BS EN ISO 10079-3:2014

Incorporating corrigendum June 2014

BSI Standards Publication

Medical suction equipment

Part 3: Suction equipment powered from a vacuum or positive pressure gas source (ISO 10079-3:2014)

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National foreword

This British Standard is the UK implementation of EN ISO 10079-3:2014. It supersedes BS EN ISO 10079-3:2009 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/121, Anaesthetic and respiratory equipment.

A list of organizations represented on this committee can be obtained on request to its secretary.

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30 June 2014	Implementation of CEN correction notice May 2014: Supersession information updated on CEN title page and foreword

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10079-3

May 2014

ICS 11.040.10

Supersedes EN ISO 10079-3:2009

English Version

Medical suction equipment - Part 3: Suction equipment powered from a vacuum or positive pressure gas source (ISO 10079-3:2014)

Appareils d'aspiration médicale - Partie 3: Appareils d'aspiration alimentés par une source de vide ou de pression (ISO 10079-3:2014)

Medizinische Absauggeräte - Teil 3: Vakuum- oder druckquellenbetriebene Absauggeräte (ISO 10079-3:2014)

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

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Foreword

This document (EN ISO 10079-3:2014) 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of an identical text or by endorsement, at the latest by November 2014, and conflicting national standards shall be withdrawn at the latest by May 2017.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 10079-3:2009.

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.

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The text of ISO 10079-3:2014 has been approved by CEN as EN ISO 10079-3:2014 without any modification.

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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 Directive 93/42/EEC.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative 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 relevant Essential Requirements of that Directive.

NOTE When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC

Clause(s) / sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/notes
4.1, 4.4, 12 t)	7.1	Partly covered There are no requirements for materials apart from a requirement to perform a risk assessment and to disclose the presence of latex. As these devices are only for extracting body fluids toxicity and biological compatibility is not considered a risk.
4.1, 5, 7.5, 7.5.2, 7.7	7.2	
4.1, 4.2, 5	7.3	Only the first part of this ER is covered
7.5.1, 7.5.2	8.1	
4.1, 6.3, 6.5	9.1	
4.1, 10	9.2	Only covered as far as temperature is concerned
7.4	12.7.1	Only covered as far as stability is concerned
7.6	12.7.3	
6.5	12.7.4	
11, 12	13.1	
11.2 a)	13.3 a)	
11.2 b)	13.3 b)	
11.2 c)	13.3 c)	
11.2 d)	13.3 d)	
11.2 e)	13.3 e)	

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11.2 f)	13.3 f)	
12 b)	13.4	Partly covered: disclosure of the intended purpose is included in the Instructions for use but not the labelling.
12	13.6a)	Covered for the items in 13.3 a), b), c), f), i) and k)
12 b), c), d), f),g), h), j), k), o), t), u)	13.6 b)	
12 k)	13.6 c)	
12 b), c), d), h), j), v)	13.6 d)	
12 i)	13.6 h)	First two paragraphs only
12 d)	13.6 i)	
12 z)	13.6 q)	

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

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 8, *Suction devices for hospital and emergency care use*.

This third edition cancels and replaces the second edition (ISO 10079-3:1999), which has been technically revised.

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*

Annex A forms a normative part of this part of ISO 10079 while Annexes B, C and D are for information only.

Annex B contains rationale statements for some of the requirements of this part of ISO 10079. The clauses and subclauses marked with an asterisk (*) after their number have corresponding rationale contained in Annex B, included to provide additional insight into the reasoning that led to the requirements and recommendations that have been incorporated in this part of ISO 10079. It is considered that knowledge of the reasons for the requirements will not only facilitate the proper application of this part of ISO 10079, but will expedite any subsequent revisions.

