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ISO 10079-1

First edition
1991-05-15

Medical suction equipment —

Part 1:
Electrically powered suction equipment — Safety requirements

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Matériel d'aspiration médical —

Partie 1: Matériel électrique d'aspiration — Prescriptions de sécurité

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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.

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.

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International Standard ISO 10079-1 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Sub-Committee SC 8, *Suction devices for hospital and emergency care use.*

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

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

— *Part 2: Non-electrical manually powered suction equipment*

— *Part 3: Non-electrical suction equipment powered from a vacuum or pressure source*

Annexes M, N and P of this part of ISO 10079 are for information only.

Introduction

This part of ISO 10079, which has been prepared under the responsibility of Sub-Committee 8 of ISO/TC 121, comprises Part 1 of the standard for Medical Suction Equipment, and deals only with safety requirements for electrically powered suction equipment.

Suction is used to clear the airway and remove unwanted material from body cavities. Suction is also used to assist drainage and decompress body cavities. Suction and vacuum systems are used widely both in health care facilities such as hospitals, for domiciliary care of patients who are nursed at home, and in emergency situations both outside hospitals in field conditions, and during transport in ambulances.

In this part of ISO 10079, vacuum readings are specified as gauge (relative) pressures to assist clinical personnel. However, this is not intended to prevent engineering groups from using absolute vacuum in their design process.

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Test methods other than those specified in this part of ISO 10079, but of equal or greater accuracy, may be used to verify compliance with the given requirements. However, in the event of a dispute, the methods specified in this part of ISO 10079 are to be used as the reference methods.

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A rationale for the most important requirements is given in annex M. It is considered that a knowledge of the reasons for the requirements will not only facilitate the proper application of the standard, but will expedite any subsequent revision. This annex does not form part of the standard.

Medical suction equipment —

Part 1:
Electrically powered suction equipment — Safety requirements

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Section 1: General

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1.1 Scope

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 601-1; in IEC 601-1 (the "General Standard"), this type of International Standard is referred to as a "Particular Standard". As stated in 1.3 of IEC 601-1 : 1988, the requirements of this International Standard take precedence over those of IEC 601-1.

The Scope and Object given in clause 1 of IEC 601-1 : 1988 applies except that 1.1 shall be replaced by the following:

This part of ISO 10079 specifies minimum safety and performance requirements for medical and surgical suction equipment (see figure 1) in health care facilities such as hospitals, for domiciliary care of patients and for field and transport use. Although equipment may be driven by centrally powered piped vacuum systems, compressed gases, electricity or be manually powered for a variety of applications, this part addresses only equipment powered electrically.

Excluded from the standard are:

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 system for wound drainage;

j) gravity gastric drainage;

k) orally operated mucous extractors;

