BS EN ISO 10079-1:2015

Incorporating corrigendum February 2016

BSI Standards Publication

Medical suction equipment

Part 1: Electrically powered suction equipment

National foreword

This British Standard is the UK implementation of EN ISO 10079-1:2015. It supersedes BS EN ISO 10079-1:2009 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/121, Anaesthetic and respiratory equipment.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10079-1

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English Version

Medical suction equipment - Part 1: Electrically powered suction equipment (ISO 10079-1:2015)

Appareils d'aspiration médicale - Partie 1: Appareils électriques d'aspiration (ISO 10079-1:2015)

Medizinische Absauggeräte - Teil 1: Elektrisch betriebene Absauggeräte (ISO 10079-1:2015)

This European Standard was approved by CEN on 13 May 2015.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Ref. No. EN ISO 10079-1:2015 E

European foreword

This document (EN ISO 10079-1:2015) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment" the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 2016, and conflicting national standards shall be withdrawn at the latest by November 2018.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 10079-1:2009.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 10079-1:2015 has been approved by CEN as EN ISO 10079-1:2015 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the essential requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered

This European Standard has been prepared under a Commission's standardization request M/023 concerning the development of European Standards related to medical devices to provide one voluntary means of conforming to essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [OJ L 169].

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding essential requirements of that Directive and associated EFTA regulations.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC as amended by 2007/47/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with Essential Requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

NOTE 3 When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 — Correspondence between this European Standard and Annex I of Directive 93/42/EEC [OJ L 169]

Essential Requirements of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
7.1 Third indent only	4.4	
7.2	5; 7.5	Partly covered There are no requirements for packaging.
7.3 First part only	6.1.3	
7.6	6.2.3; 6.5; 7.5.1; 7.5.2	
8.1	4.2; 5; 7.5.1	
8.7	11.3 c)	
9.1 First sentence only	6.2; 6.3	
9.2	4; 6.1.3	Partly covered Electrical safety is by ref to IEC 60601–1 and risk management by ref to ISO 14971.

Essential Requirements of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
10.1	6.4.6	Partly covered. There are no requirements for the manufacturer to disclose the accuracy of the vacuum level indicator.
10.2	6.4	
10.3	11.3 i)	Covered for volume measurements only
12.1	4	Covered by ref to IEC 60601–1
12.1a)	4	Covered by ref to IEC 60601–1
12.2	4	Covered by ref to IEC 60601–1 although suction equipment is not considered life-support equipment.
12.5	4	Covered by ref to IEC 60601–1 and thereby to IEC 60601–1–2
12.6	4; 6.5	Covered by ref to IEC 60601–1
12.7.1	6.1.3; 7.4	
12.7.2	4	Covered by ref to IEC 60601–1
12.7.3	7.6	
12.7.4	4	Covered by ref to IEC 60601–1
12.7.5	4	Covered by ref to IEC 60601–1
12.8.2 Second sentence only	7.5.3.2	
12.9	11.3 i); j); k); l); m); n); o); p); q); r)	
13.1	11	
13.2	11.2	
13.3a)	11.3 a)	
13.3b)	11.3 b)	
13.3c)	11.3 c)	
13.3d)	11.3 d)	
13.3e)	11.3 e)	
13.3 f)	11.3 f)	
13.3 k)	11.4 c); q); y)	
13.3 l)	11.3 d)	
13.3 m)	11.4 i)	
13.4	11.4 b)	
13.6 a)	11.4	Not covered for the requirement of ER 13.3b)
13.6 b)	11.4 d); e)	

Essential Requirements of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
13.6 c)	11.4 d) ;k)	
13.6 d)	11.4 d); j); v)	Calibration is not covered
13.6 f)	11.4 x)	
13.6 h) First two paragraphs only	11.4 i)	
13.6 i)	11.4 j)	
13.6 q)	11.4 z)	

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the products falling within the scope of this standard.

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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 10079-1:1999), 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 Annex B, Annex C, and Annex 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 (*) at the beginning of the paragraph 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 into 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.

Annex D illustrates the three parts of ISO 10079 by providing a schematic for typical systems.

