INTERNATIONAL STANDARD

ISO 10079-1

First edition
1991-05-15

Medical suction equipment —

Part 1:
Electrically powered suction equipment — Safety requirements

Matériel d'aspiration médical —

Partie 1: Matériel électrique d'aspiration — Prescriptions de sécurité

Reference number
ISO 10079-1 : 1991 (E)

Contents

International Organization for Standardization
Case postale 56 • CH-1211 Genève 20 • Switzerland
Printed in Switzerland

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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 10079-1 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Sub-Committee SC 8, *Suction devices for hospital and emergency care use.*

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

— *Part 1: Electrically powered suction equipment — Safety requirements*

— *Part 2: Non-electrical manually powered suction equipment*

— *Part 3: Non-electrical suction equipment powered from a vacuum or pressure source*

Annexes M, N and P of this part of ISO 10079 are for information only.

Introduction

This part of ISO 10079, which has been prepared under the responsibility of Sub-Committee 8 of ISO/TC 121, comprises Part 1 of the standard for Medical Suction Equipment, and deals only with safety requirements for electrically powered suction equipment.

Suction is used to clear the airway and remove unwanted material from body cavities. Suction is also used to assist drainage and decompress body cavities. Suction and vacuum systems are used widely both in health care facilities such as hospitals, for domiciliary care of patients who are nursed at home, and in emergency situations both outside hospitals in field conditions, and during transport in ambulances.

In this part of ISO 10079, vacuum readings are specified as gauge (relative) pressures to assist clinical personnel. However, this is not intended to prevent engineering groups from using absolute vacuum in their design process.

Test methods other than those specified in this part of ISO 10079, but of equal or greater accuracy, may be used to verify compliance with the given requirements. However, in the event of a dispute, the methods specified in this part of ISO 10079 are to be used as the reference methods.

A rationale for the most important requirements is given in annex M. It is considered that a knowledge of the reasons for the requirements will not only facilitate the proper application of the standard, but will expedite any subsequent revision. This annex does not form part of the standard.

Medical suction equipment —

Part 1:
Electrically powered suction equipment — Safety requirements

Section 1: General

1.1 Scope

NOTE — See also annex M (in this part of ISO 10079).

ISO 10079-1 is one of a series of International Standards based on IEC 601-1; in IEC 601-1 (the "General Standard"), this type of International Standard is referred to as a "Particular Standard". As stated in 1.3 of IEC 601-1 : 1988, the requirements of this International Standard take precedence over those of IEC 601-1.

The Scope and Object given in clause 1 of IEC 601-1 : 1988 applies except that 1.1 shall be replaced by the following:

This part of ISO 10079 specifies minimum safety and performance requirements for medical and surgical suction equipment (see figure 1) in health care facilities such as hospitals, for domiciliary care of patients and for field and transport use. Although equipment may be driven by centrally powered piped vacuum systems, compressed gases, electricity or be manually powered for a variety of applications, this part addresses only equipment powered electrically.

Excluded from the standard are:

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

b) catheter tubes, drains, curettes and suction tips;

c) syringes;

d) dental suction equipment;

e) waste gas scavenging systems;

f) laboratory suction;

g) autotransfusion systems;

h) passive urinary drainage;

i) closed system for wound drainage;

j) gravity gastric drainage;

k) orally operated mucous extractors;

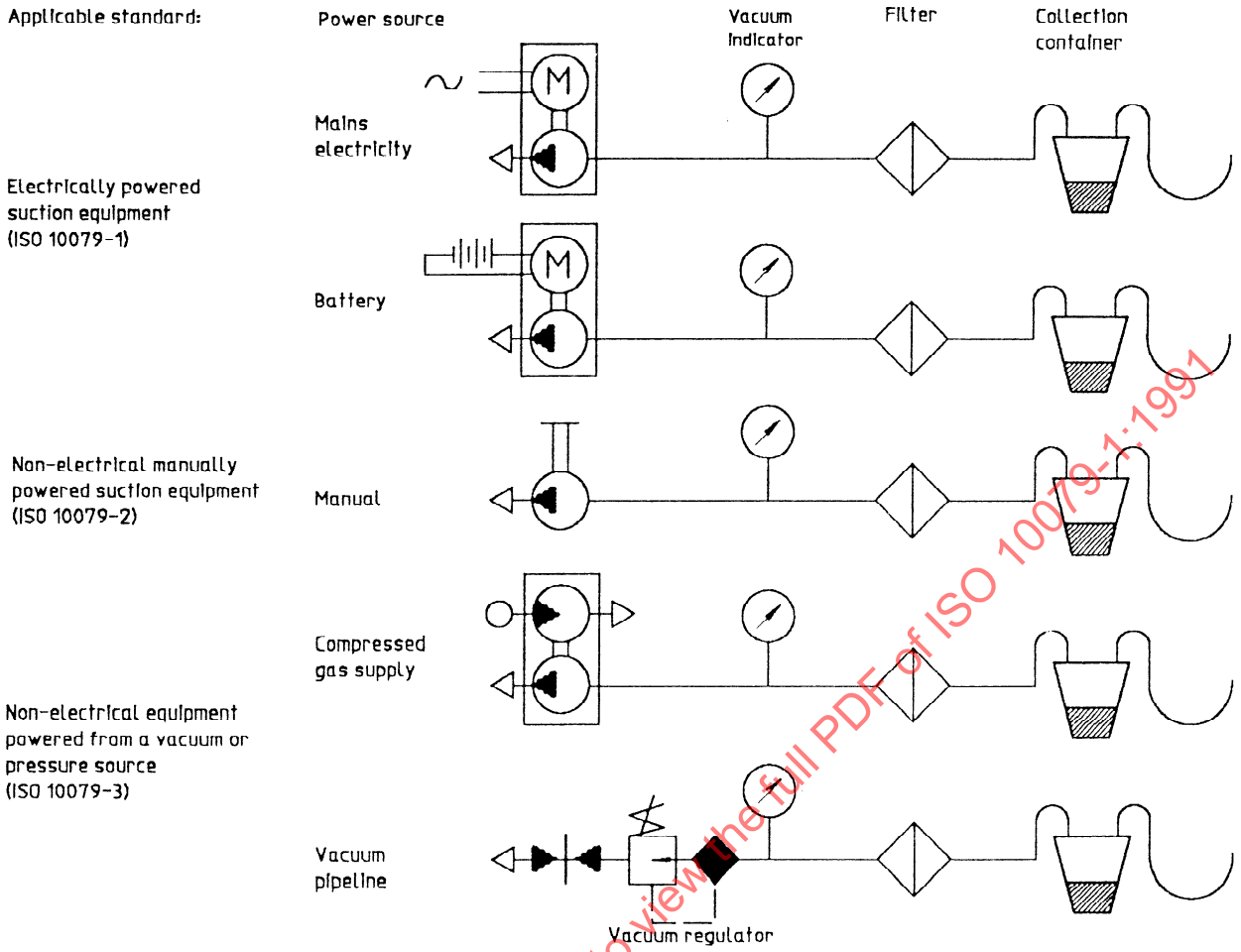
l) suction equipment where the collection container is downstream of the vacuum pump;

