INTERNATIONAL STANDARD

ISO 10079-3

Second edition
1999-08-15

Medical suction equipment —

Part 3:
Suction equipment powered from a vacuum or pressure source

Appareils d'aspiration médicale —

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

Reference number
ISO 10079-3:1999(E)

Contents

International Organization for Standardization
Case postale 56 • CH-1211 Genève 20 • Switzerland
Internet iso@iso.ch

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

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*, Subcommittee SC 8, *Suction devices for hospital and emergency care use*.

This second edition cancels and replaces the first edition (ISO 10079-3:1992), which has been technically revised.

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

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

— *Part 2: Manually powered suction equipment*

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

Annex A forms a normative part of this part of ISO 10079.

Medical suction equipment —

Part 3:
Suction equipment powered from a 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 with components controlled by electrical means, e.g. electronic timing, may also need to comply with IEC 60601-1.

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;

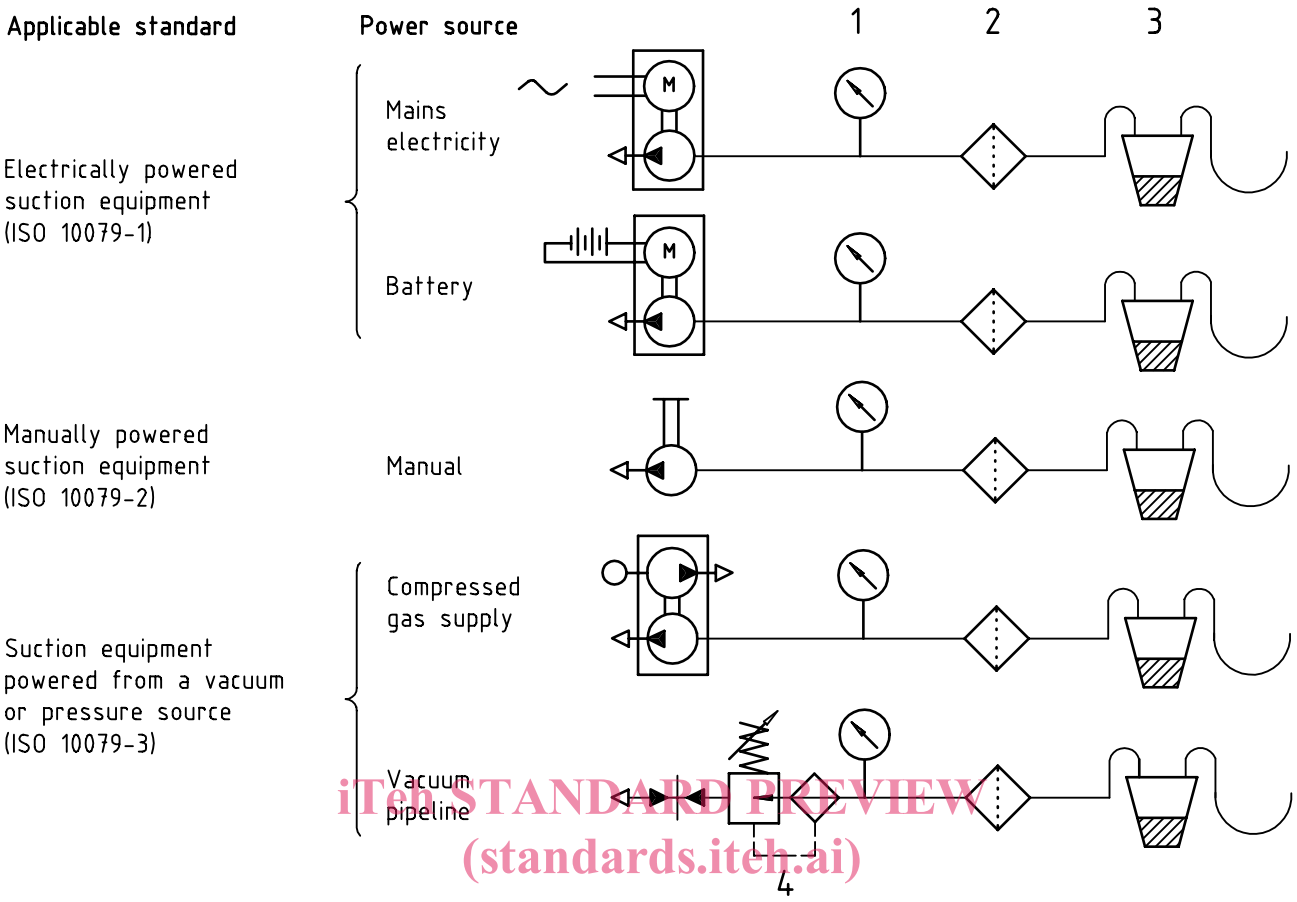
n) ventouse (obstetric) equipment;