INTERNATIONAL STANDARD ISO 10079-1:2015(E)

Medical suction equipment —

Part 1: Electrically powered suction equipment

1 Scope

This part of ISO 10079 specifies safety and performance requirements for electrically powered medical and surgical suction equipment. It applies to equipment used in health care facilities such as hospitals, for domiciliary care of patients and for field and transport use.

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-pieces such as suction catheters, drains, curettes, Yankauer suckers and suction tips;

c) syringes;

d) dental suction equipment;

e) anaesthetic gas scavenging systems;

f) laboratory suction;

g) autotransfusion systems;

h) mucus extractors including neonatal mucus extractors;

i) suction equipment where the collection container is downstream of the vacuum pump;

j) ventouse (obstetric) equipment;

k) suction equipment marked for endoscopic use only;

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

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

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

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.

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 60529, *Degrees of protection provided by enclosures (IP Code)*

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 60601-1-11:2010, *Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

IEC 60601-1-12:2014, *Medical electrical equipment — Part 1-12: General requirements for basic safety and essential performance — Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment*

IEC/TR 60878, *Graphical symbols for electrical equipment in medical practice*

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

3.3
end-piece
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.

3.4
exhaust port
opening through which exhaust gas is discharged

3.5
field use
use of suction equipment in situations outside of the health care facility and home environment

3.6
filter
device for retention of particulate matter

3.7
free air flowrate
rate of unrestricted flow of air through a designated inlet

3.8
high flowrate
free air flowrate (3.7) of 20 l/min or more

3.9
high vacuum
vacuum level (3.23) of 60 kPa or more

3.10
inlet port
opening through which liquid, solid particles or gas enter

3.11
intermediate tubing
tubing between the *collection container* (3.1) and the *vacuum source* (3.26)

3.12
intermittent vacuum
type of *suction* (3.19) in which the negative pressure applied to the *end-piece* (3.3) is automatically and periodically returned to atmospheric pressure

3.13
low flowrate
free air flowrate (3.7) less than 20 l/min

3.14
low vacuum
vacuum level (3.23) of not more than 20 kPa

3.15
medium vacuum
vacuum level (3.23) of more than 20 kPa, but less than 60 kPa

3.16
outlet port
opening through which gas exits from the *collection container* (3.1)

3.17
overfill protection device
device intended to prevent liquid or solid particles from entering the *intermediate tubing* (3.11)

3.18
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.

3.19
suction
application of vacuum to remove liquid, solid particles or gas

3.20
suction tubing
tubing for conduction of liquid, solid particles or gas between the *end-piece* (3.3) and the *collection container* (3.1)

3.21
thoracic drainage
drainage (3.2) of liquid and gas from the thoracic cavity by application of *suction* (3.19) 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.

3.22
transport use
use during patient transport outside of a health care facility (e.g. in an ambulance or airplane)

3.23
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.

3.24
vacuum level indicator
device for displaying the *vacuum level* (3.23)

3.25
vacuum regulator
device for controlling the applied *vacuum level* (3.23)

3.26
vacuum source
component of device for generating vacuum

4 General requirements

Electrically powered medical suction equipment 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 electrically powered medical 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 Electrically 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 to deal with such situations need to be determined within the risk management process.

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.

4.2 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 can be sourced from the following:

— clinical investigation(s) of the device concerned;

— 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;

— 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 and technical files.

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.

4.5 Test methods

The manufacturer can 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.

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 Clause 7 and Clause 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

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.

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 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 Clause 7 and Clause 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 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 specified by the manufacturer.

The inlet port 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 If the internal diameter is greater than 14 mm, there is a risk of misconnection.

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.

NOTE Special surgical procedures such as liposuction and suction curettage might require suction tubing and connectors of a larger bore.

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

NOTE Suction performance might be markedly affected by the length and diameter of the suction tubing between the end-piece and collection container (see Annex C).

6.4 Vacuum level indicators

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

6.4.2 The full scale of analog vacuum level indicators shall be not more than 200 % of the maximum vacuum level specified by the manufacturer.

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

Movement of a rotary analog vacuum level indicator should be anti-clockwise for an increase in vacuum level.

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

6.4.5 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.

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

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

6.4.8 Suction equipment having a vacuum regulator with a variable control shall have a vacuum indicator displaying the vacuum level on the inlet side of the vacuum regulator.

Check compliance by inspection and functional testing.

