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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 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 ISO/TC 121, *Anaesthetic and respiratory equipment* subcommittee SC 8, *Suction equipment* 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 10079-3:2014).

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 and Clause 3 of this document: italic type.*

Medical suction equipment —

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

1 Scope

This part of ISO 10079 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 stand-alone or part of an integrated system.

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 3.

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

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, *Anaesthetic and respiratory equipment — Low-pressure hose assemblies for use with medical gases*

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
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, definition 3.36]

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 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 *Medical gas pipeline systems* complying with ISO 7396-1[1] supply a vacuum level of 60 kPa (absolute pressure) at a flow of 25 l/min. A *vacuum level* of 60 kPa (absolute pressure) is the same as 40 kPa below atmospheric.

7 Performance requirements

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

9 Information to be supplied by the manufacturer

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