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INTERNATIONAL STANDARD ISO 10079-3:2014(E)

Medical suction equipment —

Part 3: Suction equipment powered from a vacuum or positive pressure gas source

1 Scope

This part of ISO 10079 specifies safety and performance requirements for medical suction equipment powered from a vacuum or positive pressure gas source generating venturi suction. It applies to equipment connected to medical gas pipeline systems or cylinders and venturi attachments. Annex D illustrates the three parts of ISO 10079 by providing a schematic for typical systems.

The equipment can be stand-alone or part of an integrated system.

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) central power supply (by vacuum/compressed air generation), piping systems of vehicles and buildings, and wall connectors;

b) end-piece such as suction catheters, Yankauer sucker and suction tips;

c) syringes;

d) dental suction equipment;

e) anaesthetic gas scavenging systems;

f) laboratory suction;

g) autotransfusion systems;

h) closed systems for wound drainage;

i) mucus extractors, including neonatal mucus extractors;

j) ventouse (obstetric) equipment;

k) breast pumps;

l) liposuction;

m) uterine aspiration;

n) plume evacuation systems.

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.

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ISO 3744, *Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound pressure — Engineering methods for an essentially free field over a reflecting plane*

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

ISO 5359, *Anaesthetic and respiratory equipment - Low-pressure hose assemblies for use with medical gases*

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 60601-1:2005+A1:2012, *Medical electrical equipment — Part 1: General requirements for safety*

IEC 60601-1-6, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance—Collateral standard: Usability*

IEC 61672-1, *Electroacoustics — Sound level meters — Part 1: Specifications*

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.

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

3.2
collection container assembly
collection container and its closure with connectors for suction

3.3
drainage
removal of liquid, solid particles or gas from body cavity or wound

3.4
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.

3.5
exhaust port
opening through which exhaust gas is discharged

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.

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3.6
field use
use of suction equipment in situations outside of the health care facility at the site of accidents or other emergencies

3.7
filter
device for retention of particulate matter

3.8
free air flowrate
rate of unrestricted flow of air through a designated inlet

3.9
high flowrate
free air flowrate of 20 l/min or more

3.10
high vacuum
vacuum level of 60 kPa or more below atmospheric pressure

3.11
inlet port
opening through which liquids, solid particles or gas enter

3.12
intermediate tubing
tubing between the collection container and the vacuum source

3.13
intermittent vacuum
type of suction in which the negative pressure applied to the end piece is automatically and periodically returned to atmospheric pressure

3.14
low flowrate
free air flowrate less than 20 l/min

3.15
low vacuum
vacuum level of not more than 20 kPa below atmospheric pressure

3.16
medical gas pipeline system
complete system which comprises a supply system, a monitoring and alarm system and a distribution system with terminal units at the points where medical gases or vacuum are required

[SOURCE: ISO 7396-1:2007, definition 3.29]

3.17
medium vacuum
vacuum level of more than 20 kPa but less than 60 kPa below atmospheric pressure

3.18
outlet port
opening through which gas exits from the collection container

3.19
overfill protection device
device intended to prevent liquid or solid particles from entering the intermediate tubing

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3.20
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.

3.21
suction
application of vacuum to remove liquid, solid particles or gas

3.22
suction tubing
tubing for conduction of liquid, solid particles or gas between the end-piece and the collection container

3.23
thoracic drainage
drainage of liquids and gas from the thoracic cavity by application of suction to the thoracic cavity of the patient

Note 1 to entry: For the purposes of this part of ISO 10079, all thoracic drainage is considered to be active.

3.24
transport use
use during patient transport outside of a health care facility (e.g. in an ambulance or airplane)

3.25
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.

3.26
vacuum level indicator
device for displaying the vacuum level

3.27
vacuum source
component of device for generating vacuum

3.28
vacuum regulator
device for controlling the applied vacuum level

4 General requirements

Suction equipment with components controlled by electrical means, e.g. electronic timing, shall meet the relevant requirements of IEC 60601-1:2005+A1:2012.

4.1 Risk management

4.1.1 This part of ISO 10079 specifies requirements that are generally applicable to risks associated with suction equipment powered from a vacuum or positive gas source. 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;

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