SVENSK STANDARD
SS-EN ISO 10079-2:2014

Fastställd/Approved: 2014-05-12
Publicerad/Published: 2014-05-19
Utgåva/Edition: 4
Språk/Language: engelska/English
ICS: 11.040.10

Medicinsk sugutrustning –
Del 2: Manuellt driven sugutrustning (ISO 10079-2:2014)

Medical suction equipment –
Part 2: Manually powered suction equipment (ISO 10079-2:2014)

Standarder får världen att fungera

SIS (Swedish Standards Institute) är en fristående ideell förening med medlemmar från både privat och offentlig sektor. Vi är en del av det europeiska och globala nätverk som utarbetar internationella standarder. Standarder är dokumenterad kunskap utvecklad av framstående aktörer inom industri, näringsliv och samhälle och befrämjar handel över gränser, bidrar till att processer och produkter blir säkrare samt effektiviserar din verksamhet.

Delta och påverka
Som medlem i SIS har du möjlighet att påverka framtida standarder inom ditt område på nationell, europeisk och global nivå. Du får samtidigt tillgång till tidig information om utvecklingen inom din bransch.

Ta del av det färdiga arbetet
Vi erbjuder våra kunder allt som rör standarder och deras tillämpning. Hos oss kan du köpa alla publikationer du behöver – allt från enskilda standarder, tekniska rapporter och standard-paket till handböcker och onlinetjänster. Genom vår webbtjänst e-nav får du tillgång till ett lättnavigerat bibliotek där alla standarder som är aktuella för ditt företag finns tillgängliga. Standarder och handböcker är källor till kunskap. Vi säljer dem.

Utveckla din kompetens och lyckas bättre i ditt arbete
Hos SIS kan du gå öppna eller företagsinterna utbildningar kring innehåll och tillämpning av standarder. Genom vår närhet till den internationella utvecklingen och ISO får du rätt kunskap i rätt tid, direkt från källan. Med vår kunskap om standarders möjligheter hjälper vi våra kunder att skapa verklig nytta och lönsamhet i sina verksamheter.

Vill du veta mer om SIS eller hur standarder kan effektivisera din verksamhet är du välkommen in på www.sis.se eller ta kontakt med oss på tel 08-555 523 00.

Standards make the world go round

SIS (Swedish Standards Institute) is an independent non-profit organisation with members from both the private and public sectors. We are part of the European and global network that draws up international standards. Standards consist of documented knowledge developed by prominent actors within the industry, business world and society. They promote cross-border trade, they help to make processes and products safer and they streamline your organisation.

Take part and have influence
As a member of SIS you will have the possibility to participate in standardization activities on national, European and global level. The membership in SIS will give you the opportunity to influence future standards and gain access to early stage information about developments within your field.

Get to know the finished work
We offer our customers everything in connection with standards and their application. You can purchase all the publications you need from us - everything from individual standards, technical reports and standard packages through to manuals and online services. Our web service e-nav gives you access to an easy-to-navigate library where all standards that are relevant to your company are available. Standards and manuals are sources of knowledge. We sell them.

Increase understanding and improve perception
With SIS you can undergo either shared or in-house training in the content and application of standards. Thanks to our proximity to international development and ISO you receive the right knowledge at the right time, direct from the source. With our knowledge about the potential of standards, we assist our customers in creating tangible benefit and profitability in their organisations.

If you want to know more about SIS, or how standards can streamline your organisation, please visit www.sis.se or contact us on phone +46 (0)8-555 523 00

Europastandarden EN ISO 10079-2:2014 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 10079-2:2014.

Denna standard ersätter SS-EN ISO 10079-2:2009, utgåva 3.

The European Standard EN ISO 10079-2:2014 has the status of a Swedish Standard. This document contains the official version of EN ISO 10079-2:2014.

This standard supersedes the Swedish Standard SS-EN ISO 10079-2:2009, edition 3.

Förhållandet till övriga delar under samma huvudtitel - Utdrag ur Förord i ISO 10079-2:2014/ Relations to other parts under the same general title - Extract from the Foreword of ISO 10079-2:2014

ISO 10079 consists of the following parts, under the general title *Medical suction equipment:*

- *Part 1: Electrically powered suction equipment*
- *Part 2: Manually powered suction equipment*
- *Part 3: Suction equipment powered from a vacuum or positive pressure gas source*

Denna standard är framtagen av kommittén för Anestesi- och respiratorutrustning, SIS/TK 329.

Har du synpunkter på innehållet i den här standarden, vill du delta i ett kommande revideringsarbete eller vara med och ta fram andra standarder inom området? Gå in på www.sis.se - där hittar du mer information.

