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SVENSK STANDARD SS-EN ISO 10079-1

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Medical suction equipment – Part 1: Electrically powered suction equipment – Safety requirements (ISO 10079-1:1999)

The European Standard EN ISO 10079-1:1999 has the status of a Swedish Standard. This document contains the official English version of EN ISO 10079-1:1999.

Swedish Standards corresponding to documents referred to in this Standard are listed in ”Catalogue of Swedish Standards”, issued by SIS. The Catalogue lists, with reference number and year of Swedish approval, International and European Standards approved as Swedish Standards as well as other Swedish Standards.

Medicinsk sugutrustning – Del 1: Elektriskt driven sugutrustning – Säkerhetskrav (ISO 10079-1:1999)

Europastandarden EN ISO 10079-1:1999 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 10079-1: 1999.

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ICS 11.040.10

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EN ISO 10079-1

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Supersedes EN ISO 10079-1:1996

English version

Medical suction equipment - Part 1: Electrically powered suction equipment - Safety requirements (ISO 10079-1:1999)

Appareils d'aspiration médicale - Partie 1: Appareils électriques d'aspiration - Prescriptions de sécurité (ISO 10079-1:1999)

Medizinische Absauggeräte - Teil 1: Elektrisch betriebene Absauggeräte - Sicherheitsanforderungen (ISO 10079-1:1999)

This European Standard was approved by CEN on 15 August 1999.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

Ref. No. EN ISO 10079-1:1999 E

Contents

Foreword

The text of the International Standard ISO 10079-1:1999 has been prepared by Technical Committee ISO/TC 121 “Anaesthetic and respiratory equipment” in collaboration with Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment”, the secretariat of which is held by BSI.

This European Standard supersedes EN ISO 10079-1:1996.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by February 2000, and conflicting national standards shall be withdrawn at the latest by February 2000.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 10079-1:1999 was approved by CEN as a European Standard without any modification.

NOTE: Normative references to International Standards are listed in annex ZA (normative).

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;

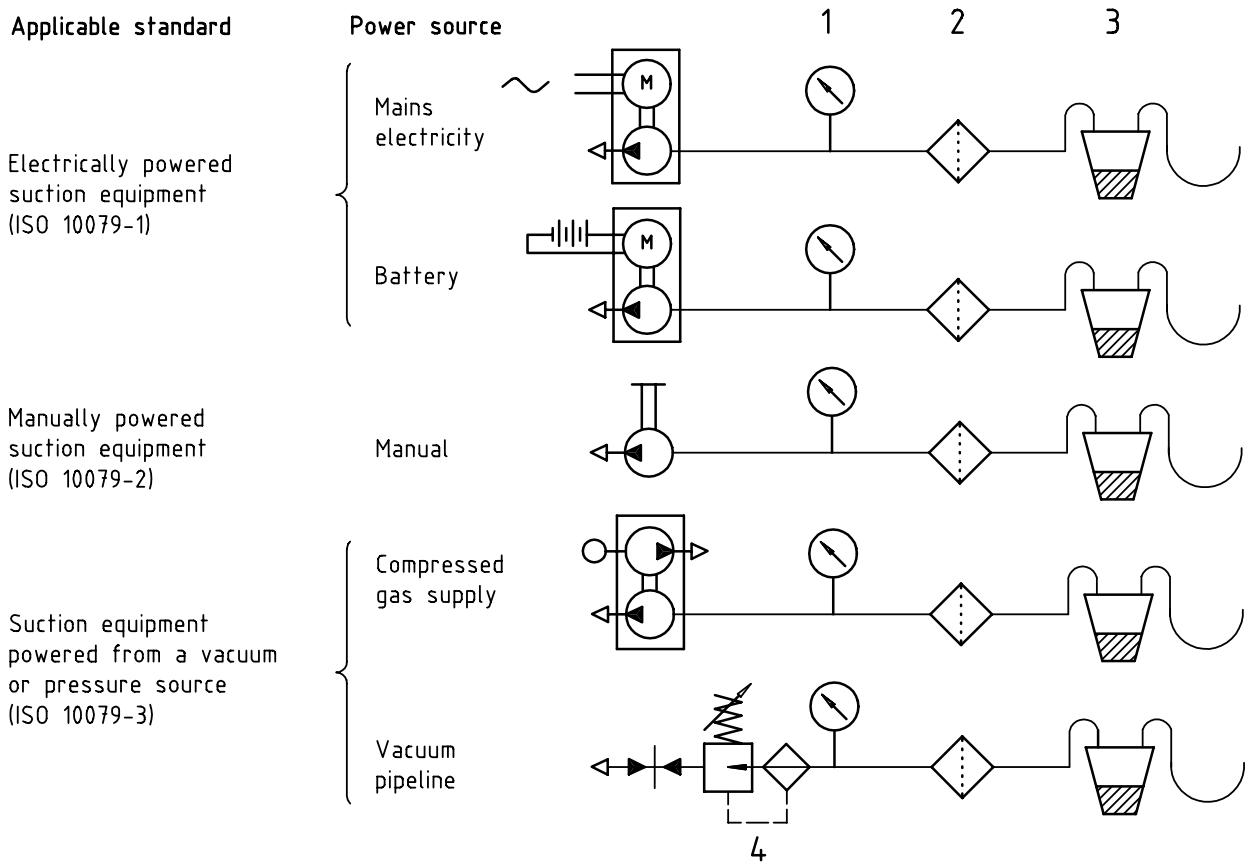
l) suction equipment where the collection container is downstream of the vacuum pump;

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*.