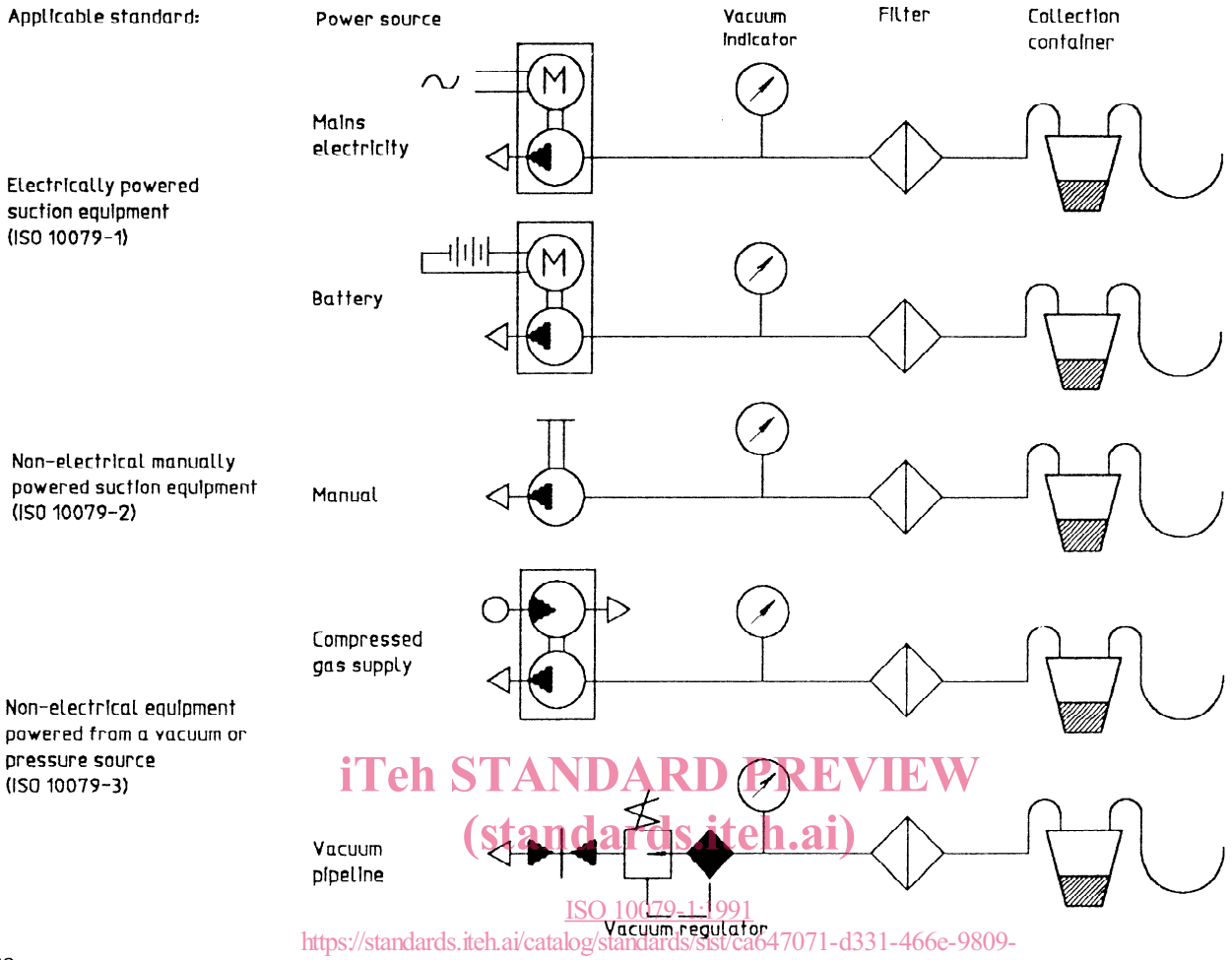
l) suction equipment where the collection container is downstream of the vacuum pump;

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.



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NOTES

1 This part of ISO 10079 applies to mains electricity and battery-powered suction equipment.

Part 2 of ISO 10079 applies to non electrical manually powered suction equipment.

Part 3 of ISO 10079 applies to non-electrical suction equipment powered from a vacuum or pressure source.

2 Components illustrated are not necessarily required by this International Standard.

3 Suction equipment shown are only examples, and actual systems may consist of other arrangements and components not illustrated in the figure.

Figure 1 — Schematic drawing illustrating suction equipment

1.4 Environmental conditions

The requirements given in 1.4 of IEC 601-1 apply except that the following modification shall be made to 1.4 b) 1).

Substitute "+ 5 °C" for "+ 10 °C" and "+ 35 °C" for "40 °C".

For field and transport use, environmental conditions shall be as specified in 53.

