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Medical suction equipment — Part 1: Electrically powered suction equipment

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Contents	Page
Foreword.....	6
1 Scope	1
2 Normative references	1
3 Terms and definitions.....	2
4 General requirements.....	5
4.1 Risk management	5
4.2 Usability	5
4.3 Clinical investigation	6
4.4 Biophysical or modelling research	6
4.5 Test methods.....	6
5 Cleaning, disinfection and sterilization.....	6
6 Design requirements.....	6
6.1 Collection container.....	6
6.1.1 General	6
6.1.2 Container capacity.....	6
6.1.3 Container strength	7
6.2 Connections	7
6.2.1 Tubing connectors for collection containers.....	7
6.2.2 Inlet port.....	7
6.2.3 Exhaust port	7
6.3 Suction tubing.....	7
6.4 Vacuum level indicators.....	8
6.5 Spillage on electrical suction equipment.....	8
7 Operational requirements	9
7.1 Ease of operation	9
7.2 Dismantling and reassembly	9
7.3 Mechanical shock.....	9
7.4 Stability	9
7.5 Protective devices	9
7.5.1 Contamination protection	9
7.5.2 Overfill protection devices.....	10
7.5.3 Pressure protection.....	10
7.6 Noise.....	10
7.6.1 Low vacuum/low flowrate equipment.....	10
7.6.2 Suction equipment other than that specified in 7.6.1	10
7.7 Air leakage	10
7.7.1 Collection containers for general use.....	10

7.7.2	Collection containers for thoracic drainage.....	10
8	Physical requirements for suction equipment for field use	11
8.1	(*) Dimensions	11
8.2	Mass.....	11
9	Performance requirements for vacuum level and flowrate	11
9.1	High vacuum/high flowrate equipment.....	11
9.2	Medium vacuum equipment	11
9.3	Low vacuum/low flowrate equipment	11
9.4	Low vacuum/high flowrate equipment.....	12
9.5	Thoracic drainage equipment for adults	12
9.6	Intermittent vacuum equipment.....	12
9.7	Vacuum regulators with fixed setting.....	12
9.8	Vacuum regulators with variable setting.....	12
9.9	Equipment intended for pharyngeal suction	12
9.10	Battery powered transportable suction equipment	13
9.11	Interruption of the power supply.....	13
10	(*) Resistance to environment of suction equipment for field and/or transport use.....	13
10.1	Operating conditions	13
10.2	Storage	13
11	Information to be supplied by the manufacturer (labelling and instructions for use)	13
11.1	Information supplied by the manufacturer shall comply with EN 1041.....	13
11.3	Labelling of equipment	13
11.4	Instructions for use	15
Annex A	(normative) Test methods.....	17
A.1	General.....	17
A.2	Test for collection container capacity and overflow protection	17
A.2.1	Devices with overflow protection	17
A.2.2	Devices with no overflow protection (field use).....	17
A.3	Test for collection container strength.....	17
A.4	Test for degree of collapse for suction tubing	18
A.5	Drop test.....	21
A.6	Test for positive-pressure protection in thoracic drainage	21
A.7	Noise test.....	21
A.8	Test for air leakage into the collection container	22
A.8.1	Collection containers for general use	22
A.8.2	Collection containers for thoracic drainage.....	23
A.9	Test for maximum vacuum level and free air flowrate (general suction equipment).....	24
A.10	Test for maximum vacuum level and free air flowrate of low vacuum equipment	25
A.11	Test for free air flowrate for thoracic drainage equipment	26
A.12	Test for intermittent vacuum equipment.....	27
A.13	Test for accuracy of vacuum regulator with fixed setting.....	27

A.13.1 Apparatus	27
A.13.2 Procedure	28
A.14 Test for accuracy of vacuum regulator with variable setting	28
A.14.1 Apparatus	28
A.14.2 Procedure	28
A.15 Test for pharyngeal suction	29
A.15.1 Test material and apparatus	29
A.15.1.1	Simulated vomitus 29
A.15.1.2	Graduated cylinder 29
A.15.2 Procedure	29
A.16 Battery powered transportable suction equipment	29
A.17 Interruption of power supply	30
A.18 Test for resistance to environment of suction equipment for field and/or transport use	30
A.18.1 General	30
A.18.2 Procedures	31
A.18.2.1	Low temperature operation 31
A.18.2.2	High temperature operation 31
A.18.2.3	Low temperature storage 31
A.18.2.4	High temperature storage 31
Annex B (informative) Rationale statement	32
B.1 General	32
B.2 Container capacity [see 6.1.2.1 and 6.1.2.2]	32
B.3 Length of suction tubing [see 6.3.2]	32
B.4 Dimensions [see 8.1]	32
B.5 Resistance to the environment [see Clause 10]	32
B.6 Labelling of equipment [see 11.3 g)]	32
Annex C (informative) Lumen size and its effect on flowrate	33
C.1 General	33
Annex D (informative) Schematic of suction equipment	34
Bibliography	36

