INTERNATIONAL STANDARD

ISO 10079-3

First edition
1992-10-15

Medical suction equipment —

Part 3:
Suction equipment powered from vacuum or pressure source

Appareils d'aspiration médicaux —

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

Reference number
ISO 10079-3:1992(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 10079-3 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.

Introduction

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

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.

Some devices specified in this standard are intended to be operated in conjunction with a pipeline complying with ISO 7396.

Annex A gives test methods to be used to verify compliance with the requirements given in this part of ISO 10079.

This page intentionally left blank

Medical suction equipment —

Part 3:
Suction equipment powered from vacuum or pressure source

1 Scope

This part of ISO 10079 specifies safety and performance requirements for medical suction equipment powered from a vacuum or pressure source (see figure 1). In particular it applies to connections for pipelines and venturi attachments.

Suction equipment, e.g. electronic timing, controlled by electrical means, may also need to comply with IEC 601-1:1988.

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 manually powered suction equipment which is dealt with in ISO 10079-2, 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.

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 407:1991, *Small medical gas cylinders — Pin-index yoke-type valve connections.*

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

ISO 5359:1989, *Low-pressure flexible connecting assemblies (hose assemblies) for use with medical gas systems.*

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

3 Definitions

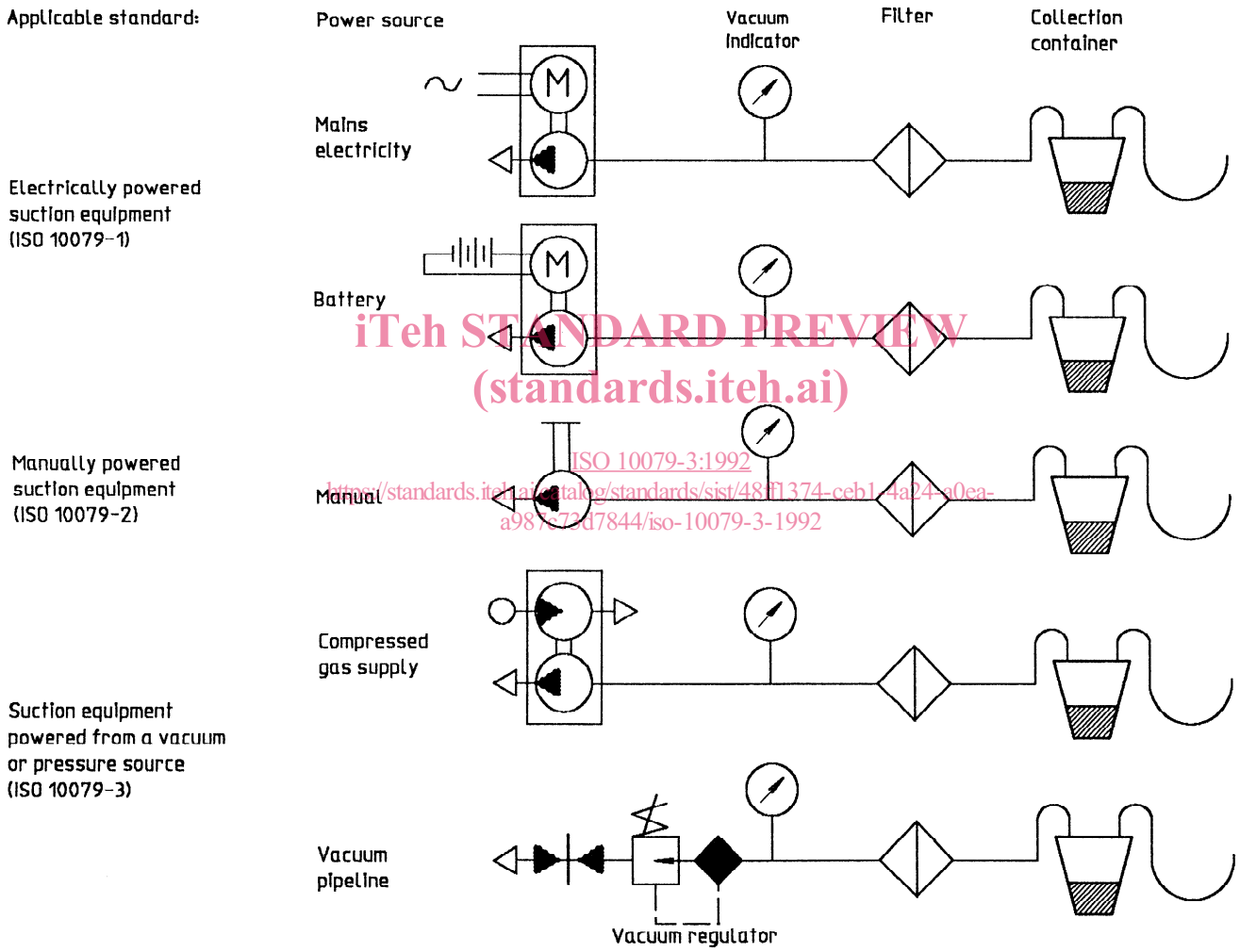
For the purposes of this part of ISO 10079, the following definitions apply.

