American National Standard



# ANSI/AAMI/ISO 10079-1:1999

## Medical Suction Equipment—Part I: Electrically Powered Suction Equipment—Safety Requirements

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**ANS/ISO 10079-1**
**1999**



# Medical Suction Equipment—

# Part 1:



# Electrically Powered Suction Equipment—

# Safety Requirements



Approved as an American National Standard by:

**ASTM International**

# ASTM Deviations to ISO 10079-1: 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 10079-1.

## 3 Terms and Definitions
## (Add the following)

interrupted suction
suction in which the negative pressure is automatically and periodically relieved to a lower negative pressure (for example, from -50 kPa to -5 kPa).

single-fault condition
condition in which a single means of protection against a hazard in equipment is defective or a single external abnormal condition is present

Rationale for ASTM deviation: These definitions are needed because the terms are used in the documents.



## 6 Identification, marking and documents
## (Add the following to 6.8.2)

16) The manufacturer shall disclose 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.

## 16.3 Components and general assembly
## (Make changes to the following subclauses)

56.5
(Add the following)

3) An intermittent regulator shall cycle through its off-time and on-time in accordance with the manufacturer's specifications.

Compliance shall be checked with the following test:

Connect the regulator to a vacuum source as recommended by the manufacturer. Set the regulator to the intermittent mode and occlude the intermittent tubing. Set the vacuum to a level in the middle third of the gauge range during the on cycle. Record the on time and off time during five full cycles.

4) An intermittent regulator shall return to atmospheric pressure during the off-time for at least 3 s before commencing the next on-cycle.

Compliance shall be checked with the following test:

Connect the regulator to a vacuum source as recommended by the manufacturer. Connect the patient side of the regulator to the vacuum end of a 2-L collection container. Occlude the patient side of the collection container with a pressure indicator having a range similar to that of the intermittent regulator. Set the intermittent regulator to the intermittent mode, occlude the intermediate tubing between the intermittent regulator and the collection container, and adjust the vacuum on the regulator to a level in the middle third of the gauge range. Release the occlusion on the intermittent tubing, ensure that the intermittent regulator is cycling normally, and record the amount of time that the vacuum indicator indicates 0 kPa during the off cycle.



5) An interrupted regulator shall cycle between the set vacuum and a less negative vacuum in accordance with the manufacturer's specifications.

Compliance shall be checked with the following tests:

a) Fixed vacuum relief

Connect the regulator to a vacuum source as recommended by the manufacturer. Adjust the regulator to a vacuum 2.7 kPa more negative than the vacuum relief pressure. Allow the regulator to cycle through five full cycles and record the maximum and minimum pressures shown on the gauge and the times that these pressures are maintained.

b) Adjustable vacuum relief

Connect the regulator to a vacuum source as recommended by the manufacturer. Adjust the regulator to a vacuum 2.7 kPa more negative than the minimum vacuum relief pressure. Allow the regulator to cycle through five full cycles and record the maximum and minimum pressures shown on the gauge and the times these pressures are maintained. Adjust the regulator to a vacuum of 2.7 kPa more negative than the maximum vacuum relief pressure. Allow the regulator to cycle through five full cycles and record the maximum and minimum pressures on the gauge and the times these pressures are maintained.

6) An interrupted regulator shall return to a lower vacuum level before returning to the vacuum relief valve set point.

Compliance shall be checked with the following tests:

a) 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. 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 vacuum relief valve set point. Allow the vacuum relief valve to cycle and record the minimum vacuum level on the 2-L collection container.

b) Adjustable 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. 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 vacuum relief valve to cycle and record the minimum vacuum level on the 2-L collection container. Repeat for the maximum vacuum relief set point.

Rationale for ASTM deviations: Above requirements can be found in CGA Z168.11-94 but not ISO 10079-1



## 56.12 Inlet port of collection container
(Remove the following note)

Note 1 Suction performance may be markedly affected by the length and diameter of the suction tubing. An indication of the magnitude of this affect is in Annex P.

Rationale for ASTM deviation: Note 1 in the ISO standard relates to suction tubing, not the collection container and the annex is incorrectly identified.

## 56.13 Suction tubing
(Add the following at the beginning)

The internal diameter of the suction tubing shall not be less than 6 mm.

Rationale for ASTM deviation: Since suction performance may be affected by the diameter of the tubing, that diameter should be specified. This is the minimum diameter specified in ISO 10079-3.

## (Add the following)

Note: Suction performance may be markedly affected by the length and diameter of the suction tubing. An indication of the magnitude of this effect is given in Annex O.

Rationale for ASTM deviation: This note, which is part of 56.12 in the ISO 10079-1 standard, belongs here.

INTERNATIONAL STANDARD

**ISO 10079-1**

Second edition
1999-08-15



# Medical suction equipment —

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



*Appareils d'aspiration médicale —*
*Partie 1: Appareils électriques d'aspiration — Prescriptions de sécurité*

Reference number
ISO 10079-1:1999(E)

## 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 10079-1 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 10079-1:1991), 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*

Annexes A to L of this part of ISO 10079 refer to Appendixes A to L of IEC 60601:1988, respectively. Annexes M, N and O are for information only.