m) equipment marked as suction unit for permanent tracheostomy;

n) ventouse (obstetric) equipment;

o) neonatal mucous extractors;

p) suction equipment marked for endoscopic use only.



NOTES

1 This part of ISO 10079 applies to mains electricity and battery-powered suction equipment.

Part 2 of ISO 10079 applies to non electrical manually powered suction equipment.

Part 3 of ISO 10079 applies to non-electrical suction equipment powered from a vacuum or pressure source.

2 Components illustrated are not necessarily required by this International Standard.

3 Suction equipment shown are only examples, and actual systems may consist of other arrangements and components not illustrated in the figure.

Figure 1 — Schematic drawing illustrating suction equipment

1.4 Environmental conditions

The requirements given in 1.4 of IEC 601-1 apply except that the following modification shall be made to 1.4 b) 1).

Substitute "+ 5 °C" for "+ 10 °C" and "+ 35 °C" for "40 °C".

For field and transport use, environmental conditions shall be as specified in 53.

1.2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 10079. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 10079 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 32 : 1977, *Gas cylinders for medical use — Marking for identification of content.*

ISO 3743 : 1988, *Acoustics — Determination of sound power levels of noise sources — Engineering methods for special reverberation test rooms.*

ISO 3744 : 1981, *Acoustics — Determination of sound power levels of noise sources — Engineering methods for free-field conditions over a reflecting plane.*

ISO 5356-1 : 1987, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets.*

IEC 529 : 1976, *Classification of degrees of protection provided by enclosures.*

IEC 601-1 : 1988, *Medical electrical equipment — Part 1: General requirements for safety.*

IEC 651 : 1979, *Sound level meters.*

IEC 695-2-2 : 1980, *Fire hazard testing — Part 2: Test methods — Needle-flame test.*

1.3 Definitions

For the purposes of this part of ISO 10079, the definitions given in clause 2 of IEC 601-1 : 1988 apply except that the definition given in 2.1.5 shall be replaced by the following:

applied part: All parts in the liquid pathway.

Add to definition 2.4.3 the following:

safety extra-low voltage (SELV): Includes the electrical sources which are isolated (e.g. car battery) and do not require a separate transformer or converter with separate windings.

For the purposes of this part of ISO 10079, the following definitions also apply.

1.3.1 vacuum: Pressure less than atmospheric pressure, normally expressed as a difference from atmospheric pressure.

1.3.2 high vacuum: Vacuum of at least − 60 kPa 1).

1.3.3 medium vacuum: Vacuum less than − 60 kPa and greater than − 20 kPa.

1.3.4 low vacuum: Vacuum not more than − 20 kPa.

1.3.5 vacuum regulator: Device for controlling the maximum vacuum applied to the patient.

1.3.6 vacuum indicator: Device for displaying the level of vacuum.

1.3.7 suction: Application of vacuum to remove fluids or solid particles.

1.3.8 high flow: Suction with a free air flow of 20 l/min or greater.

1.3.9 low flow: Suction with a free air flow less than 20 l/min.

1.3.10 inlet: Part of a component through which fluids and/or solid particles enter.

1.3.11 outlet: Part of a component through which fluids and/or solid particles exit.

1.3.12 exhaust opening: Port or ports through which exhaust is discharged.

1.3.13 collection container: Container in which fluids or solid particles are collected.

1.3.14 collection container assembly: Collection container and its closure.

1.3.15 overfill device: Device intended to prevent liquid or solid particles entering the intermediate tubing.

1.3.16 filter: Device for separation of particulate matter.

1.3.17 end-piece: That part of the suction equipment applied to the patient. The end-piece starts at the site where material is drawn in and ends upstream of the first detachable connection.

1.3.18 vacuum pump: Powered device for generating vacuum.

1.3.19 thoracic drainage: Drainage by application of suction to the thoracic cavity of the patient.

1.3.20 intermittent suction: Suction where the negative pressure applied to the end-piece is automatically and periodically returned to atmospheric pressure.

NOTE — Cycling may be determined by end-piece occlusion.

1.3.21 drainage: Removal of fluids from a body cavity or wound, assisted by vacuum.

1.3.22 free air flow: Unrestricted flow of air through a nominated inlet.

1.3.23 suction tubing: Tubing as supplied or recommended by the manufacturer for conduction of fluids from the end-piece to the collection container.

1.3.24 breast pump: Vacuum pump for the collection of breast milk.

1.3.25 pharyngeal suction: Suction applied to the human pharynx through the mouth.

1.3.26 intermediate tubing: Tubing between the collection container and the vacuum pump.

1) 1 kPa = 7,500 63 mmHg or 4,014 629 in H_2O or 10,197 16 cm H_2 or 10 hPa

1.4 General requirements and general requirements for tests

The requirements given in clauses 3 and 4 of IEC 601-1: 1988 apply together with the following addition:

— In 4.6, add the following additional item:

f) Where reference is made in test methods to tubing, that supplied or recommended by the manufacturer shall be used.

1.5 Classification

The classification given in clause 5 of IEC 601-1: 1988 applies.

1.6 Identification, marking and documents

The requirements given in clause 6 of IEC 601-1: 1988 apply except for the following additions and modifications:

— Replace 6.1 p) by the following:

1) All equipment generating suction shall be marked with words indicating suction, and with an indication of the available level of vacuum as determined by the manufacturer. This marking shall be visible in the normal working position.

NOTE — Equipment should be marked with the designation "high vacuum/high flow", "high vacuum/low flow", "medium vacuum/low flow", "low vacuum/high flow" or "low vacuum/low flow", as appropriate. Vacuum regulators should also comply with this requirement.

2) Low vacuum equipment with a level of vacuum which is not adjustable by the user shall be marked either with the level of vacuum which can be attained or with words indicating low vacuum.

3) Intermittent suction equipment shall be marked with words indicating intermittent suction. Equipment which can provide continuous and also intermittent suction shall have the mode control clearly marked.

4) If there is a single exhaust opening, it shall be marked with words indicating exhaust opening.

5) Suction equipment intended for thoracic drainage and complying with 59.7 shall be marked as such.

6) The inlet connection to the collection container shall be identified unless misconnection is prevented by a design feature.

7) If the suction equipment is intended for use in the field or in transport and does not comply with 53.1, it shall be marked on the case as not suitable for use at temperatures below "... °C" or above "... °C" with the appropriate limiting temperatures marked. If no case is provided, the statement shall be marked on the equipment.

— In 6.1, add the following additional items:

aa) Equipment containing a filter which is intended to be cleaned or changed by the user shall have clearly marked on the equipment or on the filter unit, wording to the effect that the filter should be changed in accordance with the manufacturer's recommendations.

ab) The capacity of the collection container.

— In 6.3 c), add the following:

If a progressive variation of the degree of vacuum is available, the direction of adjustment to increase vacuum shall be clearly and permanently marked.

— In 6.8.1, add the following:

The collection container capacity shall be stated in the accompanying documents.

— In 6.8.2 a), add the following:

The instructions for use shall additionally include the following information:

1) Instructions for operating the vacuum regulator, if supplied, and for setting the required vacuum.

2) The size and type of suction tubing recommended for use with the suction equipment and its means of connection to the collection container.

3) Recommended methods for cleaning and disinfection or sterilization of all applied parts.

4) The method for removing the collection container for emptying.

5) Details of the operation of any overfill device fitted to the collection container assembly and the usable capacity of the collection container in all the recommended inclined planes of operation.

6) If applicable, the method of controlling frothing in the collection container.

7) Instructions, if applicable, for the replacement or cleaning of air filters, and for cleaning or sterilization of the filter housing.

8) Either the type of equipment, e.g. medical suction, high vacuum, high flow, or the level of vacuum and flow obtainable or the vacuum and air flow characteristics obtainable from the equipment as required by 6.1 p) (1), (2) or (3), as appropriate.

9) Instructions to inspect suction tubing, collection containers and any other components that are subject to wear or damage.

10) If applicable, 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.

11) If applicable, a statement that suction ceases when the overfill device operates, and the method of correcting this situation.

12) Recommendations for cleaning or disinfection of the outer casing.

13) Instructions for cleaning and sterilization or reusable suction tubing.

14) Instructions for sterilizing any part of a filter assembly which is reusable.

15) Guidance for the intended use and limitations of the equipment, including whether or not the equipment is intended for use within a health care facility, for domiciliary use, or for field and transport use.

1.7 Power input

The requirements given in clause 7 of IEC 601-1 : 1988 apply.

Section 2: Environmental conditions

2.8 Basic safety categories

(See A.1.2 of IEC 601-1 : 1988.)

2.9 Removable protective means

[See 6.1 z) of IEC 601-1 : 1988.]

2.10 Environmental conditions

The requirements given in clause 10 of IEC 601-1 : 1988 apply.

2.11 Special measures with respect to safety

(Not used)

2.12 Single fault condition

(Not used)

Section 3: Protection against electric shock hazards

3.13 General

The requirements given in clause 13 of IEC 601-1 : 1988 apply.

3.14 Requirements related to classification

The requirements given in clause 14 of IEC 601-1 : 1988 apply.

3.15 Limitation of voltage and/or energy

The requirements given in clause 15 of IEC 601-1 : 1988 apply.

3.16 Enclosures and protective covers

The requirements given in clause 16 of IEC 601-1 : 1988 apply together with the following additional requirement:

h) The housing shall be constructed of fire-retarding material which withstands the needle-flame test specified in IEC 695-2-2 when the flame is applied to any point on the inside or outside surface of the housing for 20 s.

3.17 Separation

The requirements given in clause 17 of IEC 601-1 : 1988 apply except as follows:

— Replace item c) by the following:

For mains-powered equipment, accessible unearthed conductive parts shall not be connected to any part of the applied part.

Compliance shall be checked by applying the normal operating voltage and frequency between any part of the applied part and accessible unearthed conductive paths.

Leakage current shall not exceed 5 mA for Type B or BF equipment and 0,05 mA for Type CF equipment. Measurements shall be made with the applied part filled with saline solution containing 9 g/l sodium chloride until the overfill device operates or until saline solution emerges from the exhaust opening. For the purposes of the test for Type B or BF equipment, an electrically isolated conductive cap on a collection container is not considered to be part of the accessible unearthed conductive path.

3.18 Protective earthing, functional earthing and potential equalization

The requirements given in clause 18 of IEC 601-1 : 1988 apply.

3.19 Continuous leakage current and patient auxiliary currents

The requirements given in clause 19 of IEC 601-1 : 1988 apply together with the following addition:

— In 19.4 h), add the following additional item:

12) Measurement shall be made with any overfill device operative. Fluid shall be drawn through a suction catheter immersed in a container filled with saline solution containing 9 g/l sodium chloride, along the complete fluid path, until the overfill device operates or until saline solution emerges from the exhaust opening. Measurement shall be made from the saline solution in the container.

3.20 Dielectric strength

The requirements given in clause 20 of IEC 601-1 : 1988 apply.

