# INTERNATIONAL STANDARD

**ISO 10079-2**

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## Medical suction equipment —

## Part 2:
Manually powered suction equipment

*Appareils d'aspiration médicaux —*

*Partie 2: Appareils d'aspiration manuels*

Reference number
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## Contents







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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.

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 10079-2 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: Manually powered suction equipment*

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

Annex A forms an integral part of this part of ISO 10079. Annexes B and C are for information only.

## Introduction

This International Standard, which has been prepared under the responsibility of Sub-Committee 8 of ISO/TC 121, comprises part 2 of the standard for medical suction equipment, and deals only with manually powered suction equipment. Part 1 deals with safety requirements for electrically powered equipment. Part 3 deals with suction equipment powered from a vacuum or pressure source.

This International Standard has been prepared in response to a need for a safety and performance standard for suction systems. 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.

As far as possible, this International Standard has been written specifying performance requirements corresponding with those needed for effective and safe treatment of the patient.

Annex A gives test methods to be used to verify compliance with the requirements given in this part of ISO 10079. Annex B gives a table of a typical range of volumes for collection containers for specific uses. Annex C gives a rationale statement for some requirements.

# Medical suction equipment —

# Part 2:
Manually powered suction equipment



## 1 Scope

This part of ISO 10079 specifies safety and performance requirements for manually powered medical suction equipment intended for oro-pharyngeal suction to establish and maintain the patency of the airway. It covers equipment operated by foot or by hand or both (see figure 1). Non-electrical suction equipment which may be integrated with electrical equipment is within the scope of this part.

This part of ISO 10079 does not apply to electrically powered suction equipment, whether mains electricity or battery-powered, which is dealt with in ISO 10079-1, nor to suction equipment powered from a vacuum or pressure source which is dealt with in ISO 10079-3, nor to the following:

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 systems 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) breast pumps;

q) liposuction;

r) uterine aspiration;

s) thoracic drainage.

## 2 Normative reference

The following standard contains provisions which, through reference in this text, constitute provisions of this part of ISO 10079. At the time of publication, the edition indicated was 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 edition of the standard indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

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

## 3 Definitions

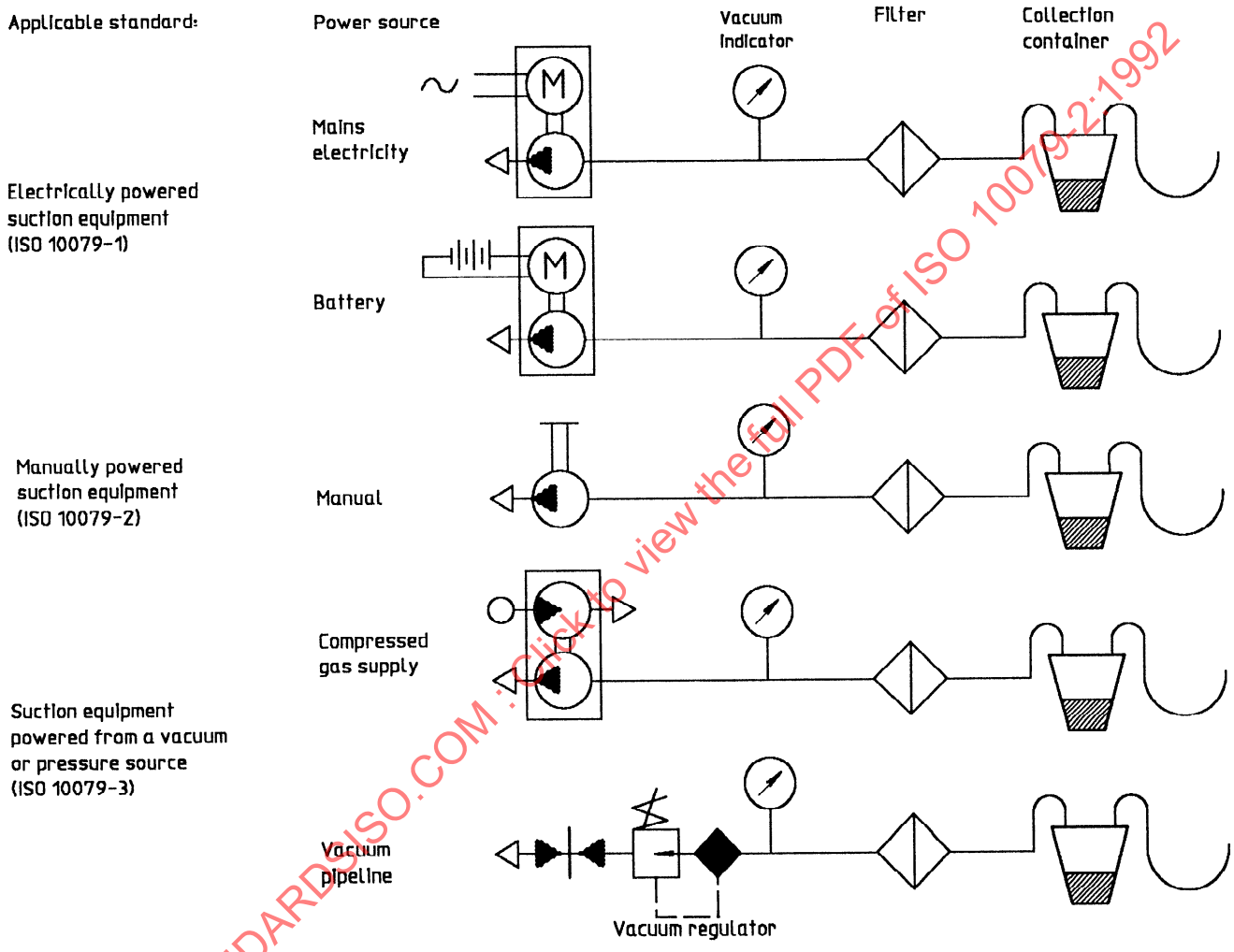
For the purposes of this part of ISO 10079, the following definitions apply.

