SLOVENSKI STANDARD
oSIST prEN ISO 10079-4:2020

01-marec-2020

Medicinska sukcijska (aspiracijska) oprema - 4. del: Splošne zahteve (ISO/DIS 10079-4:2020)

Medical suction equipment - Part 4: General requirements (ISO/DIS 10079-4:2020)

Ta slovenski standard je istoveten z: **prEN ISO 10079-4**

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment

oSIST prEN ISO 10079-4:2020 **en**

DRAFT INTERNATIONAL STANDARD

ISO/DIS 10079-4

ISO/TC **121**/SC **8**

Secretariat: **SA**

Voting begins on:
2020-01-03

Voting terminates on:
2020-03-27

Medical suction equipment — Part 4: General requirements

ICS: 11.040.10

This document is circulated as received from the committee secretariat.

ISO/CEN PARALLEL PROCESSING

Reference number
ISO/DIS 10079-4:2020(E)

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Published in Switzerland

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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 voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee *121*, *Anaesthetic and respiratory equipment* Subcommittee SC 8, *suction devices for hospital and emergency care use*.

This is the first edition.

The ISO 10079 [1][2][3] series comprises 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.*

Part 4: *Medical suction equipment –general requirements.*

Throughout this document the following print types are used:

— Requirements and definitions: roman type;

— *Test specifications: italic type;*

— Informative material appearing outside of tables, such as notes, examples and references: smaller type. The normative text of tables is also in smaller type;

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex A.

Introduction

The 10079 series of medical *suction* equipment comprised three parts which had many common requirements. It was thought combining these common requirements into this one document would prevent inconsistencies that result from developing three different parts with common requirements and would make any future revision/amendment/corrigendum easier to manage.

This document contains those requirements that are common to electrically, manually and gas-powered medical *suction* equipment and will be cross referenced by the separate parts.

Medical suction equipment — Part 4: General requirements

1 Scope

This document specifies general requirements for medical *suction* equipment that are common to all parts of the 10079 series.

The ISO 10079 series does not apply to the following:

a) *end-pieces* such as *suction* catheters, drains, curettes, Yankauer suckers and *suction* tips;

b) syringes;

c) dental *suction* equipment;

d) anaesthetic gas scavenging systems;

e) laboratory *suction*;

f) autotransfusion systems;

g) mucus extractors including neonatal mucus extractors;

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

i) ventouse (obstetric) equipment;

j) *suction* equipment marked for endoscopic use only

k) plume evacuation systems.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. 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*

ISO 7000, *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/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*

EN 15986, *Symbol for use in the labelling of medical devices - Requirements for labelling of medical devices containing phthalates*

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at https://www.iso.org/obp

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 a body cavity or wound

3.4
thoracic drainage
drainage of liquid and gas from the thoracic cavity by application of *suction* to the thoracic cavity of the patient

3.5
suction
application of vacuum to remove liquid, solid particles or gas

3.6
end-piece
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: to entry: Examples of commonly used *end-pieces* are a Yankauer sucker and a *suction* catheter.

Source ISO 4135 [1]

3.7
exhaust port
opening through which exhaust gas is discharged

3.8
inlet port
opening through which liquid, solid particles or gas enter

3.9
outlet port
opening through which gas exits from the *collection container assembly*

3.10
field use
use of *suction* equipment in situations outside of the health care facility and home environment

3.11
transport use
use during patient transport outside of a health care facility (e.g. in an ambulance or airplane)

3.12
filter
device for retention of particulate matter

3.13
free air flow
rate of unrestricted flow of air through a designated inlet

3.14
high flow
free air flow ≥ 20 l/min

3.15
low flow
free air flow < 20 l/min

3.16
high vacuum
vacuum level of 60 kPa or more

3.17
low vacuum
vacuum level of < 20 kPa

3.18
intermittent vacuum
suction in which the negative pressure applied to the *end-piece* is automatically and periodically returned to atmospheric pressure

3.19
medium vacuum
vacuum level ≥ 20 kPa, but < 60 kPa

3.20
intermediate tubing
tubing between the *collection container* and the *vacuum source*

3.21
suction tubing
tubing for conduction of liquid, solid particles or gas between the *end-piece* and the *collection container*

3.22
overfill protection device
device to prevent liquid or solid particles from entering the *intermediate tubing*

3.23
reference box
hypothetical right parallelepiped terminating on the reflecting plane(s) on which the noise source under test is located, that just encloses the source including all the significant sound radiating components and any test table on which the source is mountedSource ISO 3744:2010

3.24
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: to entry: Maintenance of equipment is considered a normal condition.

3.25
vacuum level
pressure less than atmospheric pressure

3.26
vacuum level indicator
device for displaying the *vacuum level*

3.27
vacuum regulator
device for controlling the applied *vacuum level*

3.28
vacuum source
component of device for generating vacuum

4 General requirements

4.1 Risk management

4.1.1 An established risk management process, (e.g. ISO 14971), shall be applied to the design of the *suction* equipment. The risk management process shall include the following elements:

— risk analysis;

— risk evaluation;

— risk control;

— production and post-production information.

Check compliance by inspection of the risk management file.

4.1.2 *Suction* equipment shall, when transported, stored, installed, operated in normal use and maintained according to the instructions for use, 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.

Check compliance by inspection of the risk management file.

4.1.3 Where requirements 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 apply a usability engineering process to assess and mitigate any risks caused by usability problems associated with correct use (i.e. normal use) and use errors (see IEC 60601-1-6 and IEC 62366).

Check compliance by inspection of the usability engineering file.

4.3 Clinical studies

Where appropriate, clinical studies shall be performed under the conditions for which performance is claimed and documented in the risk management file. The clinical studies shall comply with the requirements of ISO 14155.

NOTE Clinical data can be sourced from the following:

— clinical investigation(s) of the device concerned;

— clinical investigation(s) or other studies reported in the scientific literature of a similar device for which equivalence to the device in question can be demonstrated;

— published and/or unpublished reports on other clinical experience of either the device in question or a similar device for which equivalence to the device in question can be demonstrated.

Check compliance by inspection of the risk management and technical files.

4.4 Biophysical or modelling research

Where appropriate, validated biophysical or modelling research shall be performed under the conditions for which performance is claimed and documented in the risk management file.

NOTE Biophysical or modelling research is the application of validated physical methods and theories to biological problems. Examples include the use of a combination of models, i.e. mathematical, computer, physical, cell and tissue culture, and animal, in a complementary and interactive manner to simulate the performance of medical devices.

Check compliance by inspection of the technical file.

4.5 Test methods

The manufacturer can use type tests different from those detailed within this document if an equivalent degree of safety is obtained. Alternative test methods shall be validated against the test methods specified in Annex B.

5 Materials

5.1 Natural rubber latex

If any components of the *suction* equipment incorporate natural rubber latex the manufacturer shall provide a specific justification for using this substance in their technical file. See also 9.3 g) for additional marking requirements.

Check compliance by inspection of the manufacturer's technical file.