Meditsiiniline vaakumaparatuur. Osa 1: Elektritoitel töötav vaakumaparatuur. Ohutusnõuded

Medical suction equipment - Part 1: Electrically powered suction equipment - Safety requirements

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 10079-1:2009 sisaldab Euroopa standardi EN ISO 10079-1:2009 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 10079-1:2009 consists of the English text of the European standard EN ISO 10079-1:2009.
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: elektriliselt töötavad seadmed, imiventilaatorid, meditsiiniaparatuur, ohutusnõuded, tehnilised andmed, testimine

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10079-1

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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.

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.

CEN members are the national standards bodies of 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 United Kingdom.

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

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.

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, 3, 4, 6	
-	1 (2nd paragraph, 1st dash)	This relevant Essential Requirement is not addressed in this European Standard
-	1 (2nd paragraph, 2nd dash)	This relevant Essential Requirement is not addressed in this European Standard
-	6a	This relevant Essential Requirement is not addressed in this European Standard
6	9.1, 13	
6	7.5 (2nd paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
-	12.1a)	This relevant Essential Requirement is not addressed in this European Standard.
6.1 e)	13.3 (a):	This relevant Essential Requirement is not fully addressed in this European Standard
6.1	13.3 (f)	This relevant Essential Requirement is not fully addressed in this European Standard
6 (6.1 p), 6.3 c))	12.9	
6.8.2	7.5 (3rd paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard

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

Clause(s)/sub-clause(s) of this EN	**Essential Requirements (ERs) of Directive 93/42/EEC**	**Qualifying remarks/Notes**
6.8.2	13.6 (h)(2nd paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
6.8.2	13.6 (q)	This relevant Essential Requirement is not addressed in this European Standard: covered by EN ISO 13485: 2003, subclause 4.2.3
9	12.6	
10	12.7	
10.1	9.2, 12.7.1	
10.2	9.2, 12.7.1	
10.3	9.2, 12.7.1	
10.4	9.2, 12.7.1	
10.5	9.2, 12.7.1	
10.6	12.7.2, 12.7.3	
11	11	
11.8	12.5	
12	7.1, 9.3	
13.1	12.7.5	
13.2	7.1, 9.3	
13.3	7.2, 7.5, 9.1	
13.3 (44.2)	8.1	
13.3 (44.3)	7.6	
13.3 (44.4)	7.6	
13.3 (44.6)	7.6	
13.3 (44.7) 1	8.1	
13.4	9.2, 12.7.1	

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

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
13.5	9.2, 12.8	
13.8 (49.2)	8.1	
14.2	12.8.2	
15	1 (1st paragraph), 2, 4	
15 (53.2, 53.3)	5	
15.1	4	
15.2	9.2	
16	1, 2, 3	
16.1	7.3	
16.3	9.1, 9.2	
16.3 (56.5)	12.8.2	
16.3 (56.8)	10.1, 10.2, 10.3, 12.8.2, 12.9	
16.3 (56.11)	12.7.1	
16.3 (56.12)	9.1, 12.7.4	
16.4	9.1, 12.7.4, 12.6, 12.8.1	
16.5	12.7.4	
16.6	2, 3, 12.8.1, 12.9	
16.6 (59.11)	10.1, 10.2, 10.3, 12.9	
16.6 (59.11.2)	9.2, 9.3	
16.6 (59.12)	7.2	
59	7.5 (1st paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard

For devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC on Machinery, in accordance with Article 3 of Directive 93/42/EEC the following table ZA.2 details the relevant essential requirements of Directive 2006/42/EC on Machinery to the extent to which they are more specific than those of Directive 93/42/EEC along with the corresponding clauses of this European Standard. Table ZA.2, however, does not imply any citation in the OJEU under the machinery directive and thus does not provide presumption of conformity for the machinery directive.