ISO 8836:1997, *Suction catheters for use in the respiratory tract*.

IEC 60079-4:1975, *Electrical apparatus for explosive gas atmospheres — Part 4: Method of test for ignition temperature*.

IEC 60529:1976, *Classification of degrees of protection provided by enclosures*.

IEC 60601-1:1988*, Medical electrical equipment — Part 1: General requirements for safety*; and Amd.1:1991 and Amd.2:1995.

IEC 60651:1979, *Sound level meters*.

IEC 60695-2-2:1980, *Fire hazard testing — Part 2: Test methods — Needle-flame test*.

3 Terms and definitions

For the purposes of this part of ISO 10079, the terms and definitions given in clause 2 of IEC 60601-1:1988 apply except that the definition given in 2.1.5 shall be replaced by the following:

2.1.5
applied part
all parts in the liquid pathway

Add to definition 2.4.3 the following:

2.4.3
safety extra-low voltage
SELV
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 additional terms and definitions apply.

3.1
breast pump
vacuum pump for the collection of breast milk

3.2
collection container
container in which liquids and solid particles are collected

3.3
collection container assembly
collection container and its closure with connectors for suction

3.4
drainage
removal of fluids from a body cavity or wound

3.5
end-piece
that part of the suction equipment applied to the patient which begins at the site where material is drawn in and ends at the first detachable connection

NOTE Examples of commonly used end-pieces are a Yanker sucker and a suction catheter.

3.6
exhaust opening
port or ports through which exhaust is discharged

-3.7
filter
device for retention of particulate matter

3.8
free air flow
unrestricted flow of air through a designated inlet

3.9
high flow suction
suction which produces a free air flow of 20 l/min or more

3.10
high vacuum
vacuum of 60 kPa or more below atmospheric pressure

NOTE 1 kPa = 7,50 mmHg or 4,02 inchH_2O or 10,2 cmH_2O or 10 hPa

3.11
inlet
port of a component through which fluids and/or solid particles enter

3.12
intermediate tubing
tubing between the collection container and the vacuum source

3.13
intermittent suction
type of suction in which the negative pressure applied to the end-piece is automatically and periodically returned to atmospheric pressure

3.14
low flow suction
suction which produces a free air flow less than 20 l/min

3.15
low vacuum
vacuum of not more than 20 kPa below atmospheric pressure

3.16
medium vacuum
vacuum of more than 20 kPa but less than 60 kPa below atmospheric pressure

3.17
outlet
port of a component through which fluids and/or solid particles exit

3.18
overfill protection device
system intended to prevent liquid or solid particles from entering the intermediate tubing

3.19
suction
application of vacuum to remove fluids and/or solid particles

3.20
suction tubing
tubing for conduction of fluids and/or solid particles between the end-piece and the collection container

3.21
thoracic drainage
drainage by application of suction to the thoracic cavity of the patient

NOTE For the purposes of this part of ISO 10079, all thoracic drainage is considered to be active.

3.22
vacuum
pressure less than atmospheric pressure

NOTE In this part of ISO 10079, vacuum is expressed as a difference from atmospheric pressure.

3.23
vacuum indicator
device for displaying the level of vacuum

3.24
vacuum pump
powered device for generating vacuum

3.25
vacuum regulator
device for controlling the maximum vacuum applied to the patient

4 General requirements and general requirements for tests

The requirements given in clauses 3 and 4 of IEC 60601-1:1988 apply, together with the following additional item:

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

5 Classification

The classification given in clause 5 of IEC 60601-1:1988 applies.

6 Identification, marking and documents

The requirements given in clause 6 of IEC 60601-1:1988 apply, with the following additions and modifications:

6.1 e) add the following:

The address of the manufacturer, and the name and address of the supplier responsible within the region or country if the supplier is not the manufacturer.

Wherever reasonable and practicable, the device and detachable components shall be identified, where appropriate, in terms of batches, to allow the appropriate action to detect any potential risk posed by the devices and detachable components.

6.1 f) add the following:

The equipment shall be marked with a batch or serial number and also year of manufacture, to allow all parts in the functional state to be sufficiently identified to the level that appropriate action can be undertaken if a defect or hazard arises.

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 including vacuum should be marked with the designation; “high vacuum/high flow”, “high vacuum/low flow”, “medium vacuum/high flow”, “medium vacuum/low flow”, “low vacuum/high flow” or “low vacuum/low flow”, as appropriate.

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 both continuous and 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 59.8 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 and/or transport and does not comply with 53.1, it shall be marked on the equipment 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 wording clearly marked on the equipment, or on the filter unit, to the effect that the filter should be cleaned or 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 in 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 protection 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;