



SLOVENSKI STANDARD
oSIST prEN ISO 5467-1:2022
01-januar-2022

**Zobozdravstvo - Mobilne zobozdravstvene enote in stoli za paciente - 1. del:
Splošne zahteve (ISO/DIS 5467-1:2021)**

Dentistry - Mobile dental units and patient chairs - Part 1: General requirements
(ISO/DIS 5467-1:2021)

Zahnheilkunde - Mobile Behandlungseinheiten und Patientenliegen - Teil 1: Allgemeine
Anforderungen (ISO/DIS 5467 1:2021)

Médecine bucco-dentaire - (Partie 1: Exigences générales (ISO/DIS 5467-1:2021)

Ta slovenski standard je istoveten z: EN prEN ISO 5467-1

<https://standards.iteh.ai/catalog/standards/sist/0f083a04-bf3b-4b9d-ae10-d5c66ebb1e23/osist-pr-en-iso-5467-1-2022>

ICS:

11.060.20 Zobotehnična oprema Dental equipment

oSIST prEN ISO 5467-1:2022

en,fr,de

**iTeh STANDARD
PREVIEW
(standards.iteh.ai)**

[oSIST prEN ISO 5467-1:2022](https://standards.iteh.ai/catalog/standards/sist/0f083a04-bf3b-4b9d-ae10-d5c66ebb1e23/osist-pren-iso-5467-1-2022)

<https://standards.iteh.ai/catalog/standards/sist/0f083a04-bf3b-4b9d-ae10-d5c66ebb1e23/osist-pren-iso-5467-1-2022>

DRAFT INTERNATIONAL STANDARD

ISO/DIS 5467-1

ISO/TC 106/SC 6

Secretariat: DIN

Voting begins on:
2021-11-23

Voting terminates on:
2022-02-15

Dentistry — Mobile dental units and patient chairs —

Part 1: General requirements

Partie 1: Exigences générales

ICS: 11.060.20

**iTeh STANDARD
PREVIEW
(standards.iteh.ai)**

[oSIST prEN ISO 5467-1:2022](https://standards.iteh.ai/catalog/standards/sist/0f083a04-bf3b-4b9d-ae10-d5c66ebb1e23/osist-pren-iso-5467-1-2022)

<https://standards.iteh.ai/catalog/standards/sist/0f083a04-bf3b-4b9d-ae10-d5c66ebb1e23/osist-pren-iso-5467-1-2022>

This document is circulated as received from the committee secretariat.

THIS DOCUMENT IS A DRAFT CIRCULATED FOR COMMENT AND APPROVAL. IT IS THEREFORE SUBJECT TO CHANGE AND MAY NOT BE REFERRED TO AS AN INTERNATIONAL STANDARD UNTIL PUBLISHED AS SUCH.

IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS.

RECIPIENTS OF THIS DRAFT ARE INVITED TO SUBMIT, WITH THEIR COMMENTS, NOTIFICATION OF ANY RELEVANT PATENT RIGHTS OF WHICH THEY ARE AWARE AND TO PROVIDE SUPPORTING DOCUMENTATION.

ISO/CEN PARALLEL PROCESSING



Reference number
ISO/DIS 5467-1:2021(E)

© ISO 2021

**iTeh STANDARD
PREVIEW
(standards.iteh.ai)**

[oSIST prEN ISO 5467-1:2022](https://standards.iteh.ai/catalog/standards/sist/0f083a04-bf3b-4b9d-ae10-d5c66ebb1e23/osist-pren-iso-5467-1-2022)

<https://standards.iteh.ai/catalog/standards/sist/0f083a04-bf3b-4b9d-ae10-d5c66ebb1e23/osist-pren-iso-5467-1-2022>