6.5 Spillage on electrical suction equipment

Suction equipment not intended for use in the field, other than suction equipment intended for use in the home healthcare environment, shall be classified as specified in IEC 60601-1:2005, 6.3 and 11.6.5.

Suction equipment intended for use in home healthcare environment shall be classified as specified in IEC 60601-1-11:2010, 8.3.

Suction equipment intended for use in the field shall be classified as specified in IEC 60601-1-12:2014, 8.1.

Remote foot switches with electrical switching parts shall be of watertight construction classified as at least IPX6 as specified in IEC 60529.

Check compliance by the tests specified in IEC 60529.

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 assembly or marked to indicate correct reassembly.

Suction equipment shall meet the requirements of Clause 9 as appropriate after dismantling and reassembly in accordance with the manufacturer's instructions.

Check compliance by functional testing.

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 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.

7.4.2 Suction equipment not intended for field and/or transport use shall meet the requirements given in Clause 9 as appropriate when placed in any position on a surface (10 ± 1)° slope from the horizontal.

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 pump (e.g. a filter).

Check compliance by inspection of the risk management and technical file.

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 within a period of 2 min.

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.

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

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 maximum 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 positive pressure in excess of 1 kPa.

Check compliance by the tests given in A.6.

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.

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.7.

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 test given in A.8.1.

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 test given in A.8.2.

8 Physical requirements for suction equipment for field use

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.

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

Check compliance by measuring.

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.

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

Check compliance by measuring.

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 level of at least 60 kPa within 10 s and a free air flowrate into the collection container (without suction tubing fitted) of not less than 20 l/min.

Check compliance by the test in A.9.

9.2 Medium vacuum equipment

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

Medium vacuum for breast pumps should not exceed 33 kPa.

Check compliance by the tests in A.9.

9.3 Low vacuum/low flowrate equipment

Suction equipment marked “low vacuum/low flow” shall produce a vacuum of not more than 20 kPa 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.10.

9.4 Low vacuum/high flowrate equipment

Suction equipment marked “low vacuum/high flow” shall produce a vacuum of not more than 20 kPa 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 test given in A.10.

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.

It shall be possible to set the vacuum level to between 0 kPa and 10 kPa.

For most situations the vacuum level developed should not exceed 7 kPa.

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. Such equipment shall produce a free air flowrate of at least 15 l/min and shall be capable of developing 95 % of the set vacuum level within 5 s when connected to a closed system of 4,5 l total capacity.

Suction equipment intended for thoracic drainage shall not develop a positive 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.11.

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.12.

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 test given in A.13.

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 test given in A.14.

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.15.

9.10 Battery powered transportable suction equipment

Battery powered suction equipment intended for field and/or transport use shall operate for at least 20 min during which time it shall produce a free air flowrate of not less than 20 I/min and a vacuum level of not less than 40 kPa.

Check compliance by the test in A.16.

9.11 Interruption of the power supply

Interruption and restoration of the power supply to the suction equipment shall not cause any hazard and the vacuum level and flowrate shall not vary by more than ± 10 % from the set value.

This performance requirement also applies if the original power source is replaced with another power source.

Check compliance by the test in A.17.

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 of Clause 7 and Clause 9 as appropriate after being subjected to temperatures of –18 °C and +50 °C.

Check compliance by the tests given in A.18.2.1 and A.18.2.2.

10.2 Storage

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

Check compliance by the tests given in A.18.2.3 and A.18.2.4.

11 Information to be supplied by the manufacturer (labelling and instructions for use)

11.1 Information supplied by the manufacturer shall comply with EN 1041.

Check compliance by inspection.

11.2 Where appropriate, information shall take the form of symbols complying with ISO 7000, ISO 15223-1 and IEC/TR 60878.

Check compliance by inspection.

11.3 Labelling of 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;

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

c) the word “sterile”;

d) the 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) (*) if a single opening is provided, words indicating “exhaust” or equivalent icon on the exhaust port;

h) words indicating “inlet” or equivalent icon 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 from the normal working position;

k) if the suction equipment is intended for field and/or transport use, the minimum and maximum ambient temperatures at which it is suitable for use shall be marked on the equipment case. If no case is provided, the statements shall be marked on the equipment;

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

m) the maximum vacuum level for which the equipment is designed, marked prominently on the equipment;

n) the units of measurement of the vacuum indicator, marked prominently on the equipment;

o) 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;

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

q) the direction of adjustment to increase vacuum level if a progressive variation in the degree of vacuum level is available;

r) 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.