o) neonatal mucous extractors;

p) breast pumps;

q) liposuction;

r) uterine aspiration.



Key

1 Vacuum indicator
2 Filter
3 Collection container
4 Vacuum regulator

NOTE 1 ISO 10079-1 applies to mains electricity and battery-powered suction equipment. ISO 10079-2 applies to manually powered suction equipment. ISO 10079-3 applies to suction equipment powered from a vacuum or pressure source.

NOTE 2 Components illustrated are not necessarily required by this part of ISO 10079.

NOTE 3 Suction equipment shown is an example only, and actual systems may consist of other arrangements and components not illustrated.

Figure 1 — Schematic drawing of suction equipment

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 10079. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 10079 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 3744:1994, *Acoustics — Determination of sound power levels of noise sources — Engineering methods for free-field conditions over a reflecting plane.*

ISO 5356-1:1996, *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.*

ISO 8836:1997, *Suction catheters for use in the respiratory tract.*

ISO 10079-1:1999, *Medical suction equipment — Part 1: Electrically powered suction equipment — Safety requirements.*

IEC 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety*; Amd. 1:1991 and Amd. 2:1995.

IEC 60651:1979, *Sound pressure meters.*

3 Terms and definitions

For the purposes of this part of ISO 10079, the terms and definitions given in ISO 10079-1 apply.

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 given 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

NOTE The constructional requirements may deviate from those detailed in this part of ISO 10079 if an equivalent degree of safety can be achieved.

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 solely for field use which is intended to continue operating when the collection container is full, the volume of the collection container shall be not less than 200 ml. For other suction equipment intended solely for field use, the usable volume of the collection container shall be not less than 300 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.

NOTE "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 airplanes. 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 level of 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, an

approximate indication of the volume of the contents shall be given by graduations. The intervals of the graduation should not be 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.2. 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 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 Incorrect connections have frequently been a cause of spillover into the vacuum source and/or a loss of suction.

5.2 Suction tubing

5.2.1 When tested in accordance with A.3, the degree of collapse of the suction tubing supplied with the equipment shall be less than 0,5 throughout its entire 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 Suction performance may be markedly affected by the length and diameter of the tubing between the collection container and end-piece.

5.3 End-piece

Suction catheters, if supplied or recommended by the manufacturer, shall comply with ISO 8836.

6 Operational requirements

6.1 Overfill protection devices

6.1.1 An overfill protection device shall be provided to prevent fluids entering the intermediate tubing. Suction shall cease when the overfill protection device operates. When tested in accordance with A.4, not more than 5 ml of fluid shall pass downstream of the overfill protection device.

NOTE 1 Protective means should be provided to prevent foam passing downstream into the vacuum source.

NOTE 2 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.4 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.5, the suction equipment shall meet the requirements given 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.6.1, 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 flowrate of more than 1 l/min. The pressure increase shall be less than 3,3 kPa/V in 10 s, where V is the total volume, 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.6.2, no more than three bubbles shall be observed in 10 s.

NOTE Three bubbles in 10 s is a leakage of approximately 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 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 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.7, the vacuum shall not exceed the limit by more than ± 4 kPa.

