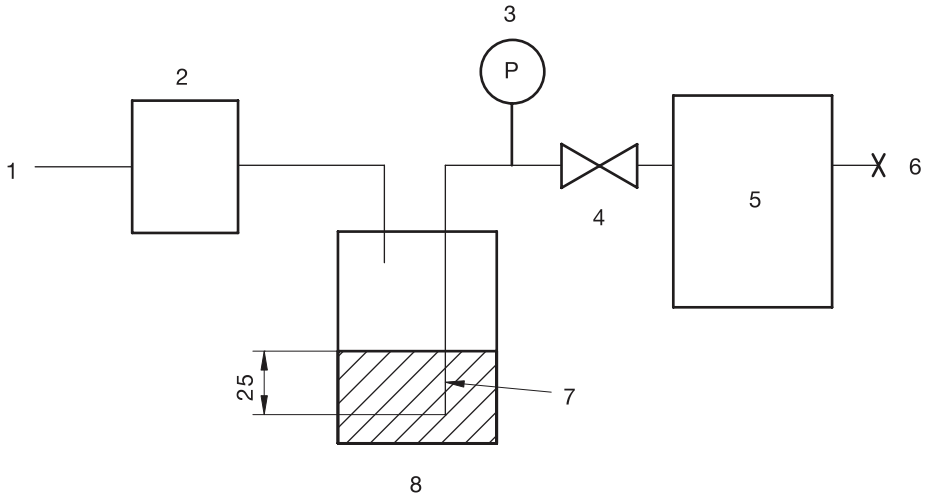
Figure A.5 — Typical apparatus for testing leakage of collection container for general use

A.9.2 Collection containers for thoracic drainage

Using the apparatus such as shown in Figure A.6, close the on/off valve. Set the vacuum regulator to 15 kPa below atmospheric pressure. Open the on/off valve and allow the container to reach the set vacuum level. Observe the water bottle and count the bubbles. Calculate the number of bubbles per minute.

NOTE Three bubbles in 10 s is a leakage of approximately 4 ml/min.

Dimensions in millimetres



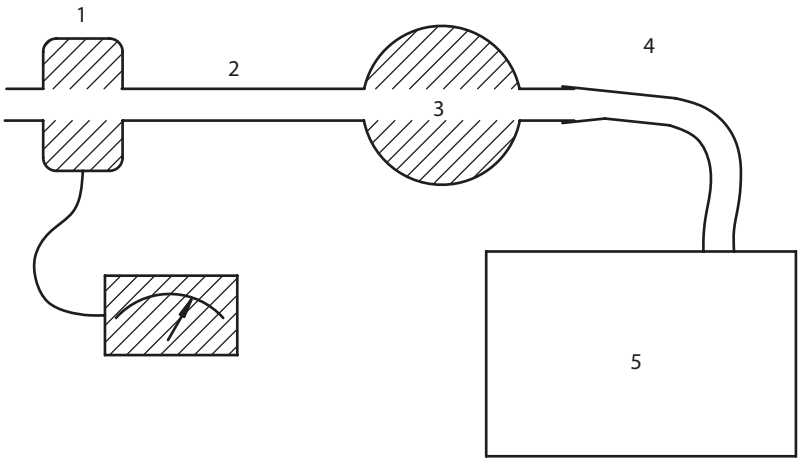
Key

1 vacuum source
2 vacuum regulator
3 vacuum level indicator, accurate to 2,5 % maximum scale value
4 on/off valve
5 component or system under test
6 closed to atmosphere
7 suction tube (6 mm inside diameter, square cut)
8 water bottle

Figure A.6 — Typical apparatus for testing leakage of collection container for thoracic drainage

A.10 Test for maximum vacuum level and free air flowrate (general suction equipment)

Connect a flow-measuring device with a response time of not more than 100 ms, an accuracy of at least 0,05 l/s over the range of 0,1 l/s to 0,5 l/s and a resistance of not more than 2 Pa/l/s (such as a pneumotachograph) in series with a chamber having a volume of (100 ± 10) ml. Attach the suction equipment in a gas-tight manner to the 100 ml chamber (see Figure A.7 for a typical test setup). Operate the suction equipment according to the manufacturer's instructions and record the flowrate.



