



SLOVENSKI STANDARD
oSIST prEN ISO 10079-2:2021
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Medicinska sukcijska (aspiracijska) oprema - 2. del: Ročna sukcijska (aspiracijska) oprema (ISO/DIS 10079-2:2021)

Medical suction equipment - Part 2: Manually powered suction equipment (ISO/DIS 10079-2:2021)

Medizinische Absauggeräte - Teil 2: Handbetriebene Absauggeräte (ISO/DIS 10079-2:2021)

Appareils d'aspiration médicale - Partie 2: Appareils d'aspiration manuelle (ISO/DIS 10079-2:2021)

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ICS:

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

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Medical suction equipment —

Part 2: Manually powered suction equipment

*Appareils d'aspiration médicale —**Partie 2: Appareils d'aspiration manuelle*

ICS: 11.040.10

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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. (standards.iteh.ai)

This document was prepared by Technical Committee 121, *Anaesthetic and respiratory equipment* subcommittee SC 8, *Suction devices* and is written following the format of ISO 10079-4 *Medical suction equipment -Part 4: General requirements*. The requirements in this device-specific standard take precedence over any conflicting requirements in the general standard.

This fourth edition cancels and replaces the third edition (ISO 10079-2:2014).

The ISO 10079 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: *General requirements*

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

With the introduction of part 4 into the 10 079 series of standards for medical *suction* equipment the general requirements can be removed from the specific parts. This document has therefore been revised to remove those general requirements and replace them by referencing the *suction* equipment general standard ISO 10079-4.

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;
- *terms defined in ISO 10079-4: italic type.*

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Medical suction equipment —

Part 2: Manually powered suction equipment

1 Scope

This part of ISO 10079 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 part of ISO 10079.

ISO 10079 Part 4 specifies general requirements for all medical *suction* equipment covered by the ISO 10079 series and is used as the basis for this Part 2.

The exemptions listed in ISO 10079-4 Clause 1 shall apply. In addition this part of ISO 10079 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 10079-4:202X, *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, Clause 3, and the following 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

manually powered suction

generation of vacuum by direct human effort

4 General requirements

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

5 Materials

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

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6 Design requirements

6.1 General

The requirements of ISO 10079-4, 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, 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, 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 $1\text{ m} \pm 0,1\text{ m}$ into a water reservoir and leave immersed for at least 10 s. Expel the water for $7\text{ s} \pm 0,5\text{ s}$, 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 Clause 9 shall apply.

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