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

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

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Europastandarden EN ISO 10079-1:2009 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 10079-1:2009.

Denna standard ersätter SS-EN ISO 10079-1, utgåva 2.

The European Standard EN ISO 10079-1:2009 has the status of a Swedish Standard. This document contains the official English version of EN ISO 10079-1:2009.

This standard supersedes the Swedish Standard SS-EN ISO 10079-1, edition 2.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10079-1

March 2009

ICS 11.040.10

Supersedes EN ISO 10079-1:1999

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 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
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN ISO 10079-1:2009: E

Contents

Foreword

The text of ISO 10079-1:1999 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 10079-1:2009 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 10079-1:1999.

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 10079-1:1999 has been approved by CEN as a EN ISO 10079-1:2009 without any modification.

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;

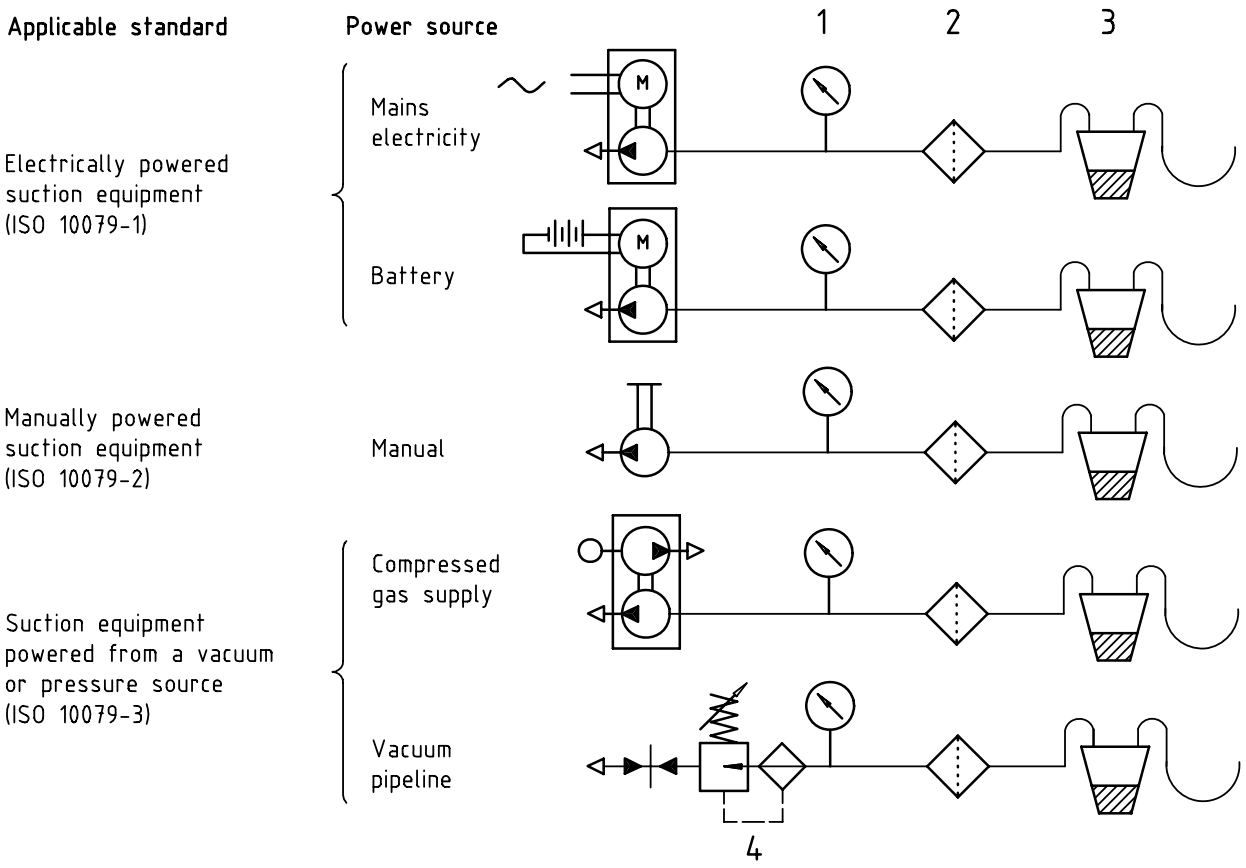
l) suction equipment where the collection container is downstream of the vacuum pump;

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