Key

1 flow measuring device

2 connecting piece (inside diameter 10 mm to 20 mm and less than 100 mm length)

3 chamber (100 ml)

4 connecting tubing (inside diameter 10 mm, length 1,3 m) or suction tubing as recommended by the manufacturer

5 equipment under test

Figure A.7 — Apparatus for testing free air flowrate

Set up the suction equipment with a 2 l collection container in place and, using a short tube, fit a vacuum level indicator to the container inlet port, thus totally occluding the inlet port. Operate the suction equipment for not less than 10 s at the maximum vacuum setting and, where appropriate, connected to a vacuum source as recommended by the manufacturer. Record the reading on the vacuum level indicator.

All vacuum level readings shall be expressed as the occluded (no-flow) value as shown on a vacuum level indicator scaled 0 kPa to 100 kPa below atmospheric pressure.

A.11 Test for maximum vacuum level and free air flowrate of low vacuum equipment

With the collection container(s) empty, switch on the suction equipment with the vacuum regulator adjusted to give the maximum vacuum. Occlude the inlet port to the collection container and note the maximum vacuum level obtained. Open the inlet port and attach a low-resistance flowmeter to it. Note the mean free air flowrate when stable conditions are reached (see Figure A.7).

A.12 Test for free air flowrate for thoracic drainage

Connect the suction inlet port of the equipment to a collection container(s) to bring the total collection container capacity to be evacuated to 4,5 l ± 0,1 l.

Occlude the inlet port to the collection container(s).

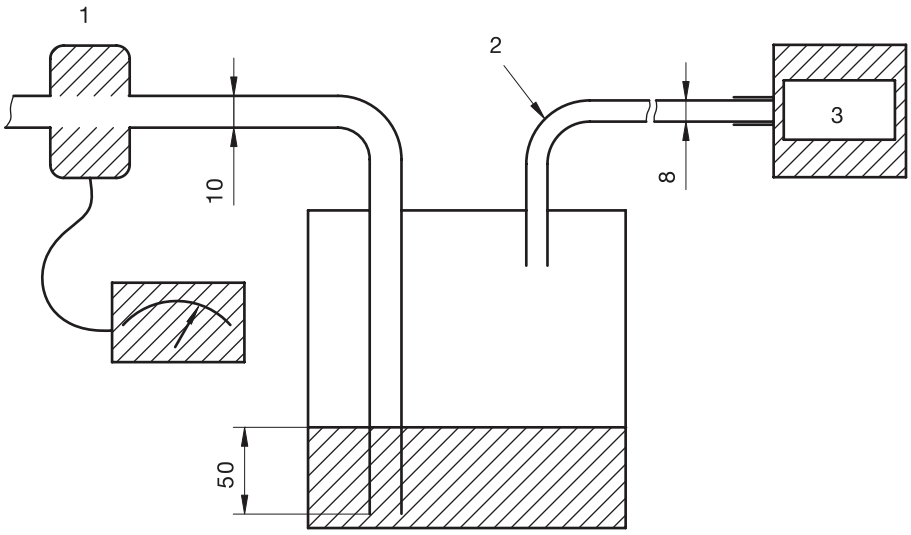
With the vacuum regulator set to between 6,6 kPa and 7,4 kPa below atmospheric pressure, switch on the suction equipment.

Note the time taken for the reading on the vacuum level indicator to increase from zero to 95 % of the set vacuum level. Note the final vacuum level.

Open the inlet port and, using 2 m of flexible hose having an inside diameter of 8 mm, attach an underwater seal having an inlet port of 10 mm inside diameter, positioned so that the end is 50 mm below the level

of the water. Connect a low resistance flowmeter immediately before the underwater seal, as shown in Figure A.8, and measure the free air flowrate.

Dimensions in millimetres



Key

1 low-resistance flowmeter (<0,1 kPa at 25 l/min)

2 tubing of length 2 m

3 equipment under test

Figure A.8 — Typical apparatus for testing free air flowrate for thoracic drainage

A.13 Test for intermittent vacuum regulator

Connect the vacuum regulator to a vacuum source as recommended by the manufacturer. Set the vacuum regulator to the inlet port mode and occlude the suction inlet port. Set the vacuum level in the middle third of the gauge range during the "on" cycle. Record the "on" time and "off" time in 5 complete cycles.

Open the suction inlet port and record the "on" and "off" time in 5 complete cycles.

