



SLOVENSKI STANDARD
oSIST prEN ISO 23402-3:2023
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**Zobozdravstvo - Prenosna dentalna oprema za začasno zdravstveno oskrbo - 3.
del: Prenosna sukcijska (aspiracijska) oprema (ISO/DIS 23402-3:2023)**

Dentistry - Portable dental equipment for use in non-permanent healthcare environment -
Part 3: Portable suction equipment (ISO/DIS 23402-3:2023)

Zahnheilkunde - Tragbare dentale Ausrüstung zur Anwendung in nicht-dauerhaften
Gesundheitseinrichtungen - Teil 3: Tragbare Absauggeräte (ISO/DIS 23402-3:2023)

Médecine bucco-dentaire - Matériel dentaire portatif utilisable dans des environnements
de soins de santé non permanents - Partie 3: Matériel d'aspiration portatif (ISO/DIS
23402-3:2023)

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Part 3: Portable suction equipment

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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 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 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 23402-3 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

This part of ISO 23402 specifies requirements and test methods pertaining to portable suction equipment for use 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 part of ISO 23402 focus on portability and certain technical aspects regarded by the working group to be appropriate for international standardization.

ISO 23402 is a series of standards (planned or published), with the objective of standardizing requirements for portable dental equipment for use in non-permanent healthcare environments. ISO 23402 consists of the following parts, under the general title, Dentistry — Portable dental equipment for use in non-permanent healthcare environments.

— Part 1: General requirements

The following parts are in preparation:

— Part 2: Portable dental units

— additional parts are planned to be added in the future

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

Part 3: Portable suction equipment

1 Scope

This document is a particular standard of ISO 23402 series that 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 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 does not apply to stationary suction equipment, mobile suction equipment or portable suction equipment that is intended to be used in clinical settings or not designed to be disassembled or packed for human transport between non-permanent healthcare environments.

Also, this document does not apply to stationary suction Equipment that may be installed in either a mobile dental facility (e.g. vehicular or containerized mobile dental clinic) or mobile medical facility, or both.

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.

In the ISO 23402 series, particular standards may modify, replace or delete requirements contained in the general standard, ISO 23402-1 and may add other basic safety and essential performance requirements.

A requirement of a particular standard takes priority over the general standard.

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 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*

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

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 23402-1:2020, IEC 60335-1, IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012/AMD2:2020 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

portable suction equipment component that produces pressure lower than atmospheric

EXAMPLE Pump, side channel blower.

3.4

suction system air flow

movement of air along a pipeline induced by a pressure difference

[SOURCE: ISO 10637:2018, 3.11]

3.5

patient environment

area contained within the walls of an operatory or in the absence of walls, within a 3 metre radius of the patient's mouth