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

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

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.

ISO 10079-2 applies to manually powered suction equipment. This part of ISO 10079 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 flow: Suction with a free air flow of 20 l/min. or greater.

3.8 high vacuum: Vacuum of at least − 60 kPa[1].

3.9 inlet: Part of a component through which fluids and/or solids enter.

3.10 intermediate tubing: Tubing between the collection container and the vacuum source.

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

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

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

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

3.15 outlet: Part of a component through which fluids and/or solids exit.

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

3.17 overfill protection container assembly: Collection container and its closure.

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

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

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

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

3.22 thoracic drainage: Drainage to the thoracic cavity of the patient.

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

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

3.25 vacuum pump: Powered device for generating vacuum.

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

3.27 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 Any filters installed shall either be of the single-use type or be capable of being cleaned, disinfected and/or sterilized for re-use.

4.2 Equipment with filters intended for re-use shall comply with the requirements specified in 8.1 to 8.7, as appropriate, after the filters have been subjected to 30 cycles of sterilization as recommended by the manufacturer.

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

4.4 Suction equipment incorporating a re-usable collection container assembly shall comply with the requirements given in 8.1 to 8.7, 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.

5 Design requirements

5.1 Collection container

5.1.1 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.

5.1.2 For suction equipment which is intended to continue operating when the collection container is full and 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.

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

NOTE 1 "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.

5.1.3 For suction equipment not intended for field use, one or more collection containers recommended by the manufacturer and either for single-use or of a re-usable type, shall be used. For all collection containers, the contents shall be clearly visible in the position of normal use. 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.

5.1.4 The collection container shall not implode, crack or permanently deform when tested in accordance with A.1. Following this test, the suction equipment shall meet the requirements of 6.1, 6.3 and 8.1 to 8.7, as appropriate.

5.1.5 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 2 The design of the connectors should impede wrongful connections. Incorrect connections have been frequently a cause of spill-over into a vacuum source.

5.2 Suction tubing

5.2.1 When tested in accordance with A.2, suction tubing supplied with the equipment shall retain at least 50 % (0,5) of its inside diameter throughout its length.

5.2.2 The inside diameter of the suction tubing shall be recommended by the manufacturer but shall not be less than 6 mm.

NOTE 3 Suction performance may be markedly affected by the length and diameter of the tubing between the collection container and the end piece.

6 Operational requirements

6.1 Overfill protection

6.1.1 An overfill protection device shall be provided to prevent liquids entering the suction equipment. Suction shall cease when the overfill protection device operates. When tested in accordance with A.3, not more than 5 ml of liquid shall pass downstream of the overfill protection device.

