INTERNATIONAL STANDARD

ISO 10079-2

Second edition
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Medical suction equipment —

Part 2:
Manually powered suction equipment

Appareils d'aspiration médicale —

Partie 2: Appareils d'aspiration manuelle

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.

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 10079-2 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 10079-2:1992), 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 vacuum or pressure source*

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

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. 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 included in the scope of this part of ISO 10079.

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) cathether 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;

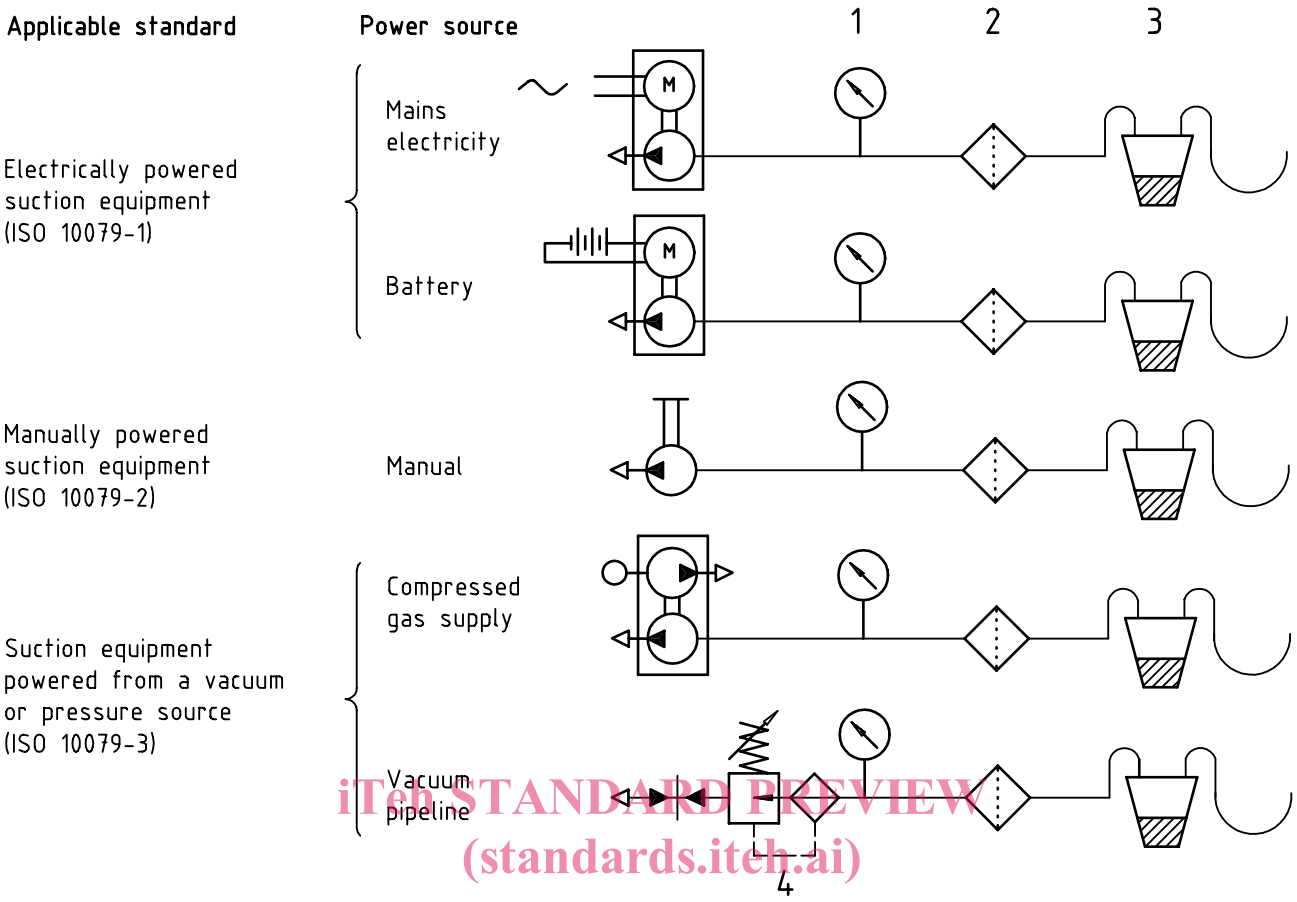
o) neonatal mucous extractors;

p) breast pumps;

q) liposuction;

r) uterine aspiration;

s) thoracic drainage.



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 which are not illustrated.

Figure 1 — Examples 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 5356-1:1996, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets.*

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.*

3 Terms and definitions

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

3.1
manually powered vacuum
manually generated vacuum
generation of vacuum by human effort with a hand or foot or both

3.2
transportable equipment
equipment which is intended to be easily moved from one place to another, whether or not connected to the vacuum supply, without an appreciable restriction of range

4 Cleaning and sterilization

4.1 The suction equipment shall meet the requirements given 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 given in 8.1 to 8.3, as appropriate, before and after the collection container assembly 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

NOTE The constructional requirements may deviate from those detailed in this part of ISO 10079 if the equivalent level of safety is obtained.

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.

The construction of the connections has frequently been a source of spillover 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.

5.2 Suction tubing

5.2.1 General

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

Suction performance may be markedly affected by the length, diameter and degree of collapse of the suction tubing. When tested in accordance with A.2, 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 Length of suction tubing for foot-operated suction equipment

When the foot-operated vacuum pump is on the floor in the operating position, the length of suction tubing, if supplied, shall be such that the endpiece can be positioned at least 1,3 m above the floor.

NOTE See also annex C for rationale.

5.3 End-pieces

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

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 given 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 drop-tested in accordance with A.3, it shall meet the requirements given in 8.1 to 8.3, as appropriate.

Field use of suction equipment is intended to cover use in situations outside 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 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.

If the suction equipment can be operated outside its carrying case, it shall meet the requirements given in 8.1 to 8.3, as appropriate, after the individual parts of the suction equipment have been drop-tested in accordance with A.3 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 given in 8.1 to 8.3, 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.

6.5 Stability

Suction equipment operated by foot and intended for field or transport use, or both, shall meet the requirements given 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 given in 8.1 to 8.3, as appropriate, in any position except that excluded by the manufacturer as specified in 11 b).

6.6 Overfill protection devices

6.6.1 For equipment with means to prevent liquids or solids entering the intermediate tubing, the collection container shall collect not less than 90 % of the stated collection capacity when tested in accordance with A.4.

NOTE Some equipment is designed to continue to pumping when the collection container is full.

6.6.2 Suction shall cease when the overfill protection device operates.

6.7 Vacuum Indicators

6.7.1 Analog 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.

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 using white (simulated day-) light.

6.7.4 The full scale of analog 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.

NOTE Movement of a rotary analog vacuum indicator should be anticlockwise for an increase in vacuum.

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 1 Suction equipment is often combined with resuscitation equipment which may make it impossible to define the 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.

NOTE 2 See also annex A.

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.