Section 4: Protection against mechanical hazards

4.21 Mechanical strength

The requirements given in clause 21 of IEC 601-1 : 1988 apply together with the following additional requirement:

> Equipment intended for field use shall meet the requirements for flow and vacuum of this part of ISO 10079 after being dropped from a height of 1 m onto a concrete floor in the worst case mode.

4.22 Moving parts

The requirements given in clause 22 of IEC 601-1 : 1988 apply.

4.23 Surfaces, corners and edges

The requirements given in clause 23 of IEC 601-1 : 1988 apply.

4.24 Stability in normal use

The requirements given in clause 24 of IEC 601-1 : 1988 apply.

4.25 Expelled parts

The requirements given in clause 25 of IEC 601-1 : 1988 apply.

4.26 Vibration and noise

The requirements given in clause 26 of IEC 601-1 : 1988 shall be replaced by the following requirements:

26.1 Low vacuum low flow equipment

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

Compliance shall be checked by the test given in 26.1.2.

26.1.2 Test the suction equipment with the inlet opened to the atmosphere and also with the inlet occluded.

Place the microphone of a sound level meter complying with the requirements for a type 1 instrument specified in IEC 651 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 over its normal working range of flow including the maximum flow 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.

26.2 Equipment intended for use in the operating room

In normal use, the maximum A-weighted sound pressure level (steady or peak value) of equipment intended for use in the operating room shall not exceed 70 dB.

Compliance shall be checked by the test given in 26.1.2.

4.27 Pneumatic and hydraulic power

The requirements given in clause 27 of IEC 601-1: 1988 do not apply as they are not relevant to suction equipment.

4.28 Suspended masses

The requirements given in clause 28 of IEC 601-1 : 1988 apply.

Section 5: Protection against hazard from unwanted or excessive radiation

5.29 X-radiation

The requirements given in clause 29 of IEC 601-1 : 1988 apply.

5.30 Alpha, beta, gamma neutron radiation and other particle radiation

The requirements given in clause 30 of IEC 601-1 : 1988 apply.

5.31 Microwave radiation

The requirements given in clause 31 of IEC 601-1 : 1988 apply.

5.32 Light radiation (including lasers)

The requirements given in clause 32 of IEC 601-1 : 1988 apply.

5.33 Infra-red radiation

The requirements given in clause 33 of IEC 601-1 : 1988 apply.

5.34 Ultraviolet radiation

The requirements given in clause 34 of IEC 601-1 : 1988 apply.

5.35 Acoustical energy (including ultra-sonics)

The requirements given in clause 35 of IEC 601-1 : 1988 apply.

5.36 Electromagnetic compatibility

The requirements given in clause 36 of IEC 601-1 : 1988 apply.

Section 6: Protection against hazards of ignition of flammable anaesthetic mixtures

6.37 Locations and basic requirements [1)]

The requirements given in clause 37 of IEC 601-1 : 1988 apply.

6.38 Marking and accompanying documents [1)]

The requirements given in clause 38 of IEC 601-1 : 1988 apply.

6.39 Common requirements for AP and APG equipment [1)]

NOTE — The abbreviations "AP" and "APG" stand for "anaesthetic-proof" and "anaesthetic-proof category G" respectively.

The requirements given in clause 39 of IEC 601-1 : 1988 apply.

6.40 Requirements and tests for AP equipment, parts or components [1)]

The requirements given in clause 40 of IEC 601 1 : 1988 apply.

6.41 Requirements and tests for APG equipment, equipment parts or components [1)]

The requirements given in clause 41 of IEC 601-1 : 1988 apply.

1) See also annex M (in this part of ISO 10079).

Section 7: Protection against excessive temperatures and other safety hazards

7.42 Excessive temperatures

The requirements given in clause 42 of IEC 601-1 : 1988 apply.

7.43 Fire prevention

The requirements given in clause 43 of IEC 601-1 : 1988 apply.

7.44 Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization and disinfection

The requirements given in clause 44 of IEC 601-1 : 1988 apply except for the following additions and modifications:

— In 44.2, add the following:

When the collection container is full, suction equipment shall either continue to operate and meet the requirements of the relevant subclauses of clause 59 or shall have an overfill device to prevent liquids entering the tubing downstream of the collection container.

If the suction equipment is fitted with an overfill device, suction shall cease when the overfill device operates and not more than 5 ml of liquid shall pass downstream of the overfill device. If the overfill device is integral with the collection container, it shall not activate until at least 90 % of the stated collection capacity has been reached.

Compliance shall be checked by the following test.

Connect the overfill device according to the manufacturer's instructions. Set the suction equipment to maximum free air flow and draw water at 23 °C ± 2 °C into the system until the overfill device is activated. Run the equipment for a further 2 min. Measure the volume of water which has passed the overfill device. If the overfill device is integral with the collection container, measure the volume collected in the collection container.

Test suction equipment intended for reuse after 30 cycles of cleaning and disinfection or sterilization as recommended by the manufacturer.

— Replace 44.3 by the following:

The suction equipment shall be so constructed that, in the event of spillage of liquids, no safety hazard shall result.

Compliance shall be checked by the following test.

Place the suction equipment in the least favourable position of normal use and subject it for 30 s to an artificial rainfall of 3 mm/min falling vertically from a height of 0,5 m above the top of the equipment.

Immediately after the 30 s exposure, remove visible moisture from the body of the equipment.

Immediately after the above test, the suction equipment shall meet the relevant dielectric strength tests specified in clauses 20.1 to 20.4 of IEC 601-1 : 1988 and meet the appropriate requirements for vacuum and flow specified in clause 59 of this part of ISO 10079.

Battery-operated transportable suction equipment intended for use in the field shall meet the requirements of 59.10 after exposure to water as specified in clause 8.3 of IEC 529 : 1976 when in the carrying mode and position as recommended by the manufacturer.

— In 44.4, add the following:

1) Collection containers for general use

For collection containers intended for single use, the leakage of air from the collection container assembly shall not exceed 200 ml/min, if the collection container is intended for suction with a free air flow of more than 1 l/min. The pressure increase shall be less than 3,3 kPa ÷ V where V is the volume, in litres, of the collection container.

