INTERNATIONAL STANDARD

ISO 10079-4

First edition
2021-08

Medical suction equipment —

Part 4: General requirements

Appareils d'aspiration médicale —

Partie 4: Exigences générales

Reference number
ISO 10079-4:2021(E)

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Published in Switzerland

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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).

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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.

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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.

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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*

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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

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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*

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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.

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