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Medical suction equipment —

Part 1: Electrically powered suction equipment

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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).

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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).

This fourth edition cancels and replaces the third edition (ISO 10079-1:2015), which has been technically revised. It also incorporates the Amendment ISO 10079-1:2015/Amd 1:2018.

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 1:
Electrically powered suction equipment

1 Scope

This document 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*.

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*

IEC 60529:1989+AMD1:1999+AMD2:2013, *Degrees of protection provided by enclosures (IP code)*

3 Terms and definitions

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

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 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
Hospital use	IP22
Home healthcare use [a]	IP22
Field use and *transport use* [b]	IP33
[a] Home healthcare use is where the device is used by the patient themselves or a lay person and can be outside of the home e.g. in a vehicle or wheelchair.	
[b] *Field use* and *transport use* is where the device is used by a trained healthcare provider.	

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 conformance by the tests specified in IEC 60529.

6.3 Battery powered *suction* equipment

Battery powered *suction* equipment shall:

a) be provided with a means to indicate the charge status of the battery (see also 9.2) and

b) when fully charged operate continuously for at least 20 min during which time it shall maintain a *free air flow* of not less than 2 l/min and a *vacuum level* of not less than 40 kPa.

Check conformance by the following test:

With a fully charged battery, set the *vacuum level* to 40 kPa at a *free air flow* of 2 l/min. Verify that this *vacuum level* and *free air flow* is maintained over a 20 min period.

NOTE This requirement applies to *suction* equipment that uses a battery as its primary or its secondary power supply.

7 Performance requirements

7.1 General

The requirements of ISO 10079-4:2021, 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 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 ±10 % of the set values.

8 Additional/alternative requirements for *suction* equipment and *suction 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

9.1 General

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

9.2 Instructions for use

In addition to 9.1, the instructions for use shall, if applicable, include information regarding replacement and disposal of batteries.