Meditsiiniline vaakumaparatuur. Osa 3: Vaakum- või surveajamiga töötav vaakumaparatuur

Medical suction equipment - Part 3: Suction equipment powered from vacuum or pressure source

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 10079-3:1999 sisaldab Euroopa standardi EN ISO 10079-3:1999 ingliskeelset teksti. Käesolev dokument on jõustatud 23.11.1999 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN ISO 10079-3:1999 consists of the English text of the European standard EN ISO 10079-3:1999. This document is endorsed on 23.11.1999 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: Standardi käesolev osa esitab ohutus- ja ekspluatatsiooninõuded vaakum- või surveajamiga töötavale meditsiinilisele vaakumaparatuurile. Eriti kehtib standard torustike ühenduste ja Venturi toru liitmike kohta.	**Scope:**

ICS 11.040.10

Võtmesõnad: jõudluse hindamine, meditsiiniaparatuur, märgistus, ohutusnõuded, suruõhu abil töötavad seadmed, tehnilised andmed

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 10079-3

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ICS 11.040.10

Supersedes EN ISO 10079-3 : 1996.

English version

Medical suction equipment

Part 3: Suction equipment powered from a vacuum or pressure source
(ISO 10079-3 : 1999)

Appareils d'aspiration médicale – Partie 3: Appareils d'aspiration alimentés par une source de vide ou de pression (ISO 10079-3 : 1999)

Medizinische Absauggeräte – Teil 3: Vakuum- oder druckquellenbetriebene Absauggeräte (ISO 10079-3 : 1999)

This European Standard was approved by CEN on 1999-08-15.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

The European Standards exist 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.

CEN members are the national standards bodies of Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

CEN

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 10079-3 : 1999 E

Foreword

International Standard

ISO 10079-3 : 1999 Medical suction equipment – Part 3: Suction equipment powered from a vacuum or pressure source,

which was prepared by ISO/TC 121 'Anaesthetic and respiratory equipment' of the International Organization for Standardization, has been adopted by Technical Committee CEN/TC 215 'Respiratory and anaesthetic equipment', the Secretariat of which is held by BSI, as a European Standard.

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 the relevant EU Directive.

For relationship with this directive, see Annex ZB.

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

In accordance with the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard:

Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 10079-3 : 1999 was approved by CEN as a European Standard without any modification.

NOTE: Normative references to international publications are listed in Annex ZA (normative).

Contents

1 Scope

This part of ISO 10079 specifies safety and performance requirements for medical suction equipment powered from a vacuum or pressure source (see Figure 1). In particular it applies to connections for pipelines and Venturi attachments.

Suction equipment with components controlled by electrical means, e.g. electronic timing, may also need to comply with IEC 60601-1.

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 manually powered suction equipment which is dealt with in ISO 10079-2, nor to the following:

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;

