FINAL DRAFT
International Standard

ISO/FDIS 23402-3

Dentistry — Portable dental equipment for use in non-permanent healthcare environment —

Part 3: Portable suction equipment

Médecine bucco-dentaire — Matériel dentaire portatif utilisable dans des environnements de soins de santé non permaments —

Partie 3: Matériel d'aspiration portatif

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Foreword

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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 document 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).

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This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 6, *Dental equipment,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

A list of all parts in the ISO 23402 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.

Introduction

The ISO 23402 series is a series of standards with the objective of standardizing requirements for portable dental equipment for use in non-permanent healthcare environments.

Dentistry — Portable dental equipment for use in non-permanent healthcare environment —

Part 3:
Portable suction equipment

1 Scope

This document specifies terminology, classification, requirements and test methods for portable suction equipment primarily intended to be used by dental professionals in non-permanent healthcare environments.

This document applies to portable suction equipment incorporated in a portable dental unit and free-standing portable suction equipment.

The requirements in this document focus on portability.

This document specifies requirements for information to be supplied by the manufacturer on the performance, operation and maintenance of portable suction equipment designed and constructed to be transported for use in non-permanent healthcare environments. This document also specifies requirements for the instructions to be supplied by the manufacturer on assembling, disassembling and packing for human transport between non-permanent healthcare environments.

This document does not apply to stationary dental equipment, wearable equipment (such as headlamps and loupes), mobile dental equipment or portable dental equipment that is not intended to be used in non-permanent healthcare environments or not designed to be disassembled, folded or packed for human transport between non-permanent healthcare environments. Also, requirements for stationary dental equipment that can be installed in a dental mobile medical facility (e.g. vehicular or containerized mobile dental clinic) are not considered in this document.

This document specifies requirements for portable suction equipment used to provide reduced pressure and flow at the cannula connector.

This document does not apply to portable suction equipment used for life support or for scavenging halogenated anaesthetic gases.

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 1942, *Dentistry — Vocabulary*

ISO 5167-1, *Measurement of fluid flow by means of pressure differential devices inserted in circular cross-section conduits running full — Part 1: General principles and requirements*

ISO 7494-2, *Dentistry — Stationary dental units and dental patient chairs — Part 2: Air, water, suction and wastewater systems*

ISO 9687, *Dentistry — Graphical symbols for dental equipment*

ISO 11143, *Dentistry — Amalgam separators*

ISO 23402-1:2020, *Dentistry — Portable dental equipment for use in non-permanent healthcare environment — Part 1: General requirements*

ISO 29463-1:2017, *High efficiency filters and filter media for removing particles from air — Part 1: Classification, performance, testing and marking*

IEC 60335-1, *Household and similar electrical appliances — Safety — Part 1: General requirements*

IEC 60601-1:2005, *+AMD1:2012+ AMD2:2020, Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 61000-6-2, *Electromagnetic compatibility (EMC) — Part 6-2: Generic standards — Immunity standard for industrial environments*

IEC 61000-6-3, *Electromagnetic compatibility (EMC) — Part 6-3: Generic standards — Emission standard for residential, commercial and light-industrial environments*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942, ISO 7494-2, ISO 23402-1, IEC 60335-1, IEC 60601-1, IEC 60601-1 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
air separator
apparatus which separates liquids and solids from the suction system air flow

[SOURCE: ISO 10637:2018, 3.1]

3.2
cannula connector
component at the inlet end of the dental suction operating hose, which joins the cannula to the operating hose

[SOURCE: ISO 10637:2018, 3.2]

3.3
suction machine
suction equipment component that produces pressure that is lower than atmospheric pressure

EXAMPLE Pump, side channel blower.

3.4
patient environment
area contained within the walls of an operatory or in the absence of walls, within a 1,5 m radius of the patient

Note 1 to entry: The area within a 1,5 m radius of the patient's body has been defined as the patient environment. See IEC 60601-1:2005, Figure A.9.

4 Classification

4.1 Applicable classifications

Classifications are in accordance with ISO 23402-1:2020, Clause 4, except those given in 4.2 and 4.3.