**3.1 collection container:** Container in which liquids or solid particles are collected.

**3.2 collection container assembly:** Collection container and its closure.

**3.3 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 at the first detachable connection.

**3.4 exhaust opening:** Port or ports through which exhaust is discharged.






NOTES

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

This part of ISO 10079 applies to manually powered suction equipment. ISO 10079-3 applies to 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**

**3.5 filter:** Device for separation of particulate matter.

**3.6 free air flow:** Unrestricted flow of air through a nominated inlet.

**3.7 high vacuum:** Vacuum of at least 60 kPa[1].

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

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

**3.10 low vacuum:** Vacuum not more than − 20 kPa.

**3.11 manually powered (generated) vacuum:** Local generation of vacuum by human effort with a hand or foot or both.

**3.12 manually powered transportable suction equipment:** Equipment in which vacuum is generated manually.

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

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

**3.15 overfill protection:** Prevention of liquid or solid particles entering the intermediate tubing.

**3.16 overfill protection device:** Any device intended to prevent liquid or solid particles entering the intermediate tubing.

**3.17 suction:** Application of vacuum to remove fluids and/or solid particles.

**3.18 suction equipment:** Single self-contained unit or combination of units which generates or controls suction.

**3.19 suction tubing:** Tubing for conduction of fluids from the end piece to the collection container.

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

**3.21 vacuum indicator:** Device for displaying the level of vacuum.

**3.22 vacuum pump:** Powered device for generating vacuum.

**3.23 vacuum source:** Means of generating vacuum. The source may be integral with the suction equipment or be separate from the suction equipment.

## 4 Cleaning, disinfection and sterilization

**4.1** The suction equipment shall meet the requirements specified in 8.1 to 8.3 after those components which are subject to contamination and which are intended for re-use have been submitted to 30 cycles of cleaning, disinfection and/or sterilization as recommended by the manufacturer.

**4.2** Any filters installed shall either be of the disposable type or be capable of being cleaned, disinfected and/or sterilized for re-use in accordance with 4.1.

**4.3** Suction equipment incorporating a re-usable collection container assembly shall comply with the requirements specified in 8.1 to 8.3, as appropriate, before and after the collection container has been subjected to 30 cycles of cleaning, disinfection and/or sterilization as recommended by the manufacturer.

**4.4** Suction tubing shall either be for single use or be capable of being cleaned, disinfected and/or sterilized as recommended by the manufacturer.

## 5 Design requirements

### 5.1 Connectors

#### 5.1.1 Collection container connectors

The connectors for the suction tubing and the intermediate tubing to the vacuum source shall be designed to facilitate correct assembly or marked to indicate correct assembly when all parts are mated. Compliance shall be checked by inspection.

NOTE 1 The construction of the connections has frequently been a cause of spill-over into a vacuum pump. The use of mechanical fittings so as to ensure correct attachment is highly desirable.

#### 5.1.2 Inside diameter of suction tubing connection

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 recommended by the manufacturer.