A.14 Test for vacuum regulator with fixed setting

A.14.1 Apparatus

Use a vacuum source for the test with a vacuum regulator capable of regulating vacuum level between 50 kPa and 90 kPa below atmospheric pressure with a free air flowrate of 50 l/min. Make the measurements with a vacuum level indicator accurate to ± 1 % of the values chosen for the test (see Figure A.9).

A.14.2 Procedure

Set the source to give a vacuum level of 50 kPa below atmospheric pressure. Occlude the inlet port and read the vacuum level pressure shown on the vacuum level indicator. Increase the source to give a vacuum level of 85 kPa below atmospheric pressure. Occlude the inlet port and read the vacuum level pressure shown on the vacuum level indicator.

Repeat the above test three times. Report the widest percentage deviation from the fixed setting.

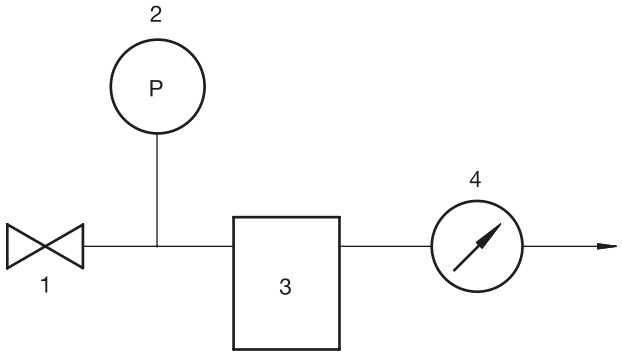
A.15 Test for vacuum regulator with variable setting

Commence with the vacuum source at 80 kPa below atmospheric pressure and reduce the vacuum level to 50 kPa below atmospheric pressure with the vacuum regulator set at 20 kPa below atmospheric pressure or one-fifth of the maximum pressure, whichever is lower. Read the new occluded vacuum level pressure on the vacuum level indicator (see Figure A.9).

Set the vacuum regulator to 55 kPa below atmospheric pressure or four-fifths full scale, whichever is lower, and increase the vacuum level from the source to 80 kPa below atmospheric pressure. Read the new occluded vacuum level pressure on the vacuum level indicator.

Reduce the vacuum level from 80 kPa to 50 kPa below atmospheric pressure and read the new occluded vacuum level pressure on the vacuum level indicator.

Repeat the above test three times. Report the widest percentage deviation from the test settings.



Key

1 on/off valve
2 vacuum level indicator
3 vacuum regulator under test
4 variable vacuum source, 45 kPa to 85 kPa below atmospheric pressure, 50 l/min

Figure A.9 — Arrangement of apparatus for testing vacuum regulators

A.16 Test for pharyngeal suction

A.16.1 Test material and apparatus

A.16.1.1 Simulated vomitus

Prepare the simulated vomitus by dissolving 10 g of food grade xanthan gum in 1 l of distilled water and adding 100 g of 1 mm diameter glass beads having a specific gravity of approximately 2,55.

NOTE 0,1 % (mass fraction) benzoic acid may be added as a preservative.

A.16.1.2 Graduated cylinder

Use a graduated cylinder, having a capacity of at least 300 ml with graduations no more than 50 ml apart.

A.16.2 Procedure

Agitate the simulated vomitus to disperse the glass beads immediately before testing. Pour 250 ml at ambient temperature into the graduated cylinder. Attach the suction tubing to the suction equipment and operate the equipment with the level of the simulated vomitus at the same horizontal level as the

top of the collection container. Place the suction tubing into the graduated cylinder and record the time taken to evacuate 200 ml of the simulated vomitus.

A.17 Test for resistance to environment of suction equipment for field and/or transport use

A.17.1 General

Following completion of each of the procedures in A.17.2, test the suction equipment for compliance with the requirements given in Clauses 7 and 9, as appropriate.

A.17.2 Procedure

A.17.2.1 Low temperature operation

Place the suction equipment in an environmental chamber, maintained at a temperature of (-18 ± 2) °C, for 4 h or until the temperature of the test system stabilizes. At the end of this period, remove the suction equipment from the chamber and allow it to stand at a temperature of between 18 °C and 22 °C and a relative humidity of between 40 % and 70 %. Within 5 min, start operating and testing the suction equipment.