4.2 Classification according to the degree of integration and location

4.2.1 General

Portable suction equipment is classified according to the degree of integration into the dental unit and the distance from the patient.

4.2.2 Type A: Fully integrated

The suction machine, air separator, solids filter, suction operating hose and cannula connector are contained in the portable dental unit, which is located within the patient environment.

4.2.3 Type B: Remote

The suction machine is not contained in the portable dental unit and can be located outside the patient environment. The air separator and solids filter are integrated in either the portable dental unit or portable suction equipment or both.

4.2.4 Type C: Standalone

The suction machine, air separator, solids filter, suction operating hose and cannula connector are contained in a self-contained portable suction unit, which is located within the patient environment and separate from the portable dental unit.

4.3 Classification according to air flow rate

Portable suction equipment is classified according to the minimum air flow rate intended to be produced by the portable suction equipment under normal use conditions.

NOTE 1 This classification is intended to facilitate communication between parties involved in the specification, design, procurement, operation and maintenance of portable suction equipment.

NOTE 2 Reference conditions for normal litres (Nl) are defined in 7.1.2.

— Type 1 portable suction equipment is intended to supply a minimum air flow rate of 250 Nl/min at one suction cannula connector on the dental unit.

NOTE 3 Type 1 portable suction equipment is often commercially referred to as “high-volume suction” in certain regions.

— Type 2 portable suction equipment is intended to supply a minimum air flow rate of 170 Nl/min at one suction cannula connector on the dental unit.

— Type 3 portable suction equipment is intended to supply a minimum air flow rate of 90 Nl/min at one suction cannula connector on the dental unit.

NOTE 4 Type 3 portable suction equipment is often commercially referred to as “medium-volume suction” in certain regions.

These specified classifications do not restrict other specifications for minimum air flow rate that can be deemed appropriate in certain applications, regions or markets. In instances where none of the specified classifications are applicable, an alternative value may be specified for the minimum air volume flow rate, to be supplied by the manufacturer.

NOTE 5 The target performance indicated for each of these types of portable suction equipment is intended to assist in communicating the performance requirements of complete portable suction equipment. See also ISO 10637:2018, 4.2.

5 Requirements

5.1 General

Requirements are according to ISO 23402-1:2020, Clause 5 except where superseded by 5.2 to 5.10.

5.2 Protection against electric shock

If applicable, portable suction equipment classified as Class I in accordance with IEC 60601-1 shall have an external protective earth terminal or conductor, and the instructions for use shall include instructions for the connection to the earth.

Devices with a voltage of 24VAC or 34VDC or less, can be used without an external protective earth terminal or conductor, when specified in the instructions for use.

5.3 Safety requirements

For the safety requirements, the following requirements shall be applied according to the classification specified in 4.2.

— For portable suction equipment intended to be located within patient environment, the requirements of IEC 60601-1 shall apply.

  Testing shall be carried out in accordance with IEC 60601-1.

— For type B portable suction equipment intended to be located outside of patient environment, the requirements of IEC 60335-1 shall apply.

  Testing shall be carried out in accordance with IEC 60335-1.

5.4 Electromagnetic compatibility

For the electromagnetic compatibility (EMC), the following requirements shall be applied according to the classification specified in 4.2.

— For portable suction equipment intended to be located within patient environment, the requirements of IEC 60601-1-2 shall apply.

  Testing shall be carried out in accordance with IEC 60601-1-2.

— For type B portable suction equipment intended to be located outside of patient environment, the following requirements shall apply.

  — Immunity requirements of IEC 61000-6-2 shall apply.

  — Emission requirements of IEC 61000-6-3 shall apply.

  — Testing shall be carried out in accordance with IEC 61000-6-2 and IEC 61000-6-3.

5.5 Utility requirements

5.5.1 Compressed air supply

If applicable, the manufacturer shall specify the characteristics of the compressed air in the instructions for use, that is to be supplied to the portable suction equipment, including pressure and flow rate.

Compliance shall be checked in accordance with 7.4.2.