1.2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 10079. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 10079 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 32: 1977, *Gas cylinders for medical use — Marking for identification of content.*

ISO 3743: 1988, *Acoustics — Determination of sound power levels of noise sources — Engineering methods for special reverberation test rooms.*

ISO 3744: 1981, *Acoustics — Determination of sound power levels of noise sources — Engineering methods for free-field conditions over a reflecting plane.*

ISO 5356-1: 1987, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets.*

IEC 529 : 1976, *Classification of degrees of protection provided by enclosures.*

IEC 601-1 : 1988, *Medical electrical equipment — Part 1: General requirements for safety.*

IEC 651 : 1979, *Sound level meters.*

IEC 695-2-2 : 1980, *Fire hazard testing — Part 2: Test methods — Needle-flame test.*

1.3 Definitions

For the purposes of this part of ISO 10079, the definitions given in clause 2 of IEC 601-1 : 1988 apply except that the definition given in 2.1.5 shall be replaced by the following:

applied part: All parts in the liquid pathway.

Add to definition 2.4.3 the following:

safety extra-low voltage (SELV): Includes the electrical sources which are isolated (e.g. car battery) and do not require a separate transformer or converter with separate windings.

For the purposes of this part of ISO 10079, the following definitions also apply.

1.3.1 vacuum: Pressure less than atmospheric pressure, normally expressed as a difference from atmospheric pressure.

1.3.2 high vacuum: Vacuum of at least − 60 kPa[1].

1.3.3 medium vacuum: Vacuum less than − 60 kPa and greater than − 20 kPa.

1.3.4 low vacuum: Vacuum not more than − 20 kPa.

1.3.5 vacuum regulator: Device for controlling the maximum vacuum applied to the patient.

1.3.6 vacuum indicator: Device for displaying the level of vacuum.

1.3.7 suction: Application of vacuum to remove fluids or solid particles.

1.3.8 high flow: Suction with a free air flow of 20 l/min or greater.

1.3.9 low flow: Suction with a free air flow less than 20 l/min.

1.3.10 inlet: Part of a component through which fluids and/or solid particles enter.

1.3.11 outlet: Part of a component through which fluids and/or solid particles exit.

1.3.12 exhaust opening: Port or ports through which exhaust is discharged.

1.3.13 collection container: Container in which fluids or solid particles are collected.

1.3.14 collection container assembly: Collection container and its closure.

1.3.15 overfill device: Device intended to prevent liquid or solid particles entering the intermediate tubing.

1.3.16 filter: Device for separation of particulate matter.

1.3.17 end-piece: That part of the suction equipment applied to the patient. The end-piece starts at the site where material is drawn in and ends upstream of the first detachable connection.

1.3.18 vacuum pump: Powered device for generating vacuum.

1.3.19 thoracic drainage: Drainage by application of suction to the thoracic cavity of the patient.

1.3.20 intermittent suction: Suction where the negative pressure applied to the end-piece is automatically and periodically returned to atmospheric pressure.

NOTE — Cycling may be determined by end-piece occlusion.

1.3.21 drainage: Removal of fluids from a body cavity or wound, assisted by vacuum.

1.3.22 free air flow: Unrestricted flow of air through a nominated inlet.

1.3.23 suction tubing: Tubing as supplied or recommended by the manufacturer for conduction of fluids from the end-piece to the collection container.

1.3.24 breast pump: Vacuum pump for the collection of breast milk.

1.3.25 pharyngeal suction: Suction applied to the human pharynx through the mouth.

1.3.26 intermediate tubing: Tubing between the collection container and the vacuum pump.

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1) 1 kPa = 7,500 63 mmHg or 4,014 629 in H_2O or 10,197 16 cm H_2 or 10 hPa

1.4 General requirements and general requirements for tests

The requirements given in clauses 3 and 4 of IEC 601-1: 1988 apply together with the following addition:

— In 4.6, add the following additional item:

f) Where reference is made in test methods to tubing, that supplied or recommended by the manufacturer shall be used.

1.5 Classification

The classification given in clause 5 of IEC 601-1: 1988 applies.

1.6 Identification, marking and documents

The requirements given in clause 6 of IEC 601-1: 1988 apply except for the following additions and modifications:

— Replace 6.1 p) by the following:

1) All equipment generating suction shall be marked with words indicating suction, and with an indication of the available level of vacuum as determined by the manufacturer. This marking shall be visible in the normal working position.

