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STN	**Stomatológia Prenosné stomatologické vybavenie na použitie mimo zdravotníckeho zariadenia Časť 1: Všeobecné požiadavky (ISO 23402-1: 2020)**	**STN EN ISO 23402-1** 85 6400

Dentistry - Portable dental equipment for use in nonpermanent healthcare environment - Part 1: General requirements (ISO 23402-1:2020)

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. 12/20

Obsahuje: EN ISO 23402-1:2020, ISO 23402-1:2020

EUROPEAN STANDARD

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EUROPÄISCHE NORM

EN ISO 23402-1

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English Version

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

Médecine bucco-dentaire - Matériel dentaire portatif utilisable dans des environnements de soins de santé non permanents - Partie 1: Exigences générales (ISO 23402-1:2020)

Zahnheilkunde - Bewegliche dentale Ausrüstung zur Anwendung in nicht-permanenten Gesundheitseinrichtungen - Teil 1: Allgemeine Anforderungen (ISO 23402-1:2020)

This European Standard was approved by CEN on 3 October 2020.

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European foreword

This document (EN ISO 23402-1:2020) 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of an identical text or by endorsement, at the latest by April 2021, and conflicting national standards shall be withdrawn at the latest by April 2021.

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.

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The text of ISO 23402-1:2020 has been approved by CEN as EN ISO 23402-1:2020 without any modification.

INTERNATIONAL STANDARD

ISO 23402-1

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

Part 1: General requirements

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

Partie 1: Exigences générales

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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 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).

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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

Transportable dental equipment is used by dental professionals to provide care to patients in a variety of settings. Because the intended use applications and intended means for transporting such equipment vary considerably, a wide variety of transportable dental equipment is commercially available. For example, certain transportable equipment is designed and constructed to be carried or rolled on its own wheels between rooms within a healthcare facility, while other transportable dental equipment is made to be folded and packed to carry over terrain which can be rugged and used in transient dental care settings which can have only limited shelter and utility services.

Transportable equipment that can be moved from one location to another while being carried by one or more persons is referred to as portable equipment. The term, portable equipment, applies to equipment that can be carried from room to room in a given facility or to remote parts of the world. This document focuses on portable dental equipment which is specifically designed and constructed to be transported between non-clinical environments and used by dental professionals to provide dental care in such settings, including temporary field clinics.

Such portable dental equipment for use in non-permanent healthcare environments enables dental professionals to provide a high standard of care to patients who do not have access to, or are not able to, travel to traditional health care facilities. Settings in which this equipment is commonly used include military field environments, humanitarian aid field clinics, public health outreach clinics, patient residences, long-term care facilities, prisons, schools and workplaces.

A number of trends in health care have driven increased utilization of portable dental equipment in non-permanent healthcare environments. Military forces use portable dental equipment in support of mobilized forces or for humanitarian outreach. A variety of government and non-government organizations are increasingly providing humanitarian dental care to underserved populations and populations affected by disasters. Civilian health care workers are also increasingly providing dental services to a growing population who are simply unable to visit traditional dental clinics due to age, disability, or income. Academic and research bodies regularly conduct dental education programs, particularly at external/off-site locations (including dentistry, dental hygiene, dental assisting).

The transport and end-use conditions for portable dental equipment used in non-permanent healthcare environments drive certain unique requirements which generally do not apply to portable, mobile or stationary dental equipment used in traditional dental clinics or hospitals. Because portable equipment used in non-permanent healthcare environments is intended to be moved between venues, and in some cases carried over rugged terrain or in inclement conditions, it needs to be designed and constructed to be safely transported by humans without damage, be efficiently assembled and disassembled, and deliver reliable service at the point of use. Special consideration is given to the austerity of the environment in which the equipment can be used and the availability and quality of utility supplies (such as electrical power, water, compressed air). In order for the equipment to be sufficiently portable and capable of operating in extreme conditions, certain requirements for dental equipment intended for use in traditional clinical settings may not be practical and is to be reconsidered for portable dental equipment for use in non-permanent healthcare environments. There can also be unique safety and infection control concerns to consider.

This document is one in a series with the objective of standardizing requirements for portable dental equipment for use in non-permanent healthcare environments.

INTERNATIONAL STANDARD **ISO 23402-1:2020(E)**

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

Part 1: General requirements

1 Scope

This document specifies general requirements and test methods for portable dental equipment for use in non-permanent healthcare environments.

Portable dental equipment within the scope of this document includes portable dental units, portable patient chairs, portable operator's stools, portable operating lights, portable suction source equipment, portable air compressors and other portable dental equipment in instances where these devices are designed and constructed to be transported for use in non-permanent healthcare environments.

NOTE Particular requirements for specific types of portable dental equipment for use in non-permanent healthcare environments are specified in subsequent parts of this document.

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.

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 4180:2019, *Packaging — Complete, filled transport packages — General rules for the compilation of performance test schedules*

ISO 21530, *Dentistry — Materials used for dental equipment surfaces — Determination of resistance to chemical disinfectants*

IEC 60529:1989/Amd 1:1999, *Degrees of protection provided by enclosures (IP Code)*

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

IEC 62366-1, *Medical devices — Part 1: Application of usability engineering to medical devices*

IEC 80601-2-60, *Medical electrical equipment — Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment*