#### 5.1.3 Exhaust opening

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

1) 1 kPa = 7,500 63 mmHg or 4,024 619 in $H_2O$ or 10,197 16 cm $H_2O$ or 19 hPa

## 5.2 Suction tubing

### 5.2.1 General

If supplied, suction tubing shall have an inside diameter of not less than 6 mm.

NOTE 2 Suction performance may be markedly affected by the length and diameter of the tubing between the collection container and the end piece.

When tested in accordance with A.1, suction tubing supplied with the equipment shall retain at least 50 % (0,5) of its inside diameter throughout its length.

### 5.2.2 Length of suction tubing for foot-operated suction equipment[2)]

The length of suction tubing shall be such that the end piece can be positioned at least 1,3 m above the floor when the foot-operated vacuum pump is on the floor in the operating position.

# 6 Operational requirements

## 6.1 Ease of operation

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

## 6.2 Dismantling and reassembly

Suction equipment intended to be dismantled by the user (for example, for cleaning) shall be designed to facilitate correct assembly or marked to indicate correct reassembly when all parts are mated. After dismantling, reassembly and testing in accordance with the manufacturer's instructions, the suction equipment shall meet the requirements specified in 8.1 to 8.3, as appropriate.

## 6.3 Mechanical shock

After suction equipment intended for field or transport use or both has been dropped in accordance with A.2, it shall meet the requirements specified in 8.1 to 8.3, as appropriate.

NOTE 3 "Field use" of suction equipment is intended to cover use in situations outside of the health care facility at the site of accidents or other emergencies. The use of suction equipment in these situations may expose the equipment to water including rain, dirt, uneven support, mechanical shock and extremes of temperature. "Transport use" of suction equipment is intended to cover situations outside of the health care facility such as in ambulances, cars or aeroplanes. Use of suction equipment in these situations may expose the equipment to uneven support, dirt, mechanical shock and a wider range of temperature than normally found in health care facilities.

If the suction equipment can be operated outside of its carrying case, it shall meet the requirements specified in 8.1 to 8.3, as appropriate, after the individual parts of the suction equipment have been dropped in accordance with A.2 and reassembled.

## 6.4 Immersion in water

After suction equipment intended for field use has been dropped in its ready-for-use condition from a height of 1 m into a water reservoir 1 m × 1 m × 1 m, has been left in the water for 10 s and the water has been expelled for 7 s, it shall meet the requirements specified in 8.1 to 8.3, as appropriate.

## 6.5 Stability

Suction equipment operated by foot and intended for field or transport use or both shall meet the requirements specified in 8.1 to 8.3, as appropriate, when placed on a surface of 20° (0,35 rad) slope from the horizontal. Other manually powered suction equipment when operated 10° (0,17 rad) from its normal orientation shall meet the requirements specified in 8.1 to 8.3, as appropriate, in any position except that excluded by the manufacturer as specified in clause 11 b).

## 6.6 Overfill protection

**6.6.1** Unless the suction equipment is intended to continue operating after overflow of liquids and solids, means shall be provided to prevent liquids entering the suction line downstream of the overfill protection device in normal use of the equipment, and, when tested in accordance with A.3, the volume collected in the collection container shall be not less than 90 % of the stated collection capacity.

**6.6.2** Suction shall cease when the overfill protection device operates.

## 6.7 Vacuum indicators

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

**6.7.2** 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.

2) See also annex C.

**6.7.3** All markings on the vacuum indicator shall be legible to an operator having visual acuity, corrected if necessary, of at least 1,0, seated or standing 1 m from the vacuum indicator at an illuminance of 215 lx.

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

**6.7.5** Vacuum indicators shall be accurate to within ± 5 % of the full scale value.

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

## 7 Physical requirements

### 7.1 Dimensions[3)]

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

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.

### 7.2 Mass

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

### 7.3 Collection container

**7.3.1** The inlet of the collection container shall have an inside diameter of not less than 6 mm and not less than the maximum inside diameter of the suction tubing recommended by the manufacturer. The inlet shall not be compatible with any conical connector specified in ISO 5356-1.

**7.3.2** For suction equipment which is intended to continue operating when the collection container is full and is intended for field use, the volume of the collection container shall be not less than 200 ml. For all other suction equipment, including suction equipment intended for field and/or transport use, the usable volume of the collection container shall be not less than 500 ml.

**7.3.3** For suction equipment not intended for field use, one or more collection containers recommended by the manufacturer and clearly visible in the position of normal use shall be used. The collection container shall be marked with its usable volume, expressed in millilitres. For collection containers having a capacity of 500 ml or greater, approximate indication of the volume of the contents shall be given by graduations at intervals of not less than 50 ml and not more than 250 ml.