NOTE — Equipment should be marked with the designation "high vacuum/high flow", "high vacuum/low flow", "medium vacuum/low flow", "low vacuum/high flow" or "low vacuum/low flow", as appropriate. Vacuum regulators should also comply with this requirement.

2) Low vacuum equipment with a level of vacuum which is not adjustable by the user shall be marked either with the level of vacuum which can be attained or with words indicating low vacuum.

3) Intermittent suction equipment shall be marked with words indicating intermittent suction. Equipment which can provide continuous and also intermittent suction shall have the mode control clearly marked.

4) If there is a single exhaust opening, it shall be marked with words indicating exhaust opening.

5) Suction equipment intended for thoracic drainage and complying with 59.7 shall be marked as such.

6) The inlet connection to the collection container shall be identified unless misconnection is prevented by a design feature.

7) If the suction equipment is intended for use in the field or in transport and does not comply with 53.1, it shall be marked on the case as not suitable for use at temperatures below "... °C" or above "... °C" with the appropriate limiting temperatures marked. If no case is provided, the statement shall be marked on the equipment.

— In 6.1, add the following additional items:

aa) Equipment containing a filter which is intended to be cleaned or changed by the user shall have clearly marked on the equipment or on the filter unit, wording to the effect that the filter should be changed in accordance with the manufacturer's recommendations.

ab) The capacity of the collection container.

— In 6.3 c), add the following:

If a progressive variation of the degree of vacuum is available, the direction of adjustment to increase vacuum shall be clearly and permanently marked.

— In 6.8.1, add the following:

The collection container capacity shall be stated in the accompanying documents.

— In 6.8.2 a), add the following:

The instructions for use shall additionally include the following information:

1) Instructions for operating the vacuum regulator, if supplied, and for setting the required vacuum.

2) The size and type of suction tubing recommended for use with the suction equipment and its means of connection to the collection container.

3) Recommended methods for cleaning and disinfection or sterilization of all applied parts.

4) The method for removing the collection container for emptying.

5) Details of the operation of any overfill device fitted to the collection container assembly and the usable capacity of the collection container in all the recommended inclined planes of operation.

6) If applicable, the method of controlling frothing in the collection container.

7) Instructions, if applicable, for the replacement or cleaning of air filters, and for cleaning or sterilization of the filter housing.

8) Either the type of equipment, e.g. medical suction, high vacuum, high flow, or the level of vacuum and flow obtainable or the vacuum and air flow characteristics obtainable from the equipment as required by 6.1 p) (1), (2) or (3), as appropriate.

9) Instructions to inspect suction tubing, collection containers and any other components that are subject to wear or damage.

10) If applicable, a statement advising removal and servicing of the equipment if liquid or solid has been drawn into the vacuum pump.

NOTE — In some cases, this may require servicing by the manufacturer or his authorized agent.

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11) If applicable, a statement that suction ceases when the overfill device operates, and the method of correcting this situation.

12) Recommendations for cleaning or disinfection of the outer casing.

13) Instructions for cleaning and sterilization or reusable suction tubing.

14) Instructions for sterilizing any part of a filter assembly which is reusable.

15) Guidance for the intended use and limitations of the equipment, including whether or not the equipment is intended for use within a health care facility, for domiciliary use, or for field and transport use.

1.7 Power input

The requirements given in clause 7 of IEC 601-1 : 1988 apply.

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Section 2: Environmental conditions

2.8 Basic safety categories

(See A.1.2 of IEC 601-1 : 1988.)

2.9 Removable protective means

[See 6.1 z) of IEC 601-1 : 1988.]

2.10 Environmental conditions

The requirements given in clause 10 of IEC 601-1 : 1988 apply.

2.11 Special measures with respect to safety

(Not used)

2.12 Single fault condition

(Not used)

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