Meditsiiniline vaakumaparatuur. Osa 2: Käsitsi käitatava ajamiga vaakumaparatuur

Medical suction equipment - Part 2: Manually powered suction equipment

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 10079-2:2009 sisaldab Euroopa standardi EN ISO 10079-2:2009 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 10079-2:2009 consists of the English text of the European standard EN ISO 10079-2:2009.
Standard on kinnitatud Eesti Standardikeskuse 31.07.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 31.07.2009 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 04.03.2009.	Date of Availability of the European standard text 04.03.2009.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

ICS 11.040.10

Võtmesõnad: jõudluse hindamine, kasutamisjuhised, käsitsi käitatava ajamiga seadmed, meditsiiniaparatuur, meditsiiniline vaakumaparatuur, märgistus, ohutusnõuded, tehnilised andmed, testimine

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10079-2

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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.

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 CEN Management Centre or to any CEN member.

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 10079-2:2009: E

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.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 - Correspondence between this European Standard and EU Directives

Clause(s)/sub-clause(s) of this EN	**Essential Requirements (ERs) of Directive 93/42/EEC**	**Qualifying remarks/Notes**
All	1, 2, 6	
4.1, 4.2, 4.3, 4.4	4, 8.1	
5	1, 2, 3	
5.1, 5.2	9.1	
5.2.2	9.2	
6	1, 2, 3, 9.2	
6.1	9.2	

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
6.2	4, 8.1, 9.2	
6.3	4, 7.6, 9.2, 12.7.1	
6.4	4, 7.6	
6.5	4, 7.2, 7.5, 9.2, 12.7.1	
6.6	7.2, 8.1, 12.8.2	
	6a	This relevant Essential Requirement is not addressed in this European Standard
6.6	7.5 (1st paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
-	7.5 (2nd paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
-	7.5 (3rd paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
6.6.1, 6.6.2	7.5	
6.7	10.1, 10.2, 10.3, 12.8.2, 12.9	
6.7.1, 6.7.2, 6.7.3	10.2	
7.1, 7.2, 7.3	9.2	

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
7.3.3	10.1, 10.2, 10.3	
7.3.4	9.2, 12.8.2	
8.1, 8.2, 8.3	12.8.1	
9.1	4, 9.2	
9.2	4, 5	
10 d), 10 e), 11 a) b) e) i) o)	9.1	
10 a) d) e)	12.9	
10, 11	13	
10	13.3 (a):	This relevant Essential Requirement is not fully addressed in this European Standard
11	13.3 (f)	This relevant Essential Requirement is not fully addressed in this European Standard
11	13.6 (h)(2nd paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
11	13.6 (q)	This relevant Essential Requirement is not addressed in this European Standard: covered by EN ISO 13485: 2003, subclause 4.2.3

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

Contents

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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;

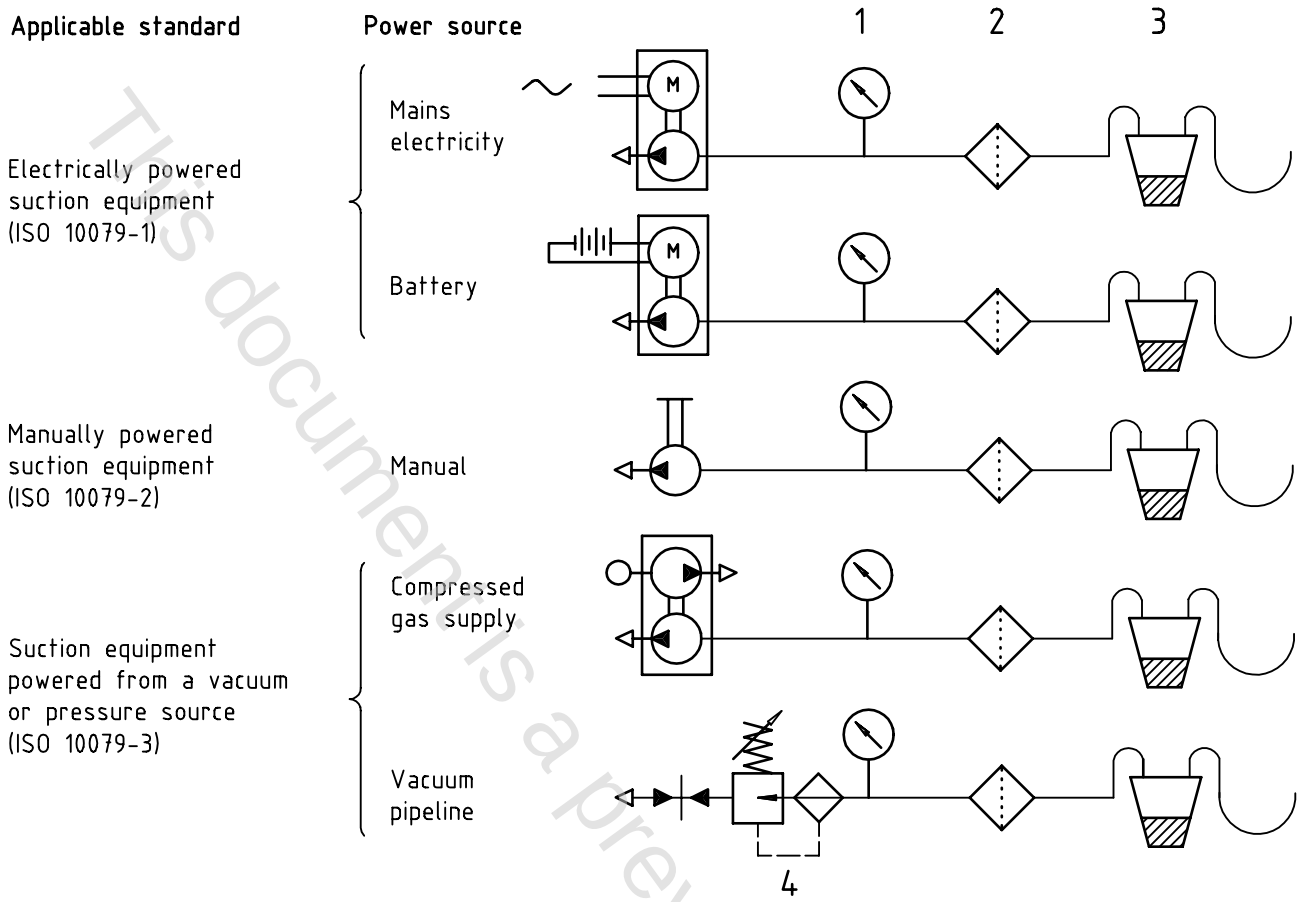
o) neonatal mucous extractors;

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, S*uction catheters for use in the respiratory tract.*

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