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

NOTE 4 An overfill protection device may be an integral part of the suction equipment.

6.1.2 If the overfill protection device is integral with the collection container, when tested in accordance with A.3, it shall not activate until at least 90 % of the stated capacity of the collection container has been reached.

6.2 Spillage

After testing in accordance with A.4, the suction equipment shall meet the requirements specified in 8.1 to 8.7, as appropriate.

6.3 Air leakage

6.3.1 Collection containers for general use

6.3.1.1 When tested in accordance with A.5.1, for single-use containers, 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 flow of more than 1 l/min. The pressure increase shall be less than 3,3 kPa $\div$ V in 10 s where V is the total volume, in litres, of the collection container.

6.3.1.2 A re-usable collection container assembly shall meet the requirements given in 6.3.1.1, before and after being subjected to 30 cycles of cleaning, disinfection and/or sterilization as recommended by the manufacturer.

6.3.2 Collection containers for thoracic drainage

6.3.2.1 When tested in accordance with A.5.2, no more than three bubbles shall be observed in 10 s.

NOTE 5 Three bubbles in 10 s approximates to a leakage of 4 ml/min.

6.3.2.2 Re-usable collection container assemblies shall meet the requirement given in 6.3.2.1 before and after being subjected to 30 cycles of cleaning and/or sterilization as recommended by the manufacturer.

NOTE 6 These tests are intended to ensure satisfactory overall performance of the vacuum system when parts are supplied by different manufacturers.

6.4 Exhaust air

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

6.5 Protective devices

6.5.1 Positive and negative pressure protection

6.5.1.1 If a device intended to limit the maximum level of vacuum is fitted, when tested in accordance with A.6, the output of the suction equipment shall not deviate from the vacuum limit by more than ± 4 kPa.

In vacuum regulators, a positive pressure relief valve should be included to prevent positive pressure build up at the patient when misconnected to a positive pressure source.

6.5.1.2 When tested in accordance with A.7, thoracic drainage systems shall not develop a pressure in excess of 1 kPa at the patient inlet.

6.5.2 Filter assembly

6.5.2.1 Any part of a filter assembly which is reusable, shall be capable of being cleaned, disinfected and/or sterilized according to the manufacturer's instructions, and shall then meet the requirements of 6.1 and 8.1 to 8.7, as appropriate.

Air leaving the collection container should pass through a microbiological filter before entering the suction equipment.

6.5.2.2 The filter assembly shall not implode, crack or permanently deform when tested in accordance with A.1.

6.5.3 Anti-blow-back in suction equipment powered by venturi device

6.5.3.1 In venturi-powered suction systems, the device shall not produce a positive pressure of more than 1 kPa in the vacuum line under any single fault condition.

6.5.3.2 When tested in accordance with A.8, a positive pressure of greater than 1 kPa shall not be developed by occlusion of the venturi outlet(s).

6.5.4 Electrical protection

When tested in accordance with A.9, suction equipment marked as "CF compatible" shall have an electrical resistance (impedance) of greater than 10 MΩ.

6.6 Vacuum indicators

6.6.1 Suction equipment having vacuum regulators with a variable control shall have a vacuum indicator displaying the vacuum on the patient side of the vacuum regulator.

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

6.6.3 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.

6.6.4 All low vacuum equipment shall be fitted with a vacuum indicator which shall be installed between the vacuum source and collection container to indicate the vacuum applied to the suction tubing.

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

6.6.6 Vacuum indicators on suction equipment, except as specified in 6.6.7, shall be accurate to within ± 5 % of the full scale value.

6.6.7 Vacuum 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 indicator range.

6.6.8 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.

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

6.7 Dismantling and reassembly

Suction equipment intended to be dismantled by the user (for example, for cleaning) shall be designed so as to minimize incorrect reassembly when all parts are mated. After dismantling and reassembly, the suction equipment shall meet the requirements specified in 6.1, 6.3 and 8.1 to 8.7, as appropriate.