A.17.2.2 High temperature operation

Place the suction equipment in an environmental chamber, maintained at a temperature of (50 ± 2) °C and with a relative humidity of at least 95 %, for at least 4 h or until stabilized. At the end of this period, remove the suction equipment from the chamber and allow it to stand at a temperature of between 18 °C and 22 °C and a relative humidity of between 40 % and 70 %. Within 5 min, start operating and testing the suction equipment.

A.17.2.3 Low temperature storage

Place the suction equipment in an environmental chamber, maintained at a temperature of (-40 ± 5) °C, for a period of at least 24 hours. At the end of this period, remove the suction equipment from the chamber and allow it to stand at a temperature of between 18 °C and 22 °C and a relative humidity of between 40 % and 70 % for 4 hours. At the end of this period, test the suction equipment.

A.17.2.4 High temperature storage

Place the suction equipment in an environmental chamber, maintained at a temperature of (60 ± 5) °C and at 40 % to 70 % relative humidity, for a period of at least 24 hours. At the end of this period, remove the suction equipment from the chamber and allow it to stand at a temperature of between 18 °C and 22 °C and a relative humidity of between 40 % and 70 % for 4 hours. At the end of this period, test the suction equipment.

Annex B
(informative)

Rationale statement

B.1 General

Remarks made in this annex apply to the relevant clauses and subclauses in the main body and are indicated in this annex by square brackets.

B.2 Container capacity [see 6.1.2.1 and 6.1.2.2]

The specified volume is intended to allow effective clearance of the pharynx twice. The pharyngeal volume is usually less than 150 ml.

B.3 Length of suction tubing [see 6.3.2]

1,3 m will allow the suction equipment to be operated on the floor when being used in a patient who is on a bed or trolley.

B.4 Dimensions [see 8.1]

The dimensions, applied to equipment intended for use outside a health care facility, were chosen to allow suction equipment to pass through narrow openings such as car windows, manholes or other narrow openings in disaster situations.

B.5 Resistance to the environment [see Clause 10]

The conditions specified for operating and storage conditions have been aligned with ISO 10651-4.

Annex C
(informative)

Lumen size and its effect on flowrate

C.1 General

Suction performance is markedly affected by the length and the diameter of the tubing between the collection container and the end-piece.

Effective suction depends on adequate flowrate and pressure. If suction tubing has an internal diameter of less than 6 mm, the pressure drop and restriction of flow may result in inadequate suction for some application.

The laminar flowrate of fluid (gas or liquid) is approximately proportional to the fourth power of the inside diameter (ID) of the lumen, and inversely proportional to the length.

For each system, it is suggested that the largest diameter and shortest tube which is practical be used.

Table C.1 shows the relative flowrates of various diameters of straight tubing under similar conditions. The flowrate through a 6,4 mm ID tube is designated as 100 %.