**7.3.4** The collection container shall not implode, crack or permanently deform when tested in accordance with A.4. Following this test, the suction equipment shall meet the requirements of 6.6.1, 6.6.2, 8.1, 8.2 and 8.3, as appropriate.

## 8 Performance requirements for vacuum and flow[4)]

### 8.1 Vacuum

When tested in accordance with A.5, suction equipment shall develop a vacuum of at least − 40 kPa within 10 s.

### 8.2 Flow

When tested in accordance with A.6, suction equipment shall evacuate 200 ml of simulated vomitus in not more than 10 s.

### 8.3 Free air flow

When tested in accordance with A.7, the peak free air flow shall be at least 0,33 l/s (20 l/min).

## 9 Resistance to environment

### 9.1 Operating conditions

When tested in accordance with A.8.2.1 and A.8.2.2, suction equipment intended for field and transport use shall meet the requirements specified in 8.1 to 8.3.

### 9.2 Storage

When tested in accordance with A.8.2.3 and A.8.2.4, suction equipment intended for field and transport use shall meet the requirements specified in 8.1 to 8.3.

3) See also annex A.

4) See also annex C.

## 10 Marking

The following information shall be permanently and legibly marked on the suction equipment:

a) for equipment not intended for field or transport use or both uses, either the words "high vacuum", "medium vacuum" or "pharyngeal suction" or the maximum vacuum that can be developed;

b) the name and/or trade-mark of the manufacturer or supplier;

c) a model number or other identification of the equipment;

d) words indicating "exhaust" on the exhaust opening, if a single opening is provided;

e) the inlet connection to the collection container, unless mis-connection is prevented by a design feature.

## 11 Information to be supplied by manufacturer

The manufacturer shall provide a manual or manuals of operating and maintenance instructions.

The manual(s) shall include the following information:

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

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

c) instructions that the user should carry out the manufacturer's recommended test procedure after dismantling and reassembly of the equipment;

d) a specification detailing the following:

   1) operating environmental limits,

   2) storage environmental limits;

e) instructions for the dismantling and reassembly of components, if applicable (see 6.2), including an illustration of the component parts in their correct relationship;

f) recommended methods of cleaning, disinfection and/or sterilization of the suction equipment and its components (see clause 4) after any contamination by body fluids or vomitus;

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

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

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

j) fault-finding and correction procedures;

k) the date of publication and/or revision of the manual;

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

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

n) name and address of the manufacturer and/or supplier;

o) the operational suitability of the suction equipment (see clause 6).

# Annex A
(normative)

# Test methods

The apparatus and test methods specified in this annex are not intended to exclude the use of other measuring devices or methods yielding 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.1 Test 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 level of vacuum to the maximum, if a maximum is specified by the manufacturer. If there is no disclosed maximum, conduct the test at − 60 kPa. Hold this vacuum for 5 min.

Calculate the degree of collapse by measuring the outside diameter of the suction tubing along its length with callipers, as illustrated in figure A.1.

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

NOTE 4 Narrow grooves may be cut in the cylinder to aid calliper measurement.

## A.2 Drop test

Drop the suction equipment from a height of 1 m onto a concrete floor in the worst case mode. Test the suction equipment for compliance with the requirements specified in 8.1 to 8.3, as appropriate.