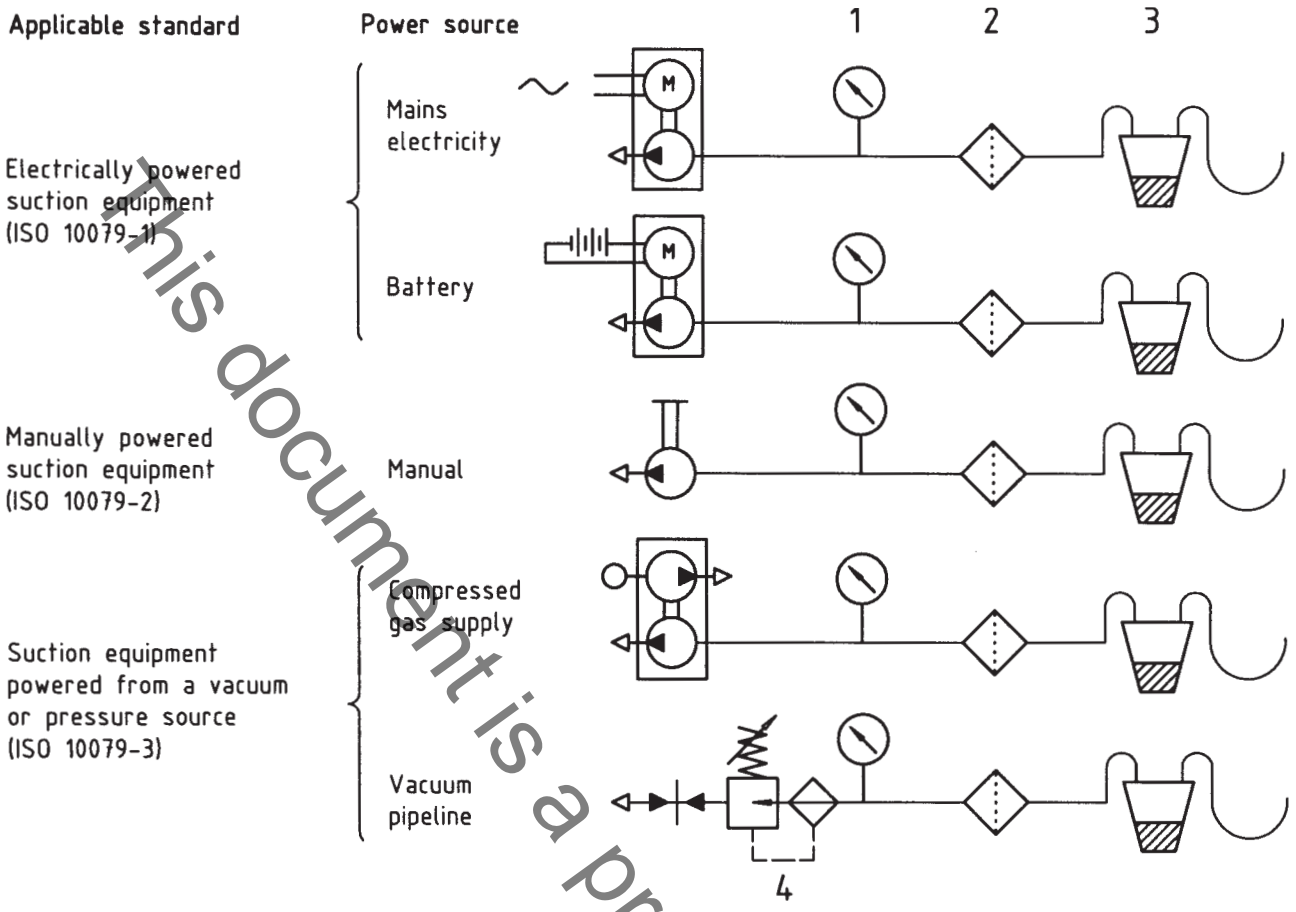
n) ventouse (obstetric) equipment;

o) neonatal mucous extractors;

p) breast pumps;

q) liposuction;

r) uterine aspiration.



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 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 5359:1989, *Low-pressure flexible connecting assemblies (hose assemblies) for use with medical gas systems.*

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.*

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

IEC 60651:1979, *Sound pressure meters.*

3 Terms and definitions

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

4 Cleaning, disinfection and sterilization

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

4.2 Equipment with filters intended for re-use shall comply with the requirements given in 8.1 to 8.7, as appropriate, after the filters have been subjected to 30 cycles of sterilization as recommended by the manufacturer.

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

4.4 Suction equipment incorporating a re-usable collection container assembly shall comply with the requirements given in 8.1 to 8.7, as appropriate, before and after the collection container has been subjected to 30 cycles of cleaning, disinfection and/or sterilization as recommended by the manufacturer.

5 Design requirements

NOTE The constructional requirements may deviate from those detailed in this part of ISO 10079 if an equivalent degree of safety can be achieved.

5.1 Collection container

5.1.1 The inlet of the collection container shall have an inside diameter of not less than 6 mm and not less than the maximum inside diameter of the suction tubing recommended by the manufacturer. The inlet shall not be compatible with any conical connector specified in ISO 5356-1.

5.1.2 For suction equipment solely for field use which is intended to continue operating when the collection container is full, the volume of the collection container shall be not less than 200 ml. For other suction equipment intended solely for field use, the usable volume of the collection container shall be not less than 300 ml. For all other suction equipment, including suction equipment intended for field and/or transport use, the usable volume of the collection container shall be not less than 500 ml.

NOTE "Field use" of suction equipment is intended to cover use in situations outside of the health care facility at the site of accidents or other emergencies. The use of suction equipment in these situations may expose the equipment to water (including rain), dirt, uneven support, mechanical shock and extremes of temperature. "Transport use" of suction equipment is intended to cover situations outside of the health care facility such as in ambulances, cars or airplanes. Use of suction equipment in these situations may expose the equipment to uneven support, dirt, mechanical shock and a wider range of temperature than normally found in health care facilities.

5.1.3 For suction equipment not intended for field use, one or more collection containers recommended by the manufacturer and either for single-use or of a re-usable type, shall be used. For all collection containers, the level of the contents shall be clearly visible in the position of normal use. The collection container shall be marked with its usable volume, expressed in millilitres. For collection containers having a capacity of 500 ml or greater, an