SLOVENSKI STANDARD
oSIST prEN ISO 10079-1:2021

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Medicinska sukcijska (aspiracijska) oprema - 1. del: Električna sukcijska (aspiracijska) oprema (ISO/DIS 10079-1:2021)

Medical suction equipment - Part 1: Electrically powered suction equipment (ISO/DIS 10079-1:2021)

Medizinische Absauggeräte - Teil 1: Elektrisch betriebene Absauggeräte (ISO/DIS 10079 -1:2021)

Appareils d'aspiration médicale - Partie 1: Appareils électriques d'aspiration (ISO/DIS 10079-1:2021)

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Medical suction equipment —

Part 1: Electrically powered suction equipment

Appareils d'aspiration médicale —

Partie 1: Appareils électriques d'aspiration

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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.

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 10079-1:2015 + Amd 1: 2018).

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 10079 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: italics.*

Medical suction equipment —

Part 1:
Electrically powered suction equipment

1 Scope *(mandatory)*

This part of ISO 10079 specifies safety and performance requirements for electrically powered medical and surgical *suction* equipment. It applies to equipment used in health care facilities such as hospitals, for domiciliary care of patients and for *field use* and *transport use*.

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 1.

The exemptions listed in ISO 10079-4, Clause 1 shall apply.

2 Normative references *(mandatory)*

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 10079-4:2020, *Medical suction equipment – Part 4:General requirements*

IEC 60529:1992, + A 2:2013, *Degrees of protection provided by enclosures (IP code)*

IEC 60601-1:2005+A1:2012, *Medical electrical equipment — Part 1: General requirements for safety*

IEC 60601-1-11:2015/DAmd 1, *Medical electrical equipment — Part 11: General requirements for basic safety and essential performance — Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

IEC 60601-1-12:2014, *Medical Electrical Equipment — Part 1-12: General requirements for basic safety and essential performance — Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the emergency medical services environment*

3 Terms and definitions (mandatory)

For the purposes of this document, the terms defined in ISO 10079-4, Clause 3 shall 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

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.

6 Design requirements

6.1 General

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

6.2 Protection against ingress of solid objects and liquids

6.2.1 Electrically powered suction equipment shall meet the performance requirements of clause 7 after undergoing the tests given in IEC 60529 for the classification for resistance to ingress of solids and liquids as given in Table 1.

Check conformance by the tests specified in IEC 60529.

Table 1 — Classification of *suction* equipment for ingress of solids and liquids.

Use	Classification	Reference standard
Hospital use	IP22	As per IEC 60601-1:2005 +Amd 1:2012 subclauses 6.3 and 11.6.5
Home healthcare use	IP22	As per IEC 60601-1-11:2010 subclause 8.3
Field use and *transport use*	IP33	As per IEC 60601-1-12:2014 subclause 8.1

6.2.2 Remote foot switches with electrical switching parts shall be of watertight construction classified as at least IPX 6 as specified in IEC 60529.

Check compliance by the tests specified in IEC 60529.

7 Performance requirements

7.1 General

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

7.2 Effect of an interruption of power supply on the *vacuum level* and *free air flow*

Interruption and restoration of the power supply to the *suction* equipment shall not cause the *vacuum level* or *free air flow* to vary by more than ± 10 % from the set value.

NOTE This performance requirement also applies if the primary power supply is replaced with a secondary power supply.

Check conformance by the following test:

With the suction equipment operating in normal condition and with the vacuum level set to half the maximum vacuum level interrupt the power supply. After a period of 5 min reconnect the power supply and switch on the suction equipment. After 30 s measure the vacuum level and free air flow. Verify that they are within ± 5 % of the set values.