A collection container assembly intended for reuse shall comply with the above requirement, before and after being subjected to 30 cycles of cleaning and disinfection or sterilization as recommended by the manufacturer.

Compliance shall be checked by the following test.

Evacuate the collection container to − 40 kPa. Close off the vacuum source, and observe the pressure increase within 10 s. (See figure 2 for a typical test apparatus.)

NOTE — The collection container will have a pneumatic compliance of approximately 10 ml/kPa per litre volume. A leakage of 200 ml/min corresponds to 33,3 ml per 10 s which would result in a pressure increase of 33,3/10 = 3,33 kPa per 10 s.

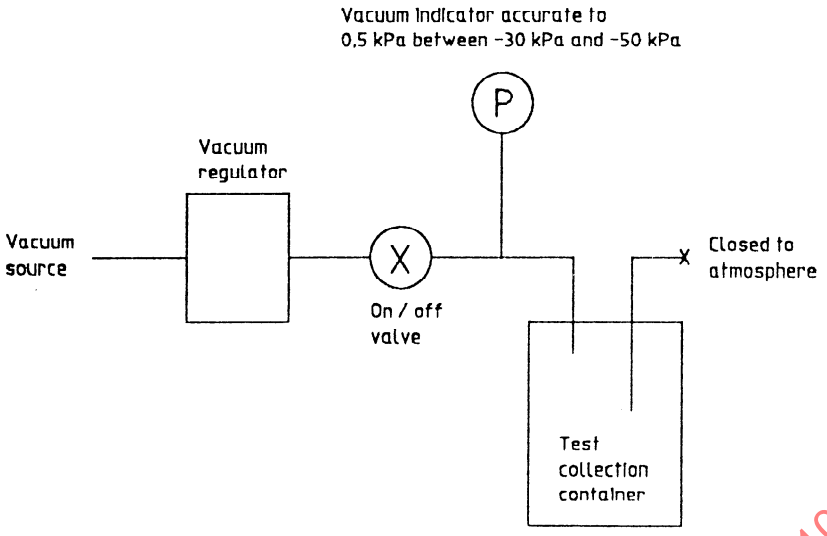


Figure 2 — Typical test apparatus for evaluating leakage of collection container for general use

2) Collection containers intended for use in a thoracic drainage system

The leakage of air from collection containers intended for reuse in a thoracic drainage system shall not exceed 4 ml/min, when tested before and after being subjected to 30 cycles of cleaning and disinfection or sterilization as recommended by the manufacturer.

Compliance shall be checked by the following test.

Set the vacuum regulator to − 15 kPa. Open the valve and allow the container to reach the set vacuum. Note the number of bubbles observed in the water bottle over a period of 10 s. (See figure 3 for a typical test apparatus.)

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

— In 44.6, add the following:

Remote foot switches with electrical switching parts shall be of watertight construction.

Compliance shall be checked by the following test.

Completely immerse the foot switch in water to a depth of 150 mm for a period of 30 min. While immersed, connect the foot switch in a circuit corresponding to its normal use and actuate it 50 times. Inspect the switch to verify that there has been no ingress of water. The foot switch shall meet the relevant requirements for dielectric strength specified in clause 20 of IEC 601-1 : 1988.

— In 44.7, add the following:

Filters within the applied part before the vacuum pump shall either be of the disposable type or be capable of being re-sterilized.

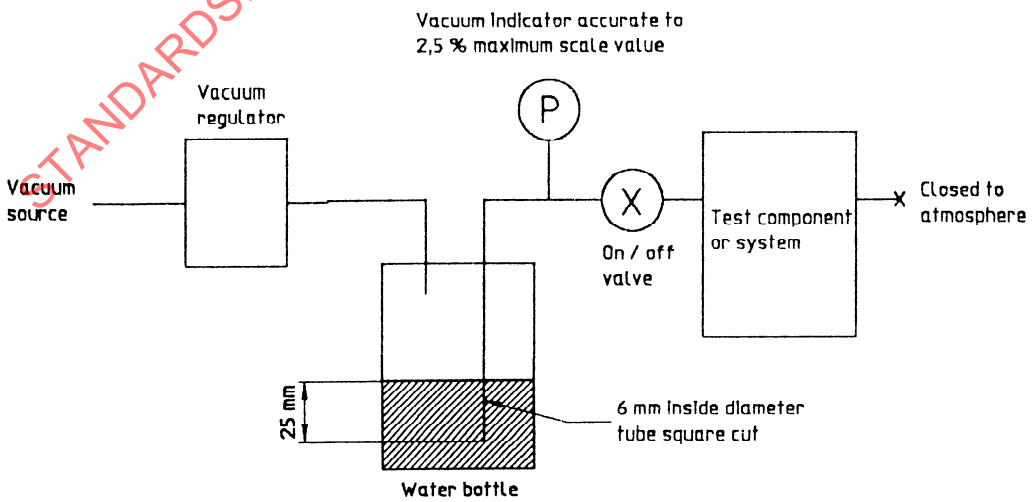


Figure 3 — Typical test apparatus for evaluating leakage of collection container designated for use in thoracic drainage system

Suction equipment containing filters intended for re-sterilization shall be capable of complying with the appropriate vacuum and flow requirements specified in clause 59 of this part of ISO 10079 after the filters have been subjected to 30 cycles of sterilization as recommended by the manufacturer.

7.45 Pressure vessels and parts subject to pressure

The requirements given in clause 45 of IEC 601-1 : 1988 apply.

7.46 Human errors

The requirements given in clause 46 of IEC 601-1 : 1988 shall be replaced by the following requirements:

a) For the purposes of this International Standard, vacuum is regarded as a medical gas.

b) It shall not be possible to connect any tubing to the exhaust opening, if present. There shall not be any connection point provided for positive pressure.

Compliance shall be checked by inspection.

c) The direction of flow shall be clearly and permanently marked.

NOTES

1 Connections which are flow-sensitive (direction-specific) to the collection container should be designed to avoid misconnection.