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](http://standards.iteh.ai/catalog/standards/sist/9be879e4-692c-496a-a14f)

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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 10079-1:1999), 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 Annex B, Annex C, and Annex 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 (*) at the beginning of the paragraph 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 into 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.

Annex D illustrates the three parts of ISO 10079 by providing a schematic for typical systems.

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Medical suction equipment — Part 1: Electrically powered suction equipment

1 Scope

This part of ISO 10079 specifies safety and performance requirements for electrically powered medical and surgical suction equipment. It applies to equipment used in health care facilities such as hospitals, for domiciliary care of patients and for field and transport use.

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-pieces such as suction catheters, drains, curettes, Yankauer suckers, and suction tips;
- c) syringes;
- d) dental suction equipment;
- e) anaesthetic gas scavenging systems;
- f) laboratory suction; [ISO 10079-1:2015](https://standards.iteh.ai/catalog/standards/sist/9be879e4-692c-496a-a14f-99b13a7de3ca/iso-10079-1-2015)
- g) autotransfusion systems; <https://standards.iteh.ai/catalog/standards/sist/9be879e4-692c-496a-a14f-99b13a7de3ca/iso-10079-1-2015>
- h) mucus extractors including neonatal mucus extractors;
- i) suction equipment where the collection container is downstream of the vacuum pump;
- j) ventouse (obstetric) equipment;
- k) suction equipment marked for endoscopic use only;
- l) 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.

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*

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

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 60529, *Degrees of protection provided by enclosures (IP Code)*

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 60601-1-11:2010, *Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

IEC 60601-1-12:2014, *Medical electrical equipment — Part 1-12: General requirements for basic safety and essential performance — Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment*

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

IEC/TR 60878, *Graphical symbols for electrical equipment in medical practice*

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

drainage

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

3.3

end-piece

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>.

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.

3.4

exhaust port

opening through which exhaust gas is discharged

3.5

field use

use of suction equipment in situations outside of the health care facility and home environment

3.6

filter

device for retention of particulate matter

3.7

free air flowrate

rate of unrestricted flow of air through a designated inlet

3.8

high flowrate

free air flowrate (3.7) of 20 l/min or more

3.9

high vacuum

vacuum level (3.23) of 60 kPa or more

3.10

inlet port

opening through which liquid, solid particles, or gas enter

3.11

intermediate tubing

tubing between the *collection container* (3.1) and the *vacuum source* (3.26)

3.12

intermittent vacuum

type of *suction* (3.19) in which the negative pressure applied to the *end-piece* (3.3) is automatically and periodically returned to atmospheric pressure

3.13

low flowrate

free air flowrate (3.7) less than 20 l/min

3.14

low vacuum

vacuum level (3.23) of not more than 20 kPa

3.15

medium vacuum

vacuum level (3.23) of more than 20 kPa, but less than 60 kPa

3.16

outlet port

opening through which gas exits from the *collection container* (3.1)

3.17

overflow protection device

device intended to prevent liquid or solid particles from entering the *intermediate tubing* (3.11)

3.18

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.

3.19

suction

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

3.20

suction tubing

tubing for conduction of liquid, solid particles, or gas between the *end-piece* (3.3) and the *collection container* (3.1)

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3.21

thoracic drainage

drainage (3.2) of liquid and gas from the thoracic cavity by application of *suction* (3.19) 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.

3.22

transport use

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

3.23

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.

3.24

vacuum level indicator

device for displaying the *vacuum level* (3.23)

3.25

vacuum regulator

device for controlling the applied *vacuum level* (3.23)

3.26

vacuum source

component of device for generating vacuum

4 General requirements

Electrically powered medical suction equipment 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 electrically powered medical 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 Electrically 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 to deal with such situations 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.

4.2 Usability

The manufacturer shall address, in accordance with IEC 60601-1-6 and IEC 62366, the usability engineering process, and the risk resulting from poor usability.

Check compliance by inspection of the usability engineering file.