American National Standard

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Medical Suction Equipment—Part 3: Suction Equipment Powered from a Vacuum or Pressure Source

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Medical Suction Equipment—

Part 3:

Suction Equipment Powered from a Vacuum or Pressure Source

Approved as an American National Standard by:

ASTM International

ASTM deviations to ISO 10079-3: 1999

2 Normative references
(Add the following)

CGA Z168.11-94, Vacuum Devices Used for Suction and Drainage

Rationale for ASTM deviation: CGA Z168.11-94 has requirements for intermittent and interrupted regulators that are not part of ISO 10079-3

5.2 Suction tubing
(Add the following)

Suction tubing supplied with the suction equipment shall have a minimum length of 1.3 m.

Rationale for ASTM deviation: This minimum length is specified in ISO 10079-1and 10079-2

8 Performance requirements for vacuum and flow rate
(Replace the following clauses and delete Subclauses 8.5 and 8.6)

8.2 Vacuum
When tested in accordance with A.12, suction equipment shall develop a vacuum of at least 40 kPa, unless either marked “low vacuum” or marked with the maximum vacuum that can be developed.

8.3 Free Air Flow
When tested in accordance with A.14, the peak free air flow shall be at least 20 L/min unless marked “low flow” in which case the peak air flow shall be less than 20 L/min.

Equipment intended for thoracic drainage, wound drainage, and intermittent and interrupted suction shall be exempt from the requirements of this clause.

Rationale for ASTM deviation: This simplifies performance categories and allows all combinations of high and flow vacuum and flow but exempts application-specific apparatus such as thoracic suction equipment.

10 Regulators
(Add the following)

10.3 Intermittent Regulators

10.3.1 Intermittent Regulator Function

When tested in accordance with A.19, an intermittent regulator shall cycle through its off-time according to the manufacturer's published specifications.

10.3.2 Intermittent Regulator Venting

When tested in accordance with A.20, an intermittent regulator shall return to atmospheric pressure (0-kPa gauge) for at least 3 s before commencing the next on-cycle.

10.4 Interrupted Regulators

10.4.1 Interrupted Regulator Function

When tested in accordance with A.21, an interrupted regulator shall cycle between the vacuum relief set point and that of a lower level according to the manufacturer's published specification.

10.4.2 Interrupted Regulator Venting

When tested in accordance with A.22, an interrupted regulator shall return to a lower vacuum level before returning to the vacuum relief set point.

Rationale for ASTM deviations: Above requirements can be found in CGA Z16811-94 but not ISO 10079-3

12.2 Equipment on carrying case
(Change title to the following)

Equipment or carrying case

Rationale for ASTM deviation: Typing error in ISO document.

(Replace a) with the following)

a) the performance category as indicated in Clause 8 or the vacuum and flow rate ranges for patient use, with the marking visible in the normal operating position;

Rationale for ASTM deviation: To make the marking consistent with performance.

13 Information to be supplied by manufacturer
(Add the following)

k) whether or not the suction equipment is suitable for use in a magnetic resonance imaging (MRI) unit.

Rationale for ASTM deviation: This knowledge is necessary for safe use.

Annex A Test methods
A.14 Test for free air flowrate of low vacuum equipment
(Change title and test as follows)

A.14 Test for free air flow

With the collection container(s) empty, switch on the suction equipment with the regulator adjusted to give the maximum vacuum. Open the inlet and attach a low resistance flowmeter to it. Note the mean free air flow when stable conditions are reached.

Rationale for ASTM deviation: To make the test procedure consistent with performance modifications. Vacuum level is tested in A.12. Therefore A.14 only needs to test for free air flow.

A.17 Test for vacuum regulator with variable setting
(Modify as follows)

Commence with the vacuum source at 79 kPa below atmospheric pressure and reduce the vacuum to 53 kPa below atmospheric pressure…

…adjust the vacuum source from 53 kPa to 80 kPa below atmospheric pressure…

Rationale for ASTM deviation: Source pressure of 53 kPa is needed in order to set the regulator to 53 kPa as required in test procedure. CGA Z168.11-94 also uses a supply pressure of 53 kPa for this test.

Annex A
(Add the following)

A.19 Test for intermittent function of intermittent regulators (See Figure A.10)

Connect the regulator to a vacuum source as recommended by the manufacturer. Set the regulator to the intermittent mode and occlude the tubing at the patient port. Set the occluded vacuum level to a point in the middle third of the gauge range during the on cycle. With the unit still occluded, record the on time and off time during five full cycles.

A.20 Test for venting of intermittent regulators (See figure A.11)

Connect the regulator to a vacuum source as recommended by the manufacturer. Connect the patient side of the regulator to the vacuum side of a 2-L collection container. Occlude the patient side of the regulator. Set the regulator to the intermittent mode,

occlude the tubing between the regulator and the collection container, and adjust the regulator to a point in the middle third of the gauge range during the on cycle. Release the occlusion on the tubing, ensuring that the regulator is cycling normally, and record the amount of time that the vacuum indicator is at 0-kPa gauge (atmospheric pressure) during the off cycle.

A.21 Test for interrupted function of interrupted regulators (See figure A.12)

A.21.1 Fixed vacuum relief valves

Connect the regulator to a vacuum source as recommended by the manufacturer. Adjust the regulator static set point to 2.7 ± 0.2 kPa (20 mmHg) above the vacuum relief valve set point. Allow the vacuum relief valve to cycle and record the maximum vacuum obtained.