NOTE In vacuum regulators, a positive-pressure relief valve should be included to prevent positive-pressure buildup at the patient if misconnected to a positive-pressure source.

6.5.1.2 When tested in accordance with A.8, thoracic drainage systems shall not develop a pressure in excess of 1 kPa.

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.2.

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

6.5.3.1 In Venturi-powered suction equipment, the device shall not produce a positive pressure of more than 1 kPa under any single fault condition.

6.5.3.2 When tested in accordance with A.9, 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.10, 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 a vacuum regulator with a variable control shall have a vacuum indicator displaying the vacuum level on the inlet side of the vacuum regulator.

6.6.2 Analog 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 level 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 between the vacuum source and collection container.

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

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 of white (simulated day-) light.

NOTE Movement of a rotary analog vacuum indicator should be anticlockwise 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 given in 6.1, 6.3 and 8.1 to 8.7, as appropriate.

6.8 Mechanical shock

After suction equipment intended for field and/or transport use has been drop-tested in accordance with A.11, it shall meet the requirements given in 6.1, 6.3 and 8.1 to 8.7, as appropriate.

If the suction equipment can be operated outside of its carrying case, it shall meet the requirements given in 6.1 and 8.1 to 8.7, as appropriate, after the individual parts of the suction equipment, excluding the cylinder and regulator, have been drop-tested in accordance with A.11 and reassembled.

6.9 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 given in 6.1 and 8.1 to 8.7, as appropriate.

NOTE Equipment for field use is likely to experience extreme outdoor conditions and should therefore be designed to withstand immersion in water and continue to perform satisfactorily.

6.10 Stability

Suction equipment intended for field and/or transport use shall meet the requirements given in 6.1 and 8.1 to 8.7, as appropriate, when operated 20° (0,35 rad) from its normal orientation.

6.11 Noise

6.11.1 Low vacuum/low flowrate equipment (see 8.5 and 8.7)

In normal use the maximum A-weighted sound pressure level (peak or steady value) of low vacuum/low flowrate equipment, including equipment for thoracic drainage, shall not exceed 60 dB. Compliance shall be checked by the test given in 6.11.3.

6.11.2 Suction equipment other than that specified in 6.11.1

In normal use, the maximum A-weighted sound pressure level (steady or peak value) of suction equipment other than low vacuum/low flowrate equipment shall not exceed 70 dB. Compliance shall be checked by the test given in 6.11.3.

6.11.3 Test of suction equipment with inlet open to atmosphere and also with inlet occluded

Place the microphone of a sound-level meter complying with the requirements for a type I instrument specified in IEC 60651 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 flowrate, including the maximum flowrate recommended by the manufacturer. Measurements shall be taken using the frequency-weighting characteristic A and the time-weighting characteristic S on the sound-level meter. The measurements shall be taken in a free field over a reflecting plane as specified in ISO 3744.

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

7 Physical requirements

7.1 Dimensions

Suction equipment intended for field use, including any carrying case or frame, shall pass through a rectangular opening having dimensions of 600 mm × 300 mm.

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

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.

8 Performance requirements for vacuum and flowrate

8.1 General

Suction equipment intended for use with piped vacuum or installed Venturi systems and which does not itself generate vacuum, shall meet the requirements of 8.2 to 8.7, as appropriate, when a vacuum of 95 kPa below atmospheric pressure is applied.

If the level of vacuum or suction described in 8.2, 8.3, 8.4, 8.5, 8.6 or 8.7 is not specified, then the level of vacuum and flowrate obtained with a vacuum of 95 kPa below atmospheric pressure and free air flowrate of 50 l/min or another nominated vacuum and flowrate shall be described.

8.2 High vacuum/high flowrate equipment

When tested in accordance with A.12, suction equipment marked “high vacuum/high flow” shall develop a vacuum of at least 60 kPa below atmospheric pressure within 10 s.

8.3 Medium vacuum equipment

When tested in accordance with A.12, suction equipment marked “medium vacuum” shall develop a vacuum of between 20 kPa and 60 kPa below atmospheric pressure.