Table ZA.2 – Relevant Essential Requirements from Directive 2006/42/EC on machinery that are addressed by this European Standard
(according to article 3 of amended Directive 93/42/EEC)

Clause(s)/sub-clause(s) of this EN	Essential Health and Safety Requirements (EHSRs) of Directive 2006/42/EC	Qualifying remarks/Notes
-	1.1.4	This relevant EHSR is not addressed in this European Standard
-	1.2.2	This relevant EHSR is not addressed in this European standard; only partially covered by EN 60601-1-6 and EN 14971
-	1.5.4	This relevant EHSR is not fully addressed in this European Standard: only partially covered in EN 14971 and EN 62366
-	1.6.1	This relevant EHSR is not addressed in this European Standard
-	1.6.2	This relevant EHSR is not addressed in this European Standard
-	1.6.3	This relevant EHSR is not addressed in this European Standard
-	3.4.5	This relevant EHSR is not addressed in this European Standard
-	3.6.2	This relevant EHSR is not addressed in this European Standard

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 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;

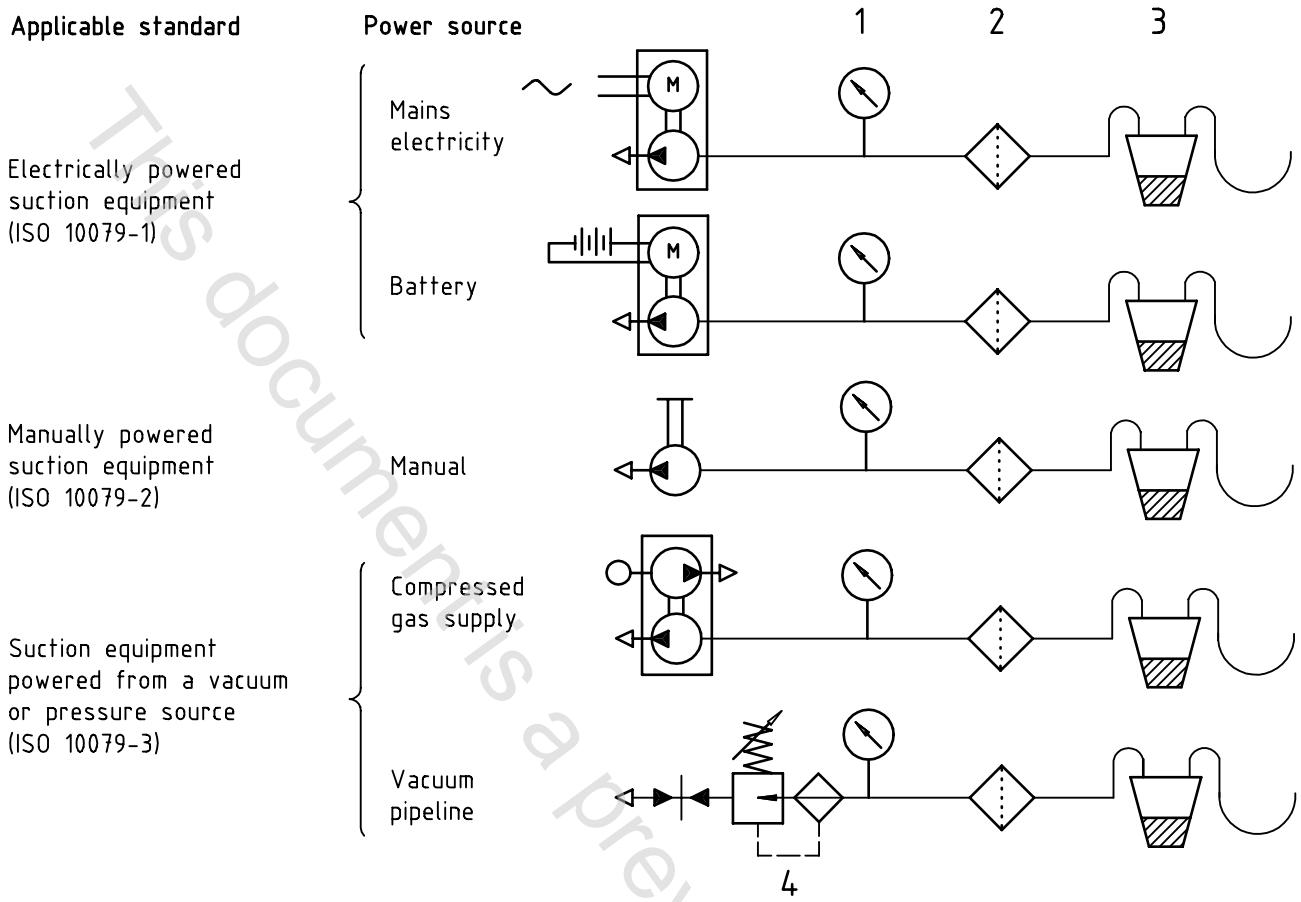
l) suction equipment where the collection container is downstream of the vacuum pump;

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*.