2 Incorrect connections have frequently been a cause of spill-over into a vacuum source.

d) Flow through the suction equipment, including battery-powered equipment, shall not be reversed if the input power leads are transposed.

Compliance shall be checked by transposing the input lower leads and switching on the suction equipment.

7.47 Electrostatic charges

(Not used)

7.48 Materials in applied parts in contact with body of patient

(Not used)

7.49 Interruption of power supply

The requirements given in clause 49 of IEC 601-1 : 1988 apply except for the following modification:

— Replace 49.2 by the following:

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

Compliance shall be checked by the following test.

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

Section 8: Accuracy of operating data and protection against hazardous output

8.50 Accuracy of operating data

(Not used)

8.51 Protection against hazardous output

The requirements given in clause 51 of IEC 601-1 : 1988 apply together with the following additional sub-clause:

51.5 For the purposes of this part of ISO 10079, output includes vacuum and suction flow.

Section 9: Abnormal operation and fault conditions: environmental tests

9.52 Abnormal operation and fault conditions

The requirements given in clause 52 of IEC 601-1 : 1988 apply together with the following additional sub-clauses:

52.6 Mains-powered high vacuum/high flow suction equipment and low vacuum suction equipment shall be so constructed that in prolonged normal use neither electrical nor mechanical failure will impair the performance as specified in this International Standard.

Compliance shall be checked by the test given in 52.7.

52.7 Carry out the test at an ambient temperature of 22 °C ± 3 °C. Connect the suction equipment to a supply mains having a voltage 1,10 times the maximum rated voltage. Operate the equipment for 240 h continuously with alternate total occlusion and free air flow for 15 s. Ensure that any thermal cut-out does not operate during the test.

Do not replace any components during the tests.

After the completion of the test cycles, the suction equipment shall comply with all the requirements of this part of ISO 10079.

52.8 Mains-powered suction equipment intended for use in transport or in the field shall be so constructed that in prolonged normal use neither electrical nor mechanical failure will impair the performance.

Compliance shall be checked by the following test performed at 40 °C ± 3 °C and (85 ± 5) % relative humidity.

Connect the suction equipment to a supply voltage. Operate for 1 h continuously with alternate total occlusion and free air flow for 15 s. Ensure that any thermal cut-out does not operate during the test.

After completion of the test cycles, the equipment shall comply with all the requirements of this part of ISO 10079.

9.53 Environmental tests

The requirements given in clause 53 of IEC 601-1 : 1988 apply together with the following additional sub-clauses:

53.1 Except if marked in accordance with clause 6.1 p) 7) of this part of ISO 10079, suction equipment intended for field and transport use shall meet the performance requirements specified in 59.5, 59.6, 59.7, 59.8, 59.9 or 59.10, as appropriate, over a range of high and low temperatures, both in storage and during use.

Compliance shall be checked by the tests given in 53.2, 53.3, 53.4 and 53.5.

53.2 For high temperature storage, place the suction equipment in an environmental chamber, maintained at a temperature of 60 °C ± 5 °C and at 40 % to 70 % relative humidity, for a period of not less than 4 h or until 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 at 40 % to 70 % relative humidity. Allow the suction equipment to stabilize for 4 h. At the end of this period, test the suction equipment for compliance with the requirements specified in 53.1.

53.3 For low temperature storage, place the suction equipment in an environmental chamber, maintained at a temperature of − 40 °C ± 5 °C, for a period of at least 4 h or until 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. Allow the suction equipment to stabilize for at least 4 h. At the end of this period, test the suction equipment for compliance with the requirements specified in 53.1.

53.4 For high temperature operation, place the suction equipment in an environmental chamber, maintained at a temperature of 50 °C ± 2 °C with a relative humidity of at least 95 %, for at least seven days. At the end of this period, remove the suction equipment from the chamber and allow it to stand at a temperature between 18 °C and 22 °C and at 40 % to 70 % relative humidity. Within 5 min, operate and test the suction equipment for compliance with the requirements specified in 53.1.

53.5 For low temperature operation, place the suction equipment in an environmental chamber, maintained at a temperature of − 18 °C ± 2 °C, for 4 h or until 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 between 18 °C and 22 °C and a relative humidity of between 40 % and 70 %. Within 5 min, operate and test the suction equipment for compliance with the requirements specified in 53.1.

If suction equipment intended for transport or field use does not comply with the above requirements for high or low temperature operation, it shall be retested at less severe temperatures until it complies with the performance requirements. These limiting temperatures shall be marked as specified in clause 6.1 p) 7) of this part of ISO 10079.

Section 10: Constructional requirements

10.54 General

The requirements given in clause 54 of IEC 601-1 : 1988 apply together with the following additional sub-clause:

54.4 Suction equipment shall not be capable of administering positive pressure.

10.55 Enclosures and covers

(Not used)

10.56 Components and general assembly

The requirements given in clause 56 of ISO 601-1 : 1988 apply except for the following additions or modifications:

— In 56.1, add an additional item as follows:

g) For equipment intended for field and transport use,

1) the dimensions shall be such that the equipment, including the carrying case or frame, if present, complete with contents shall pass through a rectangular opening having dimensions 600 mm × 300 mm,

2) the mass of the equipment complete with carrying case, frame and accessories, if present, 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 clause may not apply but the mass of all equipment intended for field use should be as light as possible.

— In 56.3 b), add the following:

Connections for the suction tubing and the intermediate hose to the vacuum pump shall be so designed as to minimize the risk of wrong assembly when all parts are mated.

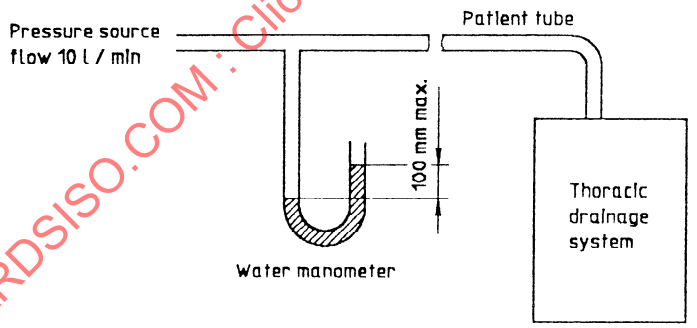
Compliance shall be checked by inspection.