11.4 Instructions for use

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);

   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;

h) a specification detailing the following:

   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, including part numbers, that can be replaced by the user;

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 can 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 if applicable;

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 or the version number.

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 capacity 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 and 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.

When carrying out this test, water may be ejected from the exhaust port or from an overflow outlet.

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, whichever is less. Hold the vacuum level for 5 min and then release. Repeat the procedure once.

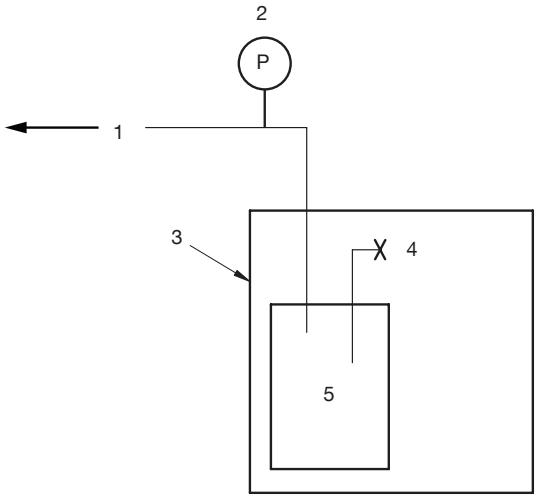
CAUTION — This test can be hazardous. Proper care should be taken to protect personnel from possible flying debris.

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 Clause 7 and Clause 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 vacuum level of 60 kPa. Hold the vacuum level for 5 min. Calculate the degree of collapse A by measuring the outside diameter of the suction tubing along its length with callipers as illustrated in Figure A.2.

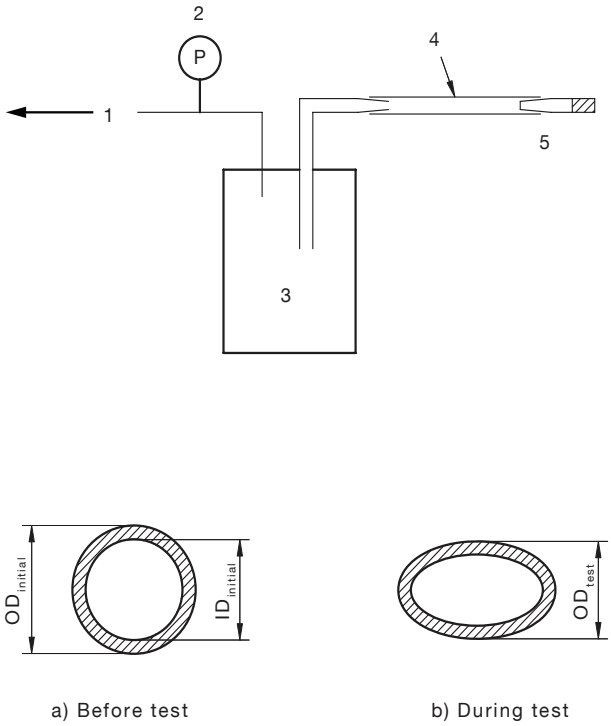
Repeat the test while the tube is loosely coiled around a 100 mm diameter cylinder.

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

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

Pass $A < 0{,}5$

Fail $A > 0{,}5$



Key

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

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

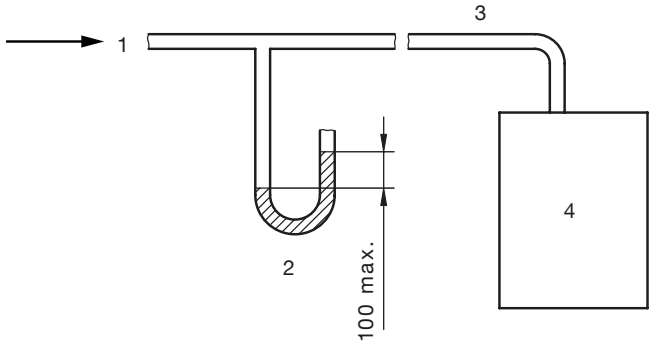
A.5 Drop test

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 Clause 9 as appropriate.

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

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

Dimensions in millimetres



Key

1 vacuum 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 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.

