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Medical suction equipment —

Part 4: General requirements

Appareils d'aspiration médicale —

Partie 4: Exigences générales

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Foreword

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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 of 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 www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment* subcommittee SC 8, *Suction devices*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

A list of all parts in the ISO 10079 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Previously the ISO 10079 series of medical *suction* equipment standards comprised parts ISO 10079-1,[2] ISO 10079-2 [3] and ISO 10079-3 [4] which had many common requirements. It was thought that combining these common requirements into this new part 4 would prevent the inconsistencies that had resulted from developing three different parts with common requirements and would make any future revision/amendment easier to manage.

This document contains those requirements that are common to electrically, manually and gas-powered medical *suction* equipment.

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 ISO 10079 series.

This document is not applicable 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; and

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 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

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 20417, *Medical devices — Information to be provided by the manufacturer*

ISO 80369-2, *Small-bore connectors for liquids and gases in healthcare applications — Part 2: Connectors for respiratory applications*

ISO 80369-3, *Small-bore connectors for liquids and gases in healthcare applications — Part 3: Connectors for enteral applications*

ISO 80369-6, *Small bore connectors for liquids and gases in healthcare applications — Part 6: Connectors for neuraxial applications*

ISO 80369-7, *Small-bore connectors for liquids and gases in healthcare applications—Part 7 Connectors for intravascular or hypodermic applications*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, *Medical electrical equipment — Part 1: General requirements for safety*

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

IEC 80369-5, *Small-bore connectors for liquids and gases in healthcare applications—Part 5 Connectors limb cuff inflation applications*

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:

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

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

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
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

EXAMPLE Commonly used *end-pieces* include Yankauer suckers and *suction* catheters.

[Source: ISO 4135:2001, 8.2.7][1]

3.5
exhaust port
opening through which exhaust gas is discharged

3.6
field use
use of *suction* equipment in situations outside of a healthcare facility or home environment

3.7
filter
device for retention of particulate matter

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

3.9
high flow
free air flow ≥ 20 l/min

3.10
high vacuum
vacuum level of 60 kPa or stronger (absolute pressure 0 to 40 kPa)

3.11
inlet port
opening through which liquid, solid particles or gas enters

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

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

3.14
low flow
free air flow < 20 l/min

3.15
low vacuum
vacuum level of 20 kPa or weaker (absolute pressure 80 kPa to 100 kPa)

3.16
medium vacuum
vacuum level between 20 kPa and 60 kPa (absolute pressure 40 kPa to 80 kPa)

3.17
overfill protection device
device to prevent liquid or solid particles from entering the *intermediate tubing*

3.18
single fault condition
condition in which a single means for reducing a risk is defective or a single abnormal condition is present

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

[SOURCE: IEC 60601:2005+AMD1:2012+AMD 2:2020, 3.116 modified by removing ME equipment.]

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* and the *collection container*

3.21
thoracic drainage
drainage of liquid and gas from the thoracic cavity by application of *suction* to the thoracic cavity of the patient

3.22
transport use
use during patient transport outside of a healthcare facility

EXAMPLE ambulance or aeroplane.

3.23
vacuum level
pressure less than atmospheric pressure

3.24
vacuum level indicator
device for displaying the *vacuum level*

3.25
vacuum regulator
device for controlling the applied *vacuum level*

3.26
vacuum source
component or device for generating a 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; and

— production and post-production information.

Check conformance 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 is considered a *single fault condition*. Specific risk control measures to deal with such situations can be determined within the risk management process.

Check conformance 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 conformance 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 (e.g. IEC 60601-1-6 [5] and IEC 62366-1 [8]).

Check conformance 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; or

— 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 conformance 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 conformance by inspection of the technical file.

4.5 Test methods

Manufacturers 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 conformance by inspection of the technical file.

5.2 Cleaning, disinfection and sterilization

5.2.1 Parts of the *suction* equipment which can be subject to contamination shall either be for single use or capable of being cleaned and disinfected or sterilized as appropriate.

Check conformance by inspection of the technical file.

5.2.2 Parts of the *suction* equipment intended for re-use shall meet the requirements of Clause 7, as appropriate, after those components have been subjected to 30 cycles of cleaning and disinfection or sterilization as recommended by the manufacturer [see 9.4 g)].

Check conformance by the tests given in Annex B.

6 Design requirements

6.1 General

6.1.1 *Suction* equipment classified as medical electrical equipment, as defined in 3.63 of IEC 60601-1:2005+AMD1:2012 +AMD2:2020 shall meet the relevant requirements of IEC 60601-1.

NOTE This applies not only to electrically powered *suction* equipment but also to *suction* equipment with electrical components e.g. timers, indicators etc.

Check conformance by inspection of the technical file.

6.1.2 *Suction* equipment intended to be dismantled by the user (e.g. for cleaning) shall be designed to facilitate correct assembly or marked to indicate correct reassembly.

Check conformance by inspection of the technical file.

6.1.3 *Suction* equipment shall meet the requirements of Clause 7, as appropriate, after dismantling and reassembly in accordance with the manufacturer's instructions.

Check conformance by the tests given in Annex B after the *suction* equipment has been reassembled.

6.1.4 *Suction* equipment shall be designed to be operated by one person, unaided.

Check conformance by functional testing.

6.1.5 Means shall be provided to prevent foam passing from the *collection container* into the *vacuum source*.

NOTE This does not apply to *suction* equipment designed to continue to operate when the *collection container* is full. [See 8.5 b)].

Check conformance by the tests given in B.2.3.

6.2 *Collection containers*

6.2.1 Capacity

Collection containers shall:

a) clearly show the level of contents, and

b) have a usable volume ≥ 500 ml.

NOTE 1 See A.2 for rationale.

NOTE 2 Transparent or translucent *collection containers* allow a qualitative assessment of the contents.

NOTE 3 See Clause 8 for additional/alternative requirements for the capacity of *collection containers* for *suction* equipment for *field use* or *transport use*.

Check conformance by the tests given in B.2.

6.2.2 Strength

Collection containers shall not implode, crack or permanently deform and shall meet the requirements of Clause 7, as appropriate, after being subjected to a pressure of either 120 % of the manufacturer's recommended maximum *vacuum level* or 95 kPa below atmospheric, whichever is the stronger *vacuum level*, for 5 min.

Reusable *collection containers* shall be tested after 30 cycles of cleaning and disinfection or sterilization as recommended by the manufacturer [see 9.4 g)].

Check conformance by the tests given in B.3.

6.3 Connections

6.3.1 Tubing connectors

Connectors for *suction tubing* and *intermediate tubing* shall:

a) be designed to facilitate correct assembly or clearly marked to indicate correct assembly when all parts are mated and

b) have an inside diameter equal to or larger than the inside diameter of the largest *suction tubing* or *intermediate tubing* size specified by the manufacturer [see 9.4 n)].

NOTE Incorrect connections have frequently been a cause of spill over into the *vacuum source* and a loss of *suction*.

Check conformance by functional testing and inspection.

6.3.2 *Collection container inlet ports*

Collection container inlet ports shall:

a) not be compatible with any of the conical connectors specified in ISO 5356-1 or any of the small-bore connectors specified in ISO 80369-2, ISO 80369-3, IEC 80369-5, ISO 80369-6, ISO 80369-7 and

b) have an inside diameter ≥ 6 mm.

Check conformance by functional testing.

6.3.3 *Collection container exhaust ports*

It shall not be possible to connect *suction tubing* or *intermediate tubing* to *collection container exhaust ports*.

Check conformance by functional testing.