— In 56.5, add the following:

1) If suction equipment is intended to limit the vacuum to a set level, the output of the equipment shall not exceed the specified vacuum.

2) Suction equipment intended for thoracic drainage shall not develop a pressure in excess of 1 kPa at the patient inlet at an applied free air flow of 10 l/min. Compliance shall be checked by the following test.

Attach the patient inlet of the thoracic drainage system set up for normal use according to the manufacturer's recommendations (see figure 4). Adjust the pressure source to produce a free air flow of 10 l/min and measure the pressure at the patient inlet.



NOTE — For suction equipment fitted with an overfill device, protective means should be available to prevent foam passing downstream into the vacuum pump.

Figure 4 — Typical test apparatus for evaluating thoracic drainage system performance

— In 56.8, add the following:

1) Vacuum regulators with a variable control shall have a vacuum indicator displaying the vacuum on the patient side of the vacuum regulator.

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

3) Digital displays shall display vacuum at intervals of not greater than 2 % of the full scale value. The maximum vacuum for which the equipment is designed shall be marked prominently on the display case or immediately adjacent to it.

4) All marking on the vacuum indicator shall be legible to an operator having visual acuity, corrected if necessary, of at least 1,0 positioned 1 m from the vacuum indicator at an illuminance of 215 Lx.

5) The full scale of analogue vacuum indicators shall be not more than 200 % of the maximum designed negative pressure of the suction equipment.

6) Except for equipment intended for field and transport use, suction equipment shall be fitted with a vacuum indicator.

7) A vacuum indicator shall be installed between the vacuum source and collection container to indicate the vacuum applied to the suction tubing.

8) Vacuum indicators for suction equipment intended for thoracic drainage shall have an accuracy of ± 5 % of the full scale value in the middle three-fifths of the indicator range.

NOTE — Movement of a vacuum rotary indicator should be counter-clockwise for an increase in vacuum.

9) Vacuum indicators for use with high vacuum suction equipment shall have an accuracy within ± 5,0 % of the full scale value.

— In 56.11, add the following to item b):

The force required to actuate a foot switch shall be not less than 10 N and not more than 50 N.

Compliance shall be checked by applying a slowly increasing force to the switch and recording the pressure at which the switch operates.

— Add the following sub-clauses:

56.12 Inlet port of collection container

The inlet port of the collection container shall have a fluid pathway not less than 6 mm internal diameter. In addition, the inlet port shall not be compatible with any of the conical connectors specified in ISO 5356-1.

NOTES

1 Suction performance may be markedly affected by the length and diameter of the tubing between the collection container and the patient. An indication of the severity of this effect is given in annex P.

2 Because of the risk of misconnection, the internal diameter of the inlet port of the collection container should not be greater than 15 mm.

3 Special surgical situations such as suction lipectomy and suction curettage may require tubing and connectors between the patient and the collection container to be of a larger bore.

56.13 Suction tubing

Suction tubing supplied with the suction equipment shall have a minimum length of 1,3 m, unless intended for field and transport use in which case it shall comply with 56.14. The tubing shall retain at least 50 % of its nominal outside diameter throughout its length when it is subjected to the maximum vacuum stated by the manufacturer or, if the maximum vacuum is not stated, to a vacuum of − 60 kPa.

Compliance shall be checked by the test described in 56.14.

56.14 Test method

At a temperature of 20 °C to 25 °C, uncoil the suction tubing to its full length and plug one end to prevent any air flow through it. Measure the outside diameter of the suction tubing along its entire length.

Attach a vacuum source to the other end of the suction tubing as shown in figure 5 and adjust the level of vacuum to the maximum stated by the manufacturer, if applicable. If there is no disclosed maximum, conduct the test at − 60 kPa. Hold the vacuum for 5 min. Measure the outside diameter of the suction tubing again along its entire length with callipers approximately every 10 % of the length including any visible regions of collapse. Calculate the degree of collapse of the tubing from the following formula for each measurement point.

$$\text{Degree of collapse} = \frac{OD_{Initial} - OD_{Test}}{OD_{Initial}}$$

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

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

The degree of collapse shall not exceed 0,5 in both tests.

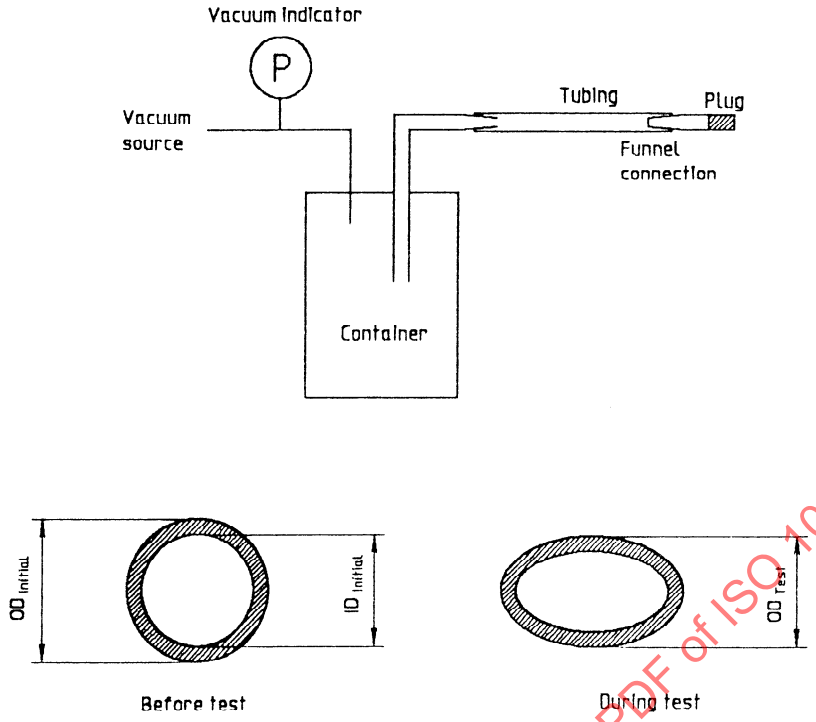


Figure 5 — Test apparatus for suction tubing

For equipment intended for field and transport use and intended to operate from the floor, the length of suction tubing shall be such that the end-piece can be positioned at least 1,3 m above the floor.