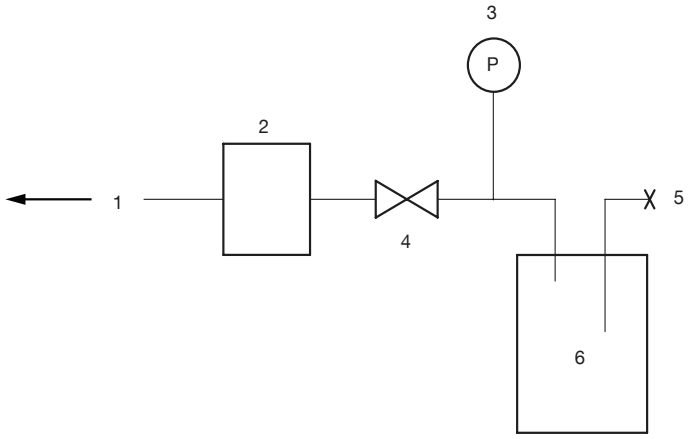
The A-weighted background level of extraneous noise shall be at least 10 dB below that measured during the test.

A.8 Test for air leakage into the collection container

A.8.1 Collection containers for general use

Evacuate the collection container to a vacuum level of 40 kPa. Close the suction tubing using the on/off valve (4 in Figure A.4) 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 collection container under test

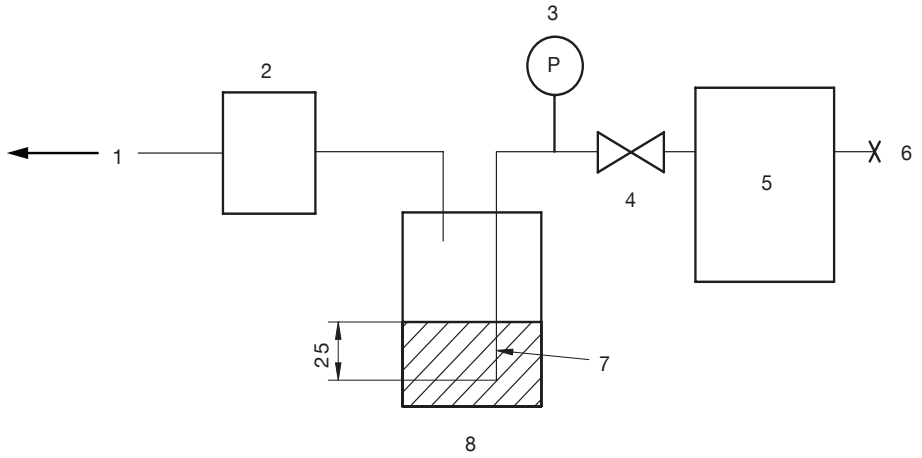
Figure A.4 — Typical apparatus for testing leakage of collection container for general use

A.8.2 Collection containers for thoracic drainage

Using the apparatus shown in Figure A.5 close the on/off valve. Set the vacuum regulator to a vacuum level of 15 kPa. 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



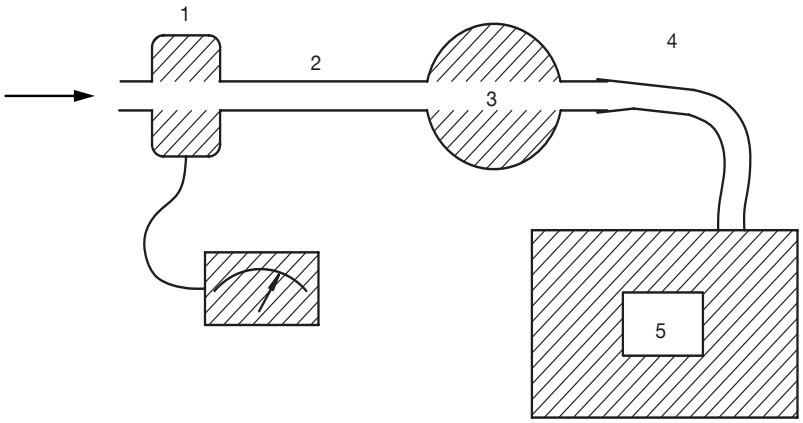
Key

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

Figure A.5 — Typical apparatus for testing leakage of collection container for thoracic drainage

A.9 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 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.6 for a typical test setup). Operate the suction equipment according to the manufacturer's instructions and record the flowrate.