# Medical suction equipment —

# Part 1:
Electrically powered suction equipment — Safety requirements



## 1 Scope

This part of ISO 10079 specifies minimum safety and performance requirements for medical and surgical suction equipment (see Figure 1) for health care facilities such as hospitals, for domiciliary care of patients and for field and transport use.

Although such equipment may be driven by centrally powered piped vacuum systems, compressed gases and electricity, or be manually powered for a variety of applications, this part of ISO 10079 addresses only mains electricity- and battery-powered suction equipment.

NOTE See also annex M in this part of ISO 10079.



ISO 10079-1 is one of a series of International Standards based on IEC 60601-1:1988; in IEC 60601-1 (the "General Standard"), this type of International Standard is referred to as a "Particular Standard". As stated in 1.3 of IEC 60601-1:1988, the requirements of this part of ISO 10079 take precedence over those of IEC 60601-1.

The scope and object given in clause 1 of IEC 60601-1:1988 apply, except that 1.1 shall be replaced by the following:

This part of ISO 10079 is not applicable to:

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;

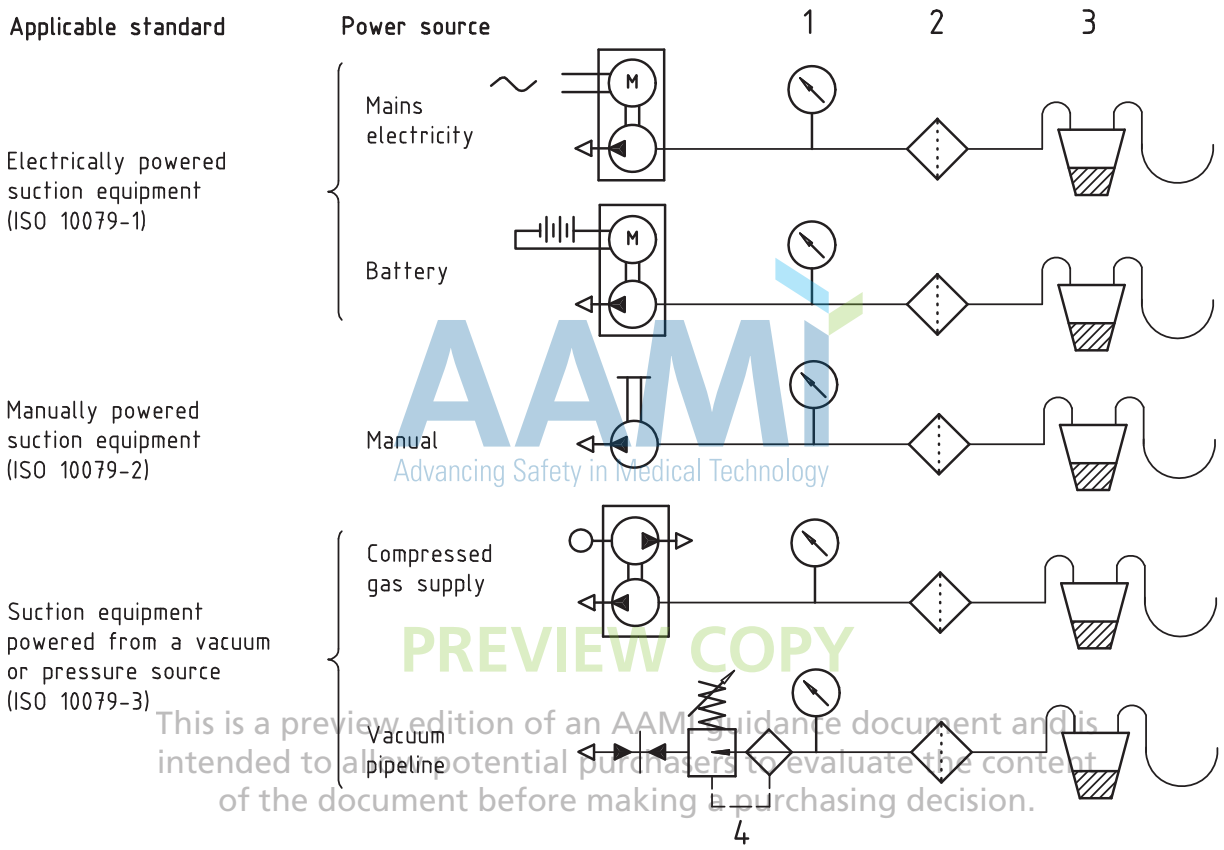
l) suction equipment where the collection container is downstream of the vacuum pump;

m) equipment marked as suction unit for permanent tracheostomy;

n) ventouse (obstetric) equipment;

o) neonatal mucous extractors;

p) suction equipment marked for endoscopic use only.






**Key**

1 Vacuum indicator
2 Filter
3 Collection container
4 Vacuum regulator

NOTE 1 This part of ISO 10079 applies to mains electricity- and battery-powered suction equipment. Part 2 of ISO 10079 applies to manually powered suction equipment. Part 3 of ISO 10079 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*.