Table C.1 — Effect of lumen size on flowrate

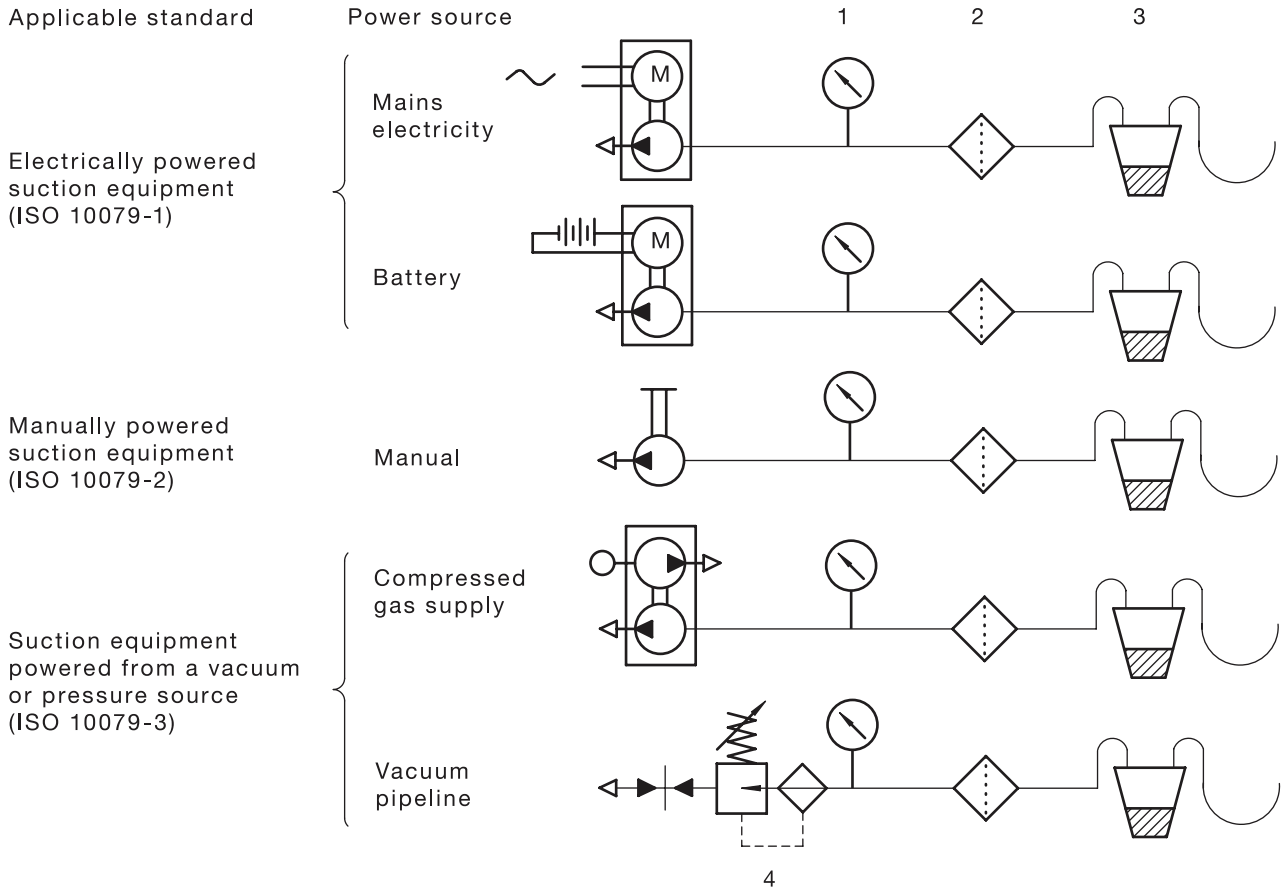
Internal diameter	Flowrate	Estimated pressure drop over 2 m length[a]	Approximate water flowrate through 2 m length[b]
mm	%	kPa	l/min
4,8	30	6,26	2,7
5	40	5,20	3,2
5,7	60	3,33	4,0
6	80	2,53	4,7
6,4	100	2,00	5,5
7	150	1,33	6,2
7,1	160	1,07	6,5
7,9	240	0,67	7,7
8	250	0,64	7,8

[a] Estimated loss of vacuum level per 2 m length of straight tubing flowing 20 l/min air at a vacuum level of 40 kPa below atmospheric pressure. Specific brands of tubing may give slightly different results depending on the smoothness of the lumen and properties of the material.

[b] These flowrates are for horizontally positioned tubing at ambient temperature and an applied vacuum level of 40 kPa below atmospheric pressure.

Annex D
(informative)

Schematic of suction equipment



Key

1 vacuum level indicator
2 filter
3 collection container
4 vacuum regulator

NOTE The items of suction equipment shown are typical examples. Actual systems may consist of other arrangements and components.

Figure D.1 — Schematic of suction equipment covered in ISO 10079

Bibliography

[1] ISO 7396-1:2007, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum*

[2] ISO 8836, *Suction catheters for use in the respiratory tract*

[3] ISO 9170-1, *Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed medical gases and vacuum*

[4] ISO 10079-1, *Medical suction equipment — Part 1: Electrically powered suction equipment — Safety requirements*

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

[6] ISO 10524-1, *Pressure regulators for use with medical gases — Part 1: Pressure regulators and pressure regulators with flow-metering devices*

[7] ISO 10651-4, *Lung ventilators — Part 4: Particular requirements for operator-powered resuscitators*

[8] ISO 18082, *Anaesthetic and respiratory equipment - Non-interchangeable screw-threaded (NIST) low-pressure connectors for medical gases*

[9] CGA V-5, *Diameter Index Safety System (non-interchangeable Low Pressure Connections For Medical Gas Applications)*

ICS 11.040.10

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