Key

1 flowrate 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.6 — 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.10 Test for maximum vacuum level and free air flowrate of low vacuum equipment

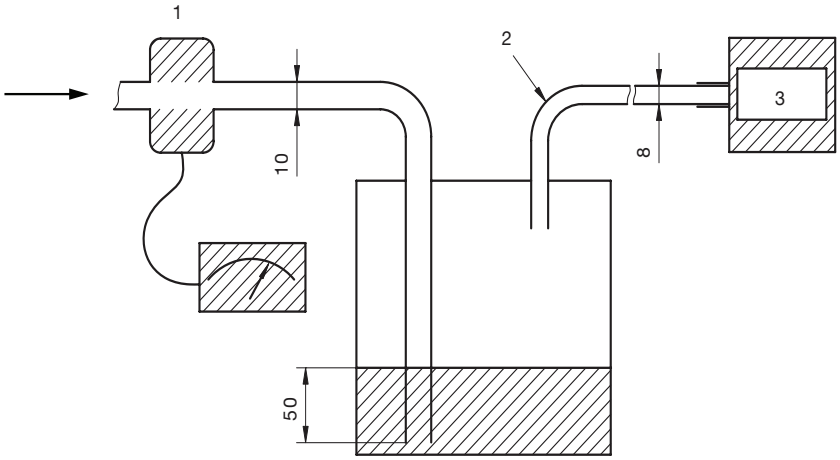
With the collection container(s) empty, switch on the suction equipment with the vacuum regulator adjusted to give the maximum vacuum. Occlude the inlet port to the collection container and note the maximum vacuum level obtained. Open the inlet port and attach a low-resistance flowmeter to it. Note the mean free air flowrate when stable conditions are reached (see Figure A.6).

A.11 Test for free air flowrate for thoracic drainage equipment

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 a vacuum level between 6,6 kPa and 7,4 kPa, 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.7 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.7 — Typical apparatus for testing free air flowrate for thoracic drainage equipment

A.12 Test for intermittent vacuum equipment

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.

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

A.13 Test for accuracy of vacuum regulator with fixed setting

A.13.1 Apparatus

Use a vacuum source with a vacuum regulator capable of regulating the vacuum level between 50 kPa and 90 kPa 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.8).

A.13.2 Procedure

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

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

A.14 Test for accuracy of vacuum regulator with variable setting

A.14.1 Apparatus

Use apparatus as per A.13.1 and Figure A.8.

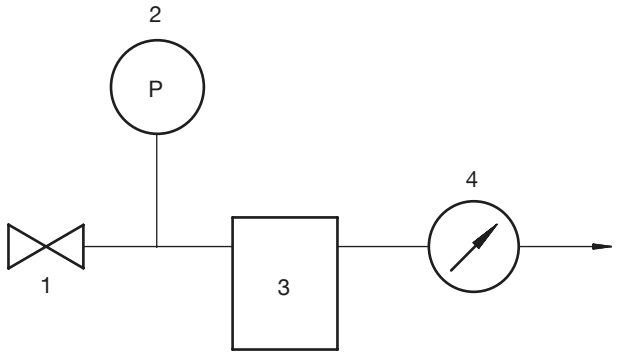
A.14.2 Procedure

Commence with the vacuum level from the vacuum source set at 80 kPa, then reduce to 50 kPa with the vacuum regulator set at 20 kPa or one-fifth of the maximum vacuum level, whichever is lower. Read the new occluded vacuum level on the vacuum level indicator (see Figure A.8).

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

Reduce the vacuum level from the vacuum source from 80 kPa to 50 kPa and read the new occluded vacuum level 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, 50 l/min

Figure A.8 — Arrangement of apparatus for testing vacuum regulators

A.15 Test for pharyngeal suction

A.15.1 Test material and apparatus

A.15.1.1 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.

Benzoic acid 0,1 % (mass fraction) can be added as a preservative.