Compliance shall be checked by inspection.

10.57 Mains parts, components and layout

The requirements given in clause 57 of IEC 601-1 : 1988 apply.

10.58 Protective earth terminals

The requirements given in clause 58 of IEC 601-1 : 1988 apply.

10.59 Construction and layout

The requirements given in clause 59 of IEC 601-1 : 1988 apply together with the following additional sub-clauses:

59.5 Mains-operated transportable high flow high vacuum equipment

Equipment intended for use in health care facilities and for domiciliary use and marked "high flow high vacuum" shall develop within 10 s a vacuum of at least − 60 kPa in a 2 l collection container, when measured at the inlet of the collection container, and a free air flow into the collection container (without suction tubing fitted) of not less than 20 l/min.

Compliance shall be checked with the collection container empty. If the collection container has a usable volume of less than 2 l, an additional volume shall be added to make up a total of 2 l with the usable volume. If the collection container has a usable volume of 2 l or more, the equipment shall be tested as supplied.

59.6 Medium vacuum equipment

Equipment marked medium vacuum shall develop a vacuum not greater than − 60 kPa.

NOTE — The use of medium vacuum for breast pumps should not exceed − 33 kPa.

Compliance shall be checked by the following test.

With the vacuum control set at maximum and the supply voltage at the rated voltage, switch on the suction equipment. Connect a vacuum indicator to the equipment and note the maximum vacuum obtained.

59.7 Low flow low vacuum equipment (drainage)

Equipment marked "low flow low vacuum" shall have a continuous free air flow of between 0,5 l/min and 10 l/min and a vacuum of not more than − 20 kPa.

Compliance shall be checked with the collection container(s) empty, as follows.

a) Switch on the equipment with the vacuum regulator adjusted so that maximum vacuum develops.

b) Occlude the intlet to the collection container.

c) Note the maximum vacuum obtained within 10 min.

d) Open the inlet and attach a low resistance flowmeter to it. Note the mean free air flow, when stable conditions are reached.

59.8 Low vacuum equipment (thoracic drainage)

Equipment marked "thoracic drainage" shall produce a free air flow of not less than 15 l/min measured at the inlet of the collection container, and the level of vacuum developed shall not exceed −20 kPa. It shall be possible to set the level of vacuum to between −2 kPa and −20 kPa.

NOTE — For most situations the level of vacuum developed should not exceed −7 kPa. However, in some situations, for example broncho-pleural fistula, higher flows such as 25 l/min may be required, and the ability to allow for higher flows is desirable.

Equipment marked "thoracic drainage" shall be adjustable to a static vacuum of −7 kPa. Such equipment shall produce a free air flow of at least 15 l/min, and shall be capable of developing within 5 s, 95 % of that set vacuum when connected to a closed system of 4,5 l total capacity.

Compliance shall be checked by inspection and by the following test with the collection container(s) empty.

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

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

c) With the vacuum regulator adjusted to between −6,6 kPa and −7,4 kPa vacuum, switch on the equipment.

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

e) Open the inlet and, using 2 m of flexible hose having an inside diameter of 8 mm, attach an underwater seal having an inlet of 10 mm inside diameter, positioned so that the end is 50 mm under the water. Connect a low resistance flowmeter immediately before the underwater seal, as shown in figure 6, and measure the free air flow.

59.9 Equipment intended for pharyngeal suction

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

Compliance shall be checked by the following test.

Prepare 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 2,55. Agitate the simulated vomitus to disperse the glass beads and pour 250 ml at an ambient temperature of 22 °C ± 3 °C into a graduated vessel having a capacity of at least 300 ml with graduations no more than 50 ml apart. 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 in the graduated vessel and record the time taken to evaluate 200 ml of the simulated vomitus.

NOTE — In the preparation of the simulated vomitus, 0,1 % benzoic acid may be added as a preservative.

59.10 Battery-powered transportable suction equipment

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

Compliance shall be checked by the following test.

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 flow to the inlet of

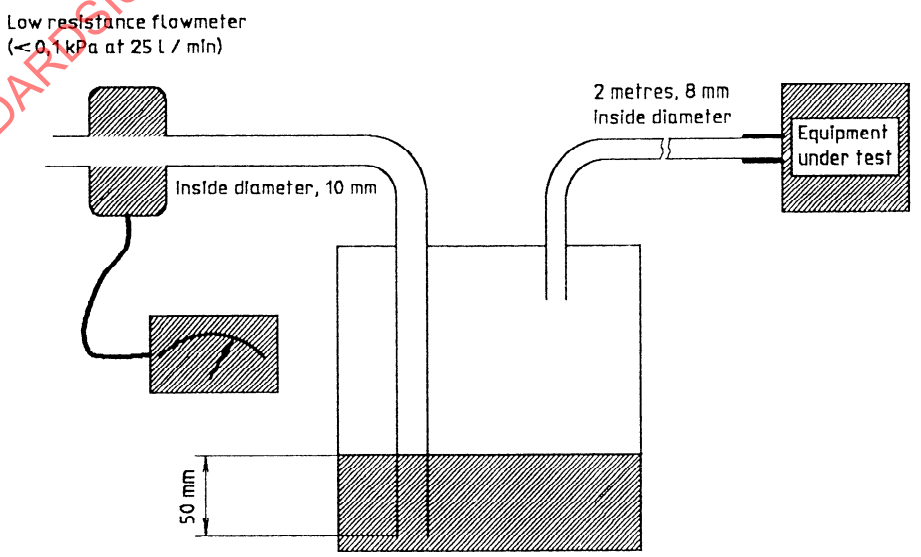


Figure 6 — Test apparatus for thoracic drainage