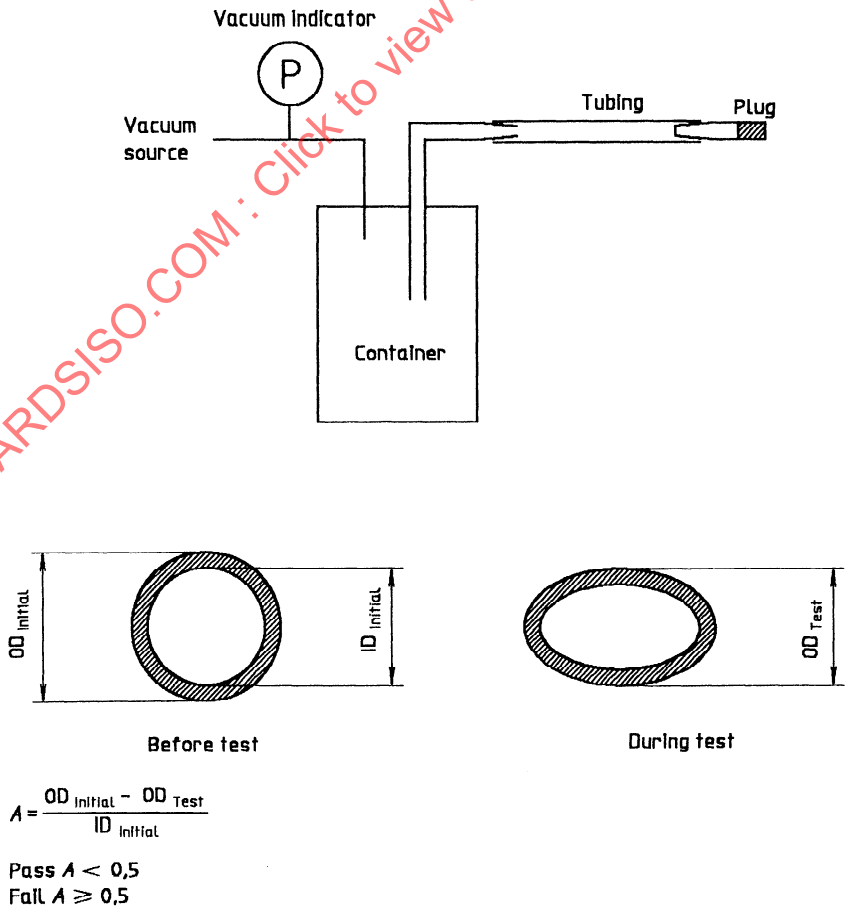



**Figure A.1 — Apparatus for flexible tubing tests**

## A.3 Test for overfill protection and collection capacity

Connect the overfill protection device in accordance with the manufacturer's instructions. Set the suction equipment to maximum free air flow. 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. Run the equipment for a further 2 min. Measure the volume of water which has passed the shut-off mechanism. Measure the volume collected in the collection container at the time the overfill protection device is activated.

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

## A.4 Test for resistance to implosion, cracking or permanent deformation

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, i.e. box or bag, 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 collection container opening. Evacuate the collection container and accessories (if present) under test to 120 % of the manufacturer's recommended maximum vacuum or to a vacuum not exceeding − 95 kPa, whichever is the lesser vacuum. Hold the vacuum for 5 min, and then release. Repeat the procedure once.

**CAUTION — This test can be hazardous and 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 30 cycles of cleaning, disinfection and/or sterilization as recommended by the manufacturer.

NOTE 5 In some suction equipment, the collection container is integrated with the suction equipment.

Check by visual inspection for implosion, cracking or permanent deformation of the collection container or the filter assembly.

A suitable test apparatus is shown in figure A.2.

## A.5 Test for vacuum

Set up the suction equipment with the collection container in place, and fit a vacuum indicator to the container inlet, thus totally occluding the tubing. For hand- or foot-operated suction equipment, operate the equipment at a frequency not exceeding 2 Hz. Record the reading of the vacuum indicator after 10 s.

## A.6 Test for pharyngeal suction

### A.6.1 Test material and apparatus

#### A.6.1.1 Simulated vomitus

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

NOTE 6 0,1 % ($m/m$) benzoic acid may be added as a preservative.

#### A.6.1.2 Graduated vessel

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

### A.6.2 Procedure

Agitate the simulated vomitus to disperse the glass beads by capping and inverting the glass cylinder at least 10 times immediately before testing. Pour 250 ml at ambient temperature into the graduated vessel. 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 vessel and record the time taken to evacuate 200 ml of the simulated vomitus.

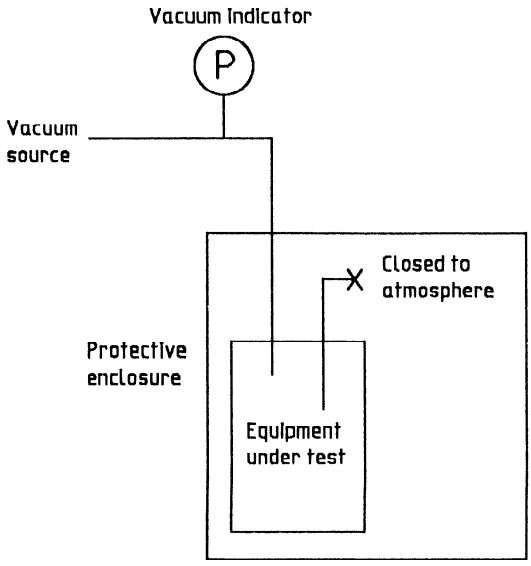



**Figure A.2 — Apparatus for testing resistance to implosion, cracking or permanent deformation**