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Medicinsk sugutrustning –
Del 2: Manuellt driven sugutrustning (ISO 10079-2:1999)

Medical suction equipment –
Part 2: Manually powered suction equipment
(ISO 10079-2:1999)

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Europastandarden EN ISO 10079-2:2009 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 10079-2:2009.

Denna standard ersätter SS-EN ISO 10079-2, utgåva 2.

The European Standard EN ISO 10079-2:2009 has the status of a Swedish Standard. This document contains the official English version of EN ISO 10079-2:2009.

This standard supersedes the Swedish Standard SS-EN ISO 10079-2, edition 2.

Upplysningar om sakinnehållet i standarden lämnas av SIS, Swedish Standards Institute, telefon 08-555 520 00.
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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10079-2

March 2009

ICS 11.040.10

Supersedes EN ISO 10079-2:1999

English Version

Medical suction equipment - Part 2: Manually powered suction equipment (ISO 10079-2:1999)

Appareils d'aspiration médicale - Partie 2: Appareils d'aspiration manuelle (ISO 10079-2:1999)

Medizinische Absauggeräte - Teil 2: Handbetriebene Absauggeräte (ISO 10079-2:1999)

This European Standard was approved by CEN on 24 February 2009.

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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 CEN Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

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Contents

Foreword

The text of ISO 10079-2:1999 has been prepared by Technical Committee ISO/TC 121 “Anaesthetic and respiratory equipment” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 10079-2:2009 by Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment” the secretariat of which is held by BSI.

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 September 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 10079-2:1999.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EC Directives.

For relationship with EC Directives, see informative Annex ZA, which is an integral part of this document.

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

Endorsement notice

The text of ISO 10079-2:1999 has been approved by CEN as a EN ISO 10079-2:2009 without any modification.

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;

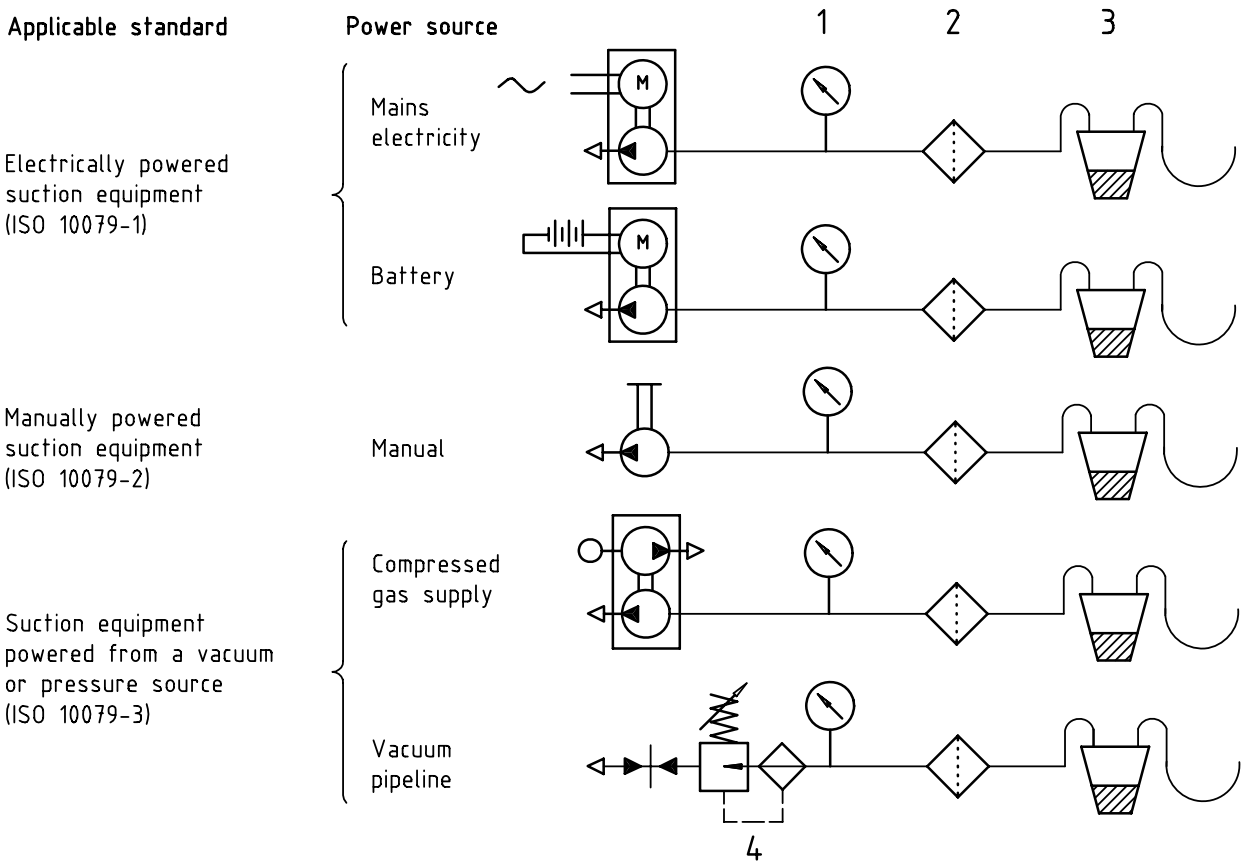
o) neonatal mucous extractors;

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, *Suction catheters for use in the respiratory tract.*

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

3 Terms and definitions

For the purposes of this part of ISO 10079, the terms and definitions given in ISO 10079-1 and the following apply.

3.1
manually powered vacuum
manually generated vacuum
generation of vacuum by human effort with a hand or foot or both

3.2
transportable equipment
equipment which is intended to be easily moved from one place to another, whether or not connected to the vacuum supply, without an appreciable restriction of range

4 Cleaning and sterilization

4.1 The suction equipment shall meet the requirements given in 8.1 to 8.3 after those components which are subject to contamination and which are intended for re-use have been submitted to 30 cycles of cleaning, disinfection and/or sterilization as recommended by the manufacturer.

4.2 Any filters installed shall either be of the disposable type or be capable of being cleaned, disinfected and/or sterilized for re-use in accordance with 4.1.

4.3 Suction equipment incorporating a re-usable collection container assembly shall comply with the requirements given in 8.1 to 8.3, as appropriate, before and after the collection container assembly has been subjected to 30 cycles of cleaning, disinfection and/or sterilization as recommended by the manufacturer.

4.4 Suction tubing shall either be for single use or be capable of being cleaned, disinfected and/or sterilized as recommended by the manufacturer.

5 Design requirements

NOTE The constructional requirements may deviate from those detailed in this part of ISO 10079 if the equivalent level of safety is obtained.

5.1 Connectors

5.1.1 Collection container connectors

The connectors for the suction tubing and the intermediate tubing to the vacuum source shall be designed to facilitate correct assembly or marked to indicate correct assembly when all parts are mated. Compliance shall be checked by inspection.

The construction of the connections has frequently been a source of spillover into a vacuum pump. The use of mechanical fittings so as to ensure correct attachment is highly desirable.

5.1.2 Inside diameter of suction tubing connection

The inside diameter of the suction tubing connection (inlet port) shall be equal to or larger than the inside diameter of the largest tubing size recommended by the manufacturer.

5.1.3 Exhaust opening

It shall not be possible to connect suction tubing to the exhaust opening.