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10079-2

May 2014

ICS 11.040.10

Supersedes EN ISO 10079-2:2009

English Version

Medical suction equipment - Part 2: Manually powered suction equipment (ISO 10079-2:2014)

Appareils d'aspiration médicale - Partie 2: Appareils d'aspiration manuelle (ISO 10079-2:2014)

Medizinische Absauggeräte - Teil 2: Handbetriebene Absauggeräte (ISO 10079-2:2014)

This European Standard was approved by CEN on 15 February 2014.

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-CENELEC 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-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Contents

Page

Foreword

This document (EN ISO 10079-2:2014) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment” the secretariat of which is held by DIN.

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 November 2014, and conflicting national standards shall be withdrawn at the latest by May 2017.

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 10079-2:2009.

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 EU Directive.

For relationship with EU Directive, 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, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 10079-2:2014 has been approved by CEN as EN ISO 10079-2:2014 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 suction equipment intended for oro-pharyngeal suction. It applies to equipment operated by foot or by hand or both. Annex D illustrates the three parts of ISO 10079 by providing a schematic for typical systems.

The commonest use of manually powered suction is in situations outside of health care settings often described as field use or transport use. Use in these situations may involve extreme conditions of weather or terrain. Additional requirements for suction equipment intended for field and/or transport use are included in this part of ISO 10079.

This part of ISO 10079 does not apply to the following:

a) end pieces such as suction catheters, Yankauer sucker and suction tips;

b) dental suction equipment;

c) mucus extractors, including neonatal mucus extractors.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 5356-1, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*

ISO 7000[1)], *Graphical symbols for use on equipment — Registered symbols*

ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 80369 (all parts), *Small-bore connectors for liquids and gases in healthcare applications*

IEC 62366, *Medical devices — Application of usability engineering to medical devices*

EN 1041, *Information supplied by the manufacturer of medical devices*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

1) The graphical symbol collections of ISO 7000, ISO 7001 and ISO 7010 are also available on the Online Browsing Platform http://www.iso.org/obp.

3.1
collection container
container in which liquids and solid particles are collected

3.2
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 1 to entry: Examples of commonly used end-pieces are a Yankauer sucker and a suction catheter.

3.3
exhaust port
opening through which exhaust gas is discharged

3.4
field use
use of suction equipment in situations outside of the health care facility at the site of accidents or other emergencies

3.5
filter
device for retention of particulate matter

3.6
free air flowrate
rate of unrestricted flow of air through a designated inlet

3.7
inlet port
opening through which liquid, solid particles or gas enter

3.8
intermediate tubing
tubing between the collection container and the vacuum source

3.9
manually powered suction
generation of vacuum by direct human effort

3.10
overfill protection device
device intended to prevent liquid or solid particles from entering the intermediate tubing

3.11
single fault condition
condition in which a single means for protection against a safety hazard in equipment is defective or a single external abnormal condition is present

Note 1 to entry: Maintenance of equipment is considered a normal condition.

3.12
suction
application of vacuum to remove liquid, solid particles or gas

3.13
suction tubing
tubing for conduction of liquid, solid particles or gas between the end-piece and the collection container

3.14
transport use
use during patient transport outside of a health care facility (e.g. in an ambulance or aeroplane)

3.15
vacuum level
pressure less than atmospheric pressure

Note 1 to entry: In this part of ISO 10079, vacuum level is expressed as a difference from atmospheric pressure.

3.16
vacuum level indicator
device for displaying the vacuum level

3.17
vacuum source
component of device for generating vacuum

4 General requirements

4.1 Risk management

4.1.1 This part of ISO 10079 specifies requirements that are generally applicable to risks associated with manually powered suction equipment. An established risk management process shall be applied to the design of the device. The risk management process shall include the following elements:

— risk analysis;

— risk evaluation;

— risk control;

— production and post-production information.

EXAMPLE ISO 14971.

Check compliance by inspection of the risk management file.

4.1.2 Manually powered suction equipment shall, when transported, stored, installed, operated in normal use and maintained according to the instructions of the manufacturer, present no risks that are not reduced to an acceptable level using risk management procedures in accordance with ISO 14971 and which are associated with their intended application, in normal and in single fault condition.

NOTE A situation in which a fault is not detected is considered a normal condition. Fault conditions/hazardous situations might remain undetected over a period of time and, as a consequence, might lead to an unacceptable risk. In that case, a subsequent detected fault condition needs to be considered as a single fault condition. Specific risk control measures need to be determined within the risk management process to deal with such situations.

Check compliance by inspection of the risk management file.

4.1.3 Where requirements of this part of ISO 10079 refer to freedom from unacceptable risk, the acceptability or unacceptability of this risk shall be determined by the manufacturer in accordance with their policy for determining acceptable risk.

Check compliance by inspection of the risk management file.

4.1.4 The manufacturer may use type tests different from those detailed within this part of ISO 10079, if an equivalent degree of safety is obtained. Alternative test methods shall be validated against the test methods specified in Annex A of this part of ISO 10079.

Check compliance by inspection of the technical file.