INTERNATIONAL STANDARD

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Medical suction equipment —

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

Appareils d'aspiration médicale —

Partie 3: Appareils d'aspiration alimentés par une source de vide ou de pression

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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 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).

This fourth edition cancels and replaces the third edition (ISO 10079-3:2014), which has been technically revised.

The main changes are as follows:

— the general requirements have been removed from this document and replaced with references to ISO 10079-4:2021;

— the list of exemptions has been removed from the scope as it now appears in ISO 10079-4:2021.

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.

Medical suction equipment —

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

1 Scope

This document specifies basic safety and performance requirements for medical *suction* equipment powered from a vacuum or positive pressure gas source generating venturi *suction*. It applies to *suction* equipment connected to *medical gas pipeline systems* or cylinders and venturi attachments and can be standalone or part of an integrated system.

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 5359:2014/Amd 1:2017, *Anaesthetic and respiratory equipment — Low-pressure hose assemblies for use with medical gases*

ISO 10079-4:2021, *Medical suction equipment – Part 4: General requirements*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 10079-4 and the following apply.

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

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

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

3.1
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 7396-1:2016, 3.36]

4 General requirements

The requirements of ISO 10079-4:2021, Clause 4, shall apply.

5 Materials

The requirements of ISO 10079-4:2021, Clause 5, shall apply.

6 Design requirements

6.1 General

The requirements of ISO 10079-4:2021, Clause 6, shall apply.

6.2 Supply connections

Suction equipment powered by gas or vacuum shall:

a) if designed to be connected directly to the terminal unit of a *medical gas pipeline system* or the outlet of a pressure regulator, be fitted with a probe complying with the relevant national standard, or

b) if designed to be connected remotely to the terminal unit of a *medical gas pipeline system* or the outlet of a pressure regulator, be fitted with a low-pressure hose assembly complying with ISO 5359.

Check conformance by inspection.

NOTE Requirements for *medical gas pipeline systems* are specified in ISO 7396-1[1].

7 Performance requirements

The requirements of ISO 10079-4:2021, Clause 7, shall apply.

8 Additional/alternative requirements for *suction* equipment, *suction tubing* and *intermittent tubing* designed for *field use* or *transport use*

The requirements of ISO 10079-4:2021, Clause 8, shall apply.

9 Information to be supplied by the manufacturer

The requirements of ISO 10079-4:2021, Clause 9, shall apply.

Bibliography

[1] ISO 7396-1:2016, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum*