American National Standard

ANSI/AAMI/ISO 10079-2:1999

Medical Suction Equipment—Part 2: Manually Powered Suction Equipment

AAMI
Advancing Safety in Medical Technology

This document was approved and published when the U.S. TAG for TC 121 was held by ASTM, but it is now an AAMI standard. The original formatting has been maintained, so there are some variations from the typical AAMI style.

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Medical Suction Equipment—

Part 2:

Manually Powered Suction Equipment

Approved as an American National Standard by:

ASTM International

ASTM deviations to ISO 10079-2: 1999

5.2.1 General
(Replace 5.2.1 with the following)

Note: Suction performance may be markedly affected by the length diameter and degree of collapse of the suction tubing.

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

5.2.1.2 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.

Rationale for ASTM deviation: Structured similar to ISO 10079 - 3

6 Operational requirements
(Add the following)

6.8 The performance criteria in Clause 8 shall be met using a force of less than 350 N for foot-operated equipment and less than 45 N for hand-operated equipment.

Rationale for ASTM deviation: These requirements are necessary so that equipment can be operated without excessive effort on the part of the operator. These requirements can be found in CGA Z168.11-94.

8.1 Vacuum
(Replace with the following)

When tested in accordance with A.6, the suction equipment shall develop a vacuum of at least 40 kPa within 10 s, unless either marked as “low vacuum” or marked with the maximum vacuum that can be developed.

Rationale for ASTM deviation: This allows for equipment other than high vacuum if appropriately labeled. This modification is based on CGA Z168.11-94.

8.3 Free air flow
(Replace with the following)

When tested in accordance with A.7, the peak free air flow shall be at least 20 L/min unless marked “low flow.”

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 allows for equipment other than high flow if appropriately labeled and exempts application-specific equipment. This modification is based on CGA Z168.11-94.

10 Marking
(Replace a) with the following)

For equipment not intended for field and/or transport use, the unit shall be marked appropriately based on the performance in Clause 8.

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

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

p) 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.

A.6 Test for vacuum
(Replace with the following)

Set up the suction equipment with the collection container in place and, using a short tube, fit a vacuum indicator to the container inlet, totally occluding the inlet. Operate the equipment at a frequency not exceeding 2 Hz. Record the reading of the vacuum indicator after 10 s.

Rationale for ASTM deviation: It may not be possible to fit a vacuum indicator directly to the container inlet.

INTERNATIONAL STANDARD

ISO 10079-2

Second edition
1999-08-15

Medical suction equipment —

Part 2:
Manually powered suction equipment

Appareils d'aspiration médicale —

Partie 2: Appareils d'aspiration manuelle

Reference number
ISO 10079-2:1999(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 10079-2 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;

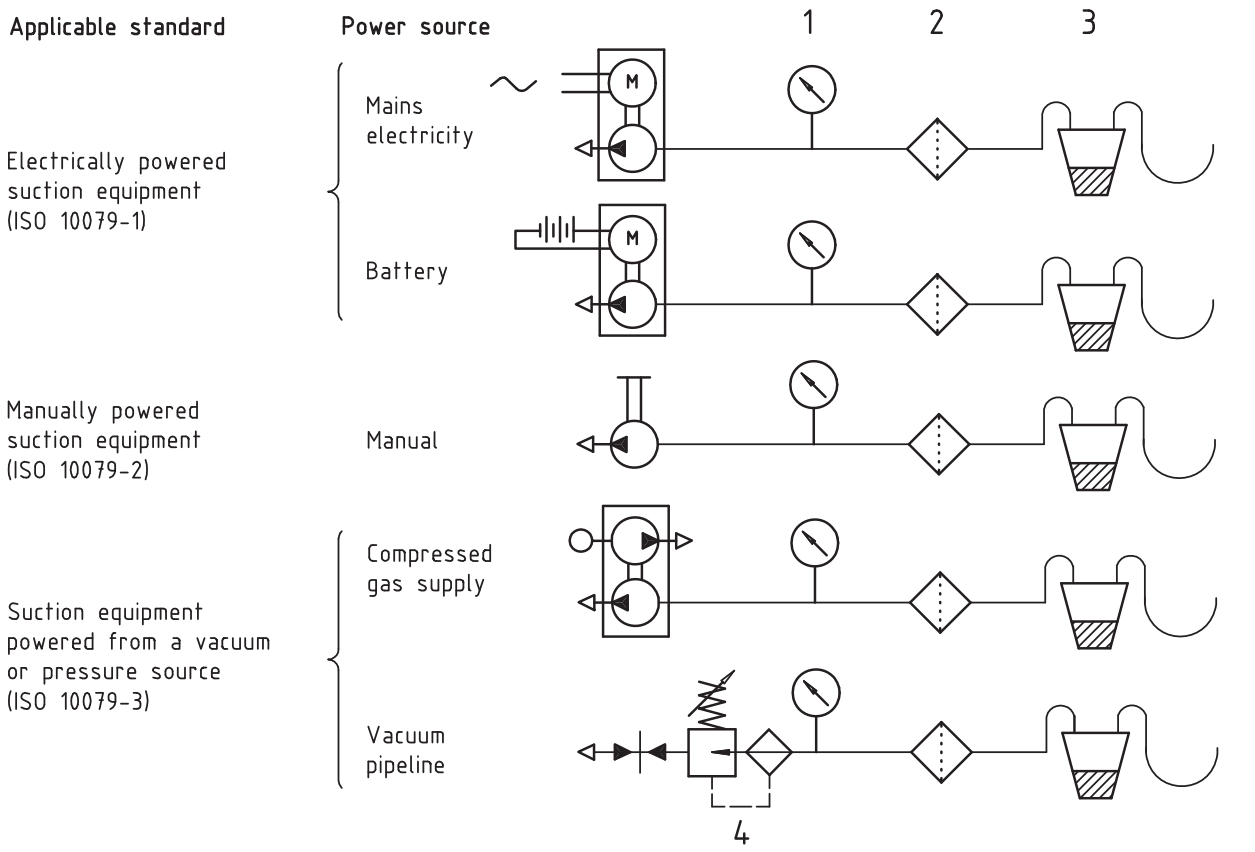
o) neonatal mucous extractors;

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, S*uction catheters for use in the respiratory tract.*

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