A.21.2 Adjustable vacuum relief valves

Connect the regulator to a vacuum source as recommended by the manufacturer. Adjust the regulator static set point to 2.7 ± 0.2 kPa (20 mmHg) above the minimum vacuum, relief valve set point. Allow the vacuum relief valve to cycle and record the maximum vacuum obtained. Repeat for the maximum vacuum relief valve set point.

A.22 Test for venting of interrupted regulators

A.22.1 Fixed vacuum relief valves

Connect the regulator to a vacuum source as recommended by the manufacturer. Connect the patient side of the interrupted regulator to the vacuum side of a 2-L collection container. Connect a vacuum indicator having a range similar to that of the regulator to the patient side of the collection container. Adjust the regulator static set point to 2.7 ± 0.2 kPa (20 mmHg) above the vacuum relief valve set point. Allow the vacuum relief valve to cycle for five full cycles and record the minimum vacuum level on the 2-L collection container.

A.22.2 Adjustable vacuum relief valves

Connect the regulator to a vacuum source as recommended by the manufacturer. Connect a vacuum indicator having a range similar to that of the regulator to the patient side of the collection container. The patient side of the collection container shall have a vacuum indicator having a range similar to that of the regulator. Adjust the regulator static set point to 2.7 ± 0.2 kPa (20 mmHg) above the minimum vacuum relief valve set point. Allow the regulator to cycle for five full cycles and record the minimum vacuum level on the 2-L collection container. Repeat for the maximum vacuum relief set point.

Rationale for ASTM deviation: The additional test methods are needed for additional requirements. Test procedures were taken from CGA Z168.11-94.

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)

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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 10079-3 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;

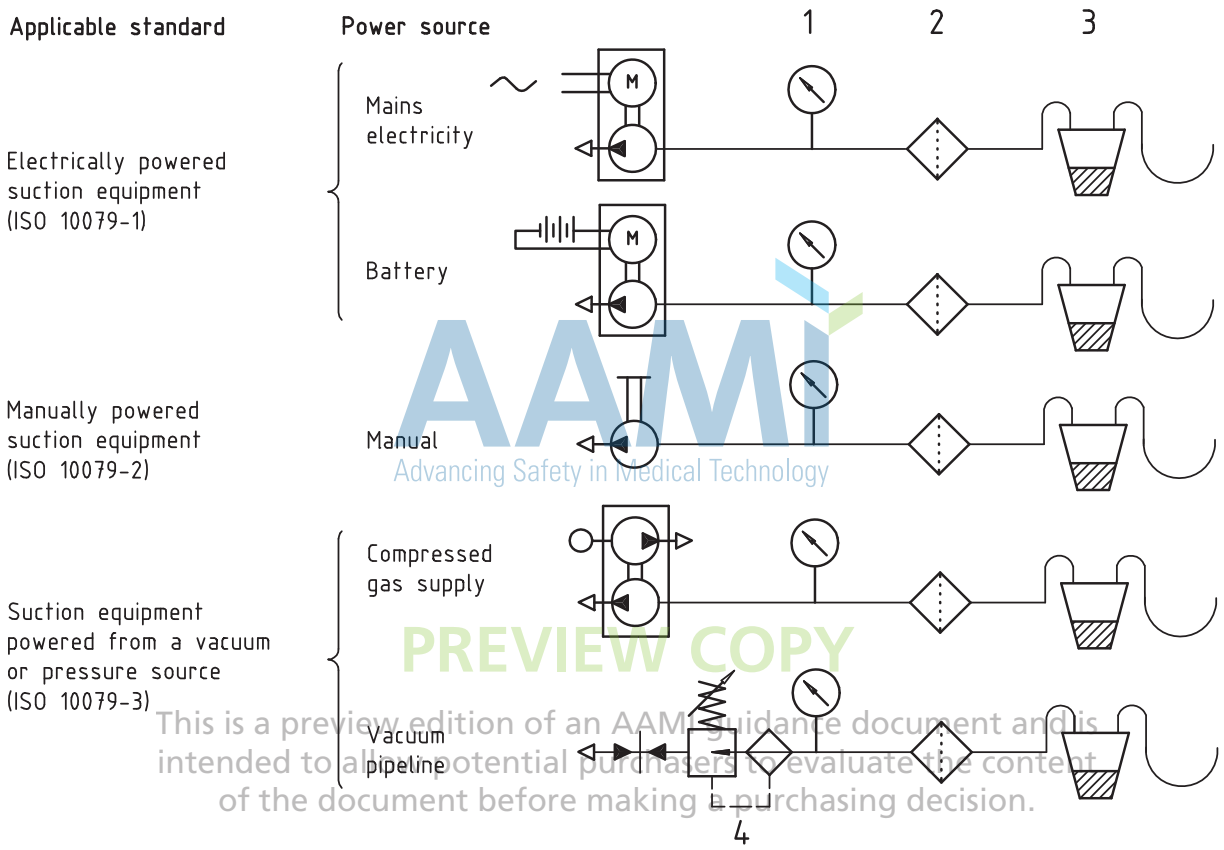
n) ventouse (obstetric) equipment;

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*.