A.15.1.2 Graduated cylinder

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

A.15.2 Procedure

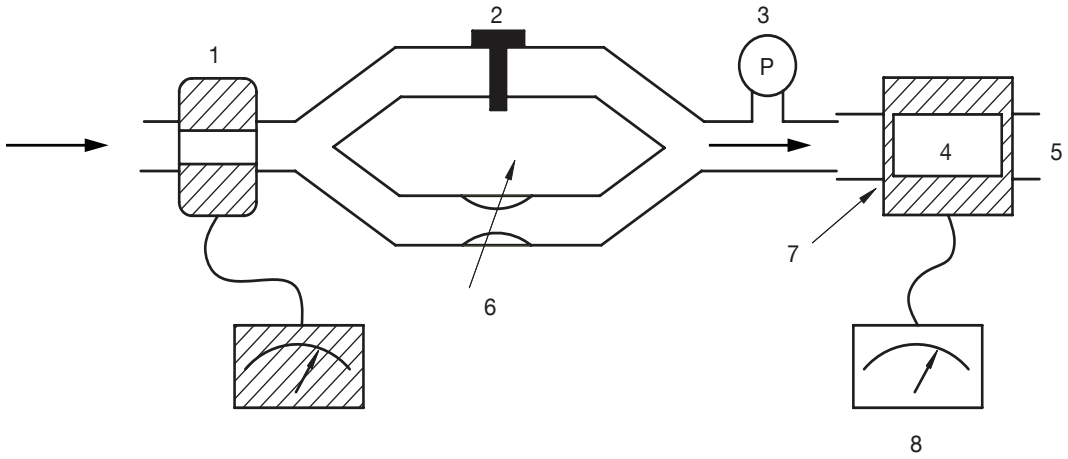
Agitate the simulated vomitus to disperse the glass beads immediately before testing. Pour 250 ml at ambient temperature into the graduated cylinder. Attach the suction tubing to the suction equipment and operate the equipment with the level of the simulated vomitus at the same horizontal level as the 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.16 Battery powered transportable suction equipment

Ensure that the power supply of the equipment is fully charged according to the manufacturer's instructions. Attach a low resistance flowmeter with a pressure drop of less than 1 kPa at 30 l/min free air flowrate to the inlet of the collection container. Insert an adjustable flow restrictor and an open tube in parallel with a switch downstream of the flowmeter as shown in Figure A.9.

Operate the equipment with the patient connection occluded and record the maximum vacuum level after 15 s. Adjust the restrictor to operate the equipment at maximum current. Run the equipment continuously alternating between 15 s maximum load and 15 s free air flow.

Record the maximum vacuum level and the first time at which either the free air flowrate drops below 20 l/min or the set patient flowrate (maximum current load) declines to 80 % of the initial flowrate value used for maximum load or if the test is conducted with no flow, the time at which the vacuum level drops below 40 kPa.



Key

1 flowrate measuring device
2 switch
3 vacuum level indicator
4 equipment under test
5 exhaust
6 adjustable resistor
7 inlet port
8 ammeter

Figure A.9 — Battery powered suction equipment

A.17 Interruption of power supply

With the suction equipment operating in normal condition and with the vacuum level set to half the maximum vacuum level, interrupt the power supply. After a period of 5 min reconnect the power supply and switch on the suction equipment. After 30 s measure the vacuum level and flowrate.

A.18 Test for resistance to environment of suction equipment for field and/or transport use

A.18.1 General

Following completion of each of the procedures in A.18.2, test the suction equipment for compliance with the requirements given in Clause 7 and Clause 9 as appropriate.

A.18.2 Procedures

A.18.2.1 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.18.2.2 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.18.2.3 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 h. 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 h. At the end of this period test the suction equipment.

A.18.2.4 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 h. 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 h. 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 located on the floor when being used on a patient who is on a bed or trolley.

B.4 Dimensions [see 8.1]

The dimensions specified for 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.

B.6 Labelling of equipment [see 11.3 g)]

An exhaust port with a single opening can allow a misconnection and should be labelled. A multiple hole exhaust system is unlikely to be misconnected.

Annex C
(informative)

Lumen size and its effect on flowrate

C.1 General

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 flowrate can result in inadequate suction for some applications.

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 sizes 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

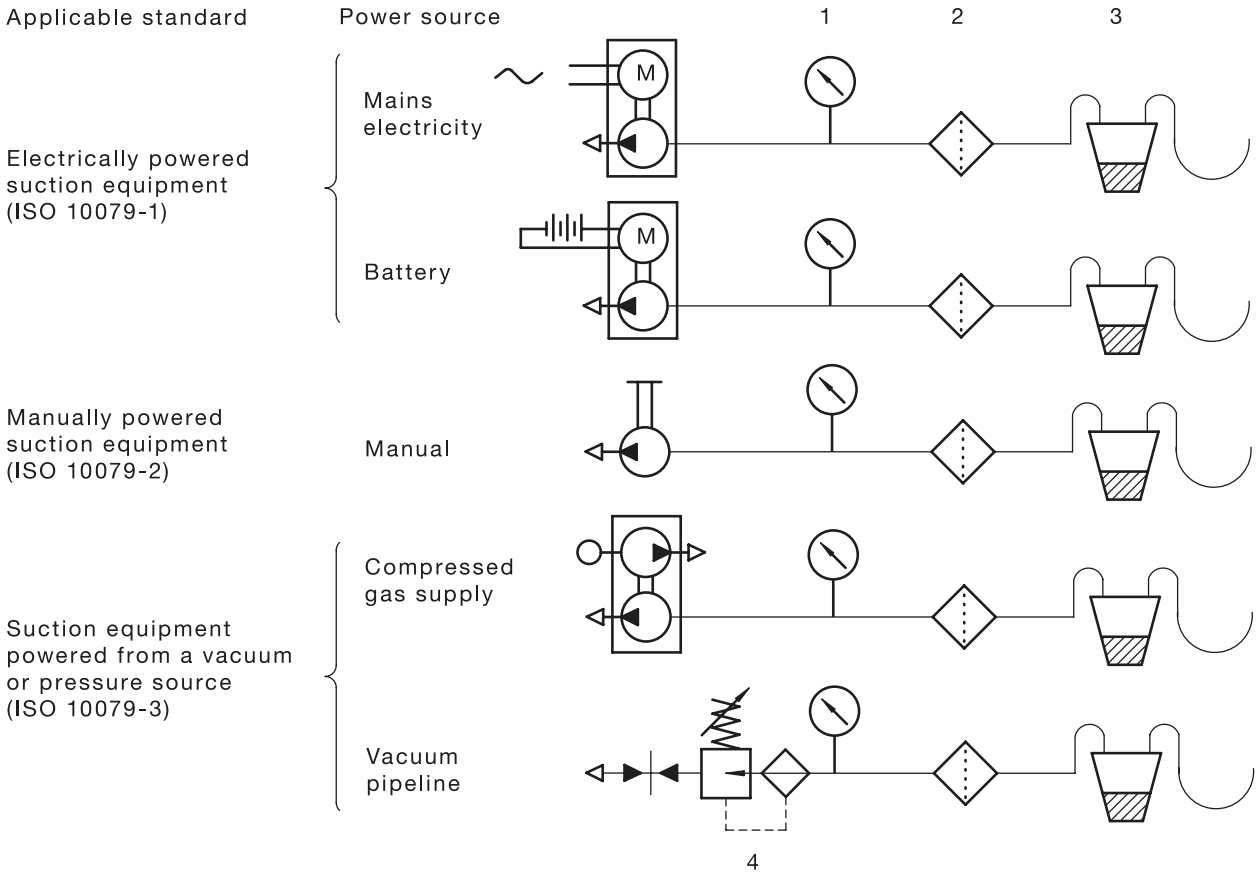
Internal diameter	Flowrate	Estimated pressure drop over 2 m length[a]	Approximate water flowrate through 2 m length[b]
mm	%	kPa	l/min
4,8	30	6,26	2,7
5	40	5,20	3,2
5,7	60	3,33	4,0
6	80	2,53	4,7
6,4	100	2,00	5,5
7	150	1,33	6,2
7,1	160	1,07	6,5
7,9	240	0,67	7,7
8	250	0,64	7,8

[a] Estimated loss of vacuum level per 2 m length of straight tubing at a flowrate of 20 l/min air at a vacuum level of 40 kPa. Specific brands of tubing can 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.

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 8836, *Suction catheters for use in the respiratory tract*

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

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

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

[5] IEC 60079-4:1975, *Electrical apparatus for explosive gas atmospheres — Part 4: Method of test for ignition temperature*

[6] IEC 60695-2-2:1980, *Fire hazard testing — Part 2: Test methods — Needle-flame test*

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