ICS 11.060.20 SLOVENSKÁ TECHNICKÁ NORMA August 2024

STN	**Stomatológia Prenosné stomatologické vybavenie na použitie mimo zdravotníckeho zariadenia Časť 3: Prenosné odsávacie zariadenie (ISO 23402-3: 2024)**	**STN EN ISO 23402-3** 85 6400

Dentistry - Portable dental equipment for use in non-permanent healthcare environment - Part 3: Portable suction equipment (ISO 23402-3:2024)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 07/24

Obsahuje: EN ISO 23402-3:2024, ISO 23402-3:2024

138819

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 23402-3

May 2024

ICS 11.060.20

English Version

Dentistry - Portable dental equipment for use in non-permanent healthcare environment - Part 3: Portable suction equipment (ISO 23402-3:2024)

Médecine bucco-dentaire - Matériel dentaire portatif utilisable dans des environnements de soins de santé non permanents - Partie 3: Matériel d'aspiration portatif (ISO 23402-3:2024)

Zahnheilkunde - Tragbare dentale Ausrüstung zur Anwendung in nicht-dauerhaften Gesundheitseinrichtungen - Teil 3: Tragbare Absauggeräte (ISO 23402-3:2024)

This European Standard was approved by CEN on 22 March 2024.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN ISO 23402-3:2024 E

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European foreword

This document (EN ISO 23402-3:2024) has been prepared by Technical Committee ISO/TC 106 "Dentistry" in collaboration with Technical Committee CEN/TC 55 “Dentistry” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by November 2024, and conflicting national standards shall be withdrawn at the latest by November 2024.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a standardization request addressed to CEN by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 23402-3:2024 has been approved by CEN as EN ISO 23402-3:2024 without any modification.

International Standard

ISO 23402-3

First edition
2024-04

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

Reference number
ISO 23402-3:2024(en)

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

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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 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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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 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 aims to standardize requirements for portable dental equipment for use in non-permanent healthcare environments.

International Standard **ISO 23402-3:2024(en)**

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, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

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

IEC 60601-1:2005/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*

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+AMD1:2012+AMD2:2020, Figure A.9.