COPYRIGHT PROTECTED DOCUMENT

© ISO 2021

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

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

Contents

	Page
Foreword	iv
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Classification	2
5 Requirements	2
5.1 General requirements.....	2
5.1.1 Basic safety and essential performance.....	2
5.1.2 Controls and indicators.....	2
5.1.3 Function stop system.....	2
5.1.4 Usability.....	3
5.1.5 Cleaning and disinfection.....	3
5.1.6 Excessive temperatures.....	3
5.1.7 Biocompatibility.....	3
5.1.8 Solids filter.....	3
5.1.9 Amalgam separator device.....	3
5.1.10 Upholstery and padding.....	3
5.1.11 Air, water suction, and waste water systems.....	3
5.2 Mechanical requirements.....	4
5.2.1 General mechanical requirements.....	4
5.2.2 Mechanical requirements for mobile dental units.....	5
5.2.3 Mechanical requirements for mobile dental patient chairs.....	5
5.3 Electrical requirements.....	6
5.3.1 General electrical requirements.....	6
5.3.2 Test points for periodic safety checks.....	6
5.3.3 Position limiting of mobile dental patient chair.....	6
5.4 Test report.....	6
6 Sampling	6
7 Testing	6
7.1 Visual inspection.....	6
7.1.1 Visual inspection of device.....	6
7.1.2 Visual inspection of documentation or test reports.....	6
7.2 Mechanical tests.....	6
7.2.1 Measurement of solids filter.....	6
7.2.2 Pressure vessels and parts subject to pneumatic or hydraulic pressure.....	7
7.2.3 Headrest of mobile dental patient chair.....	7
7.2.4 Armrest of mobile dental patient chair.....	7
7.2.5 Vertical lift of mobile dental patient chair.....	7
7.2.6 Tipping and stability of mobile dental patient chair.....	7
7.3 Electrical tests.....	8
7.3.1 Position limiting of mobile dental patient chair.....	8
7.3.2 Function stop system of mobile dental patient chairs.....	8
8 Manufacturer's instructions	9
8.1 General.....	9
8.2 Instructions for use.....	9
8.3 Technical description.....	9
9 Marking	9
10 Packaging	9
Annex A (informative) Example of a test report	10
Bibliography	14

ISO/DIS 5467-1:2021(E)

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 106, *Dentistry*, Subcommittee SC 6, *Dental equipment*.

This first edition of ISO 5467-1 was developed in consideration of ISO 7494-1:2018 to be applicable to mobile dental units and dental patient chairs. The main changes compared to ISO 7494-1:2018 are as follows:

- the scope was limited to mobile dental units and dental patient chairs;
- instability and rough handling requirements were added to [5.2.1.4](#) and [5.2.1.5](#);
- requirement for locking in position was added to [5.2.1.6](#);
- requirement for dimension was added to [5.2.1.7](#);
- requirement for impact was added to [5.2.1.8](#).

A list of all parts in the ISO 5467 series can be found on the ISO website.

Dentistry — Mobile dental units and patient chairs —

Part 1: General requirements

1 Scope

This document specifies requirements and test methods for mobile dental units and dental patient chairs that is intended to be used within a permanent healthcare facility regardless of whether they are or not electrically powered.

This document also specifies requirements for the instructions for use, for the technical description, for marking and for packaging.

Operator's stools, stationary dental equipment, other types of mobile dental equipment, portable dental equipment and operating lights are not in the scope of 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 4073, *Dentistry — Information system on the location of dental equipment in the working area of the oral health care provider*

ISO 7494-1:2018, *Dentistry — Stationary dental units and dental patient chairs — Part 1: General requirements*

ISO 5467-2, *Dentistry — Mobile dental units and dental patient chairs — Part 2: Air, water, suction and wastewater systems*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

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

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

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

IEC 80601-2-60:2019, *Medical electrical equipment — Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942, ISO 4073, ISO 7494-1, ISO 23402-1, IEC 60601-1 and IEC 80601-2-60 and the following apply.

ISO/DIS 5467-1:2021(E)

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at <https://www.electropedia.org/>
- ISO Online browsing platform: available at <https://www.iso.org/obp>

3.1
mobile dental unit
mobile dental equipment (3.3) designed to provide utilities and amenities for dental treatment, such as compressed air, water or other liquids, suction, electricity, hand- or foot-activated controllers, work surfaces, tray supports, cuspidor, and gasses

3.2
mobile dental patient chair
mobile dental equipment (3.3) designed to support and position the patient for treatment and therefore provided with a range of movements

3.3
mobile dental equipment
 transportable dental equipment intended to be moved from one location to another while supported by its own wheels or equivalent means

Note 1 to entry: Mobile dental units and dental patient chairs are categorized into this group.

Note 2 to entry: The meaning of transport defined in the IEC 60601-1:2005+AMD1:2012+AMD2:2020, 9.4.2.1 is moving the mobile dental units and dental patient chairs from room to room during normal use.

4 Classification

Clause 4 of ISO 7494-1:2018 applies.

Test in accordance with [7.1.2.](#) [oSIST prEN ISO 5467-1:2022](https://standards.iteh.ai/catalog/standards/sist/0f083a04-bf3b-4b9d-ae10-d5c66ebb1e23/osist-pren-iso-5467-1-2022)
<https://standards.iteh.ai/catalog/standards/sist/0f083a04-bf3b-4b9d-ae10-d5c66ebb1e23/osist-pren-iso-5467-1-2022>

5 Requirements

5.1 General requirements

5.1.1 Basic safety and essential performance

The requirements specified in 5.1.1 of ISO 7494-1:2018 applies by replacing dental unit and dental patient chair with mobile dental unit and mobile dental patient chair.

Conformity shall be checked in accordance with IEC 60601-1 and IEC 80601-2-60.

5.1.2 Controls and indicators

The requirements and NOTE specified