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Medical suction equipment —

Part 2: Manually powered suction equipment

Appareils d'aspiration médicale —

Partie 2: Appareils d'aspiration manuelle

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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 10079-2:2014), 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 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 2:
Manually powered suction equipment

1 Scope

This document specifies safety and performance requirements for *manually powered suction* equipment intended for oro-pharyngeal *suction*. It applies to equipment operated by foot or by hand or both.

The commonest use of *manually powered suction* is in situations outside of healthcare settings often described as *field use* or *transport use*. Use in these situations may involve extreme conditions of weather or terrain. Additional/alternative requirements for *manually powered suction* equipment intended for *field use* or *transport use* are included in this document.

This document does not apply to mucus extractors.

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 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
manually powered suction
generation of vacuum by direct human effort

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 Ease of operation

6.2.1 Foot-operated *manually powered suction* equipment should require a force of less than 350 N to operate.

6.2.2 Hand-operated *manually powered suction* equipment should require a force of less than 45 N to operate.

7 Performance requirements

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

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

8.1 General

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

8.2 Immersion in water

Manually powered suction equipment intended for *field use* and *transport use* shall meet the requirements of Clause 7, as appropriate, after being dropped into water from a height of 1 m and immersed for 10 s.

Check conformance by the following test:

Drop the *suction* equipment from a height of 1 m ± 0,1 m into a water reservoir and leave immersed for at least 10 s. Expel the water for 7 s ± 0,5 s, then test the *suction* equipment for conformance with the requirements given in Clause 7, as appropriate.

9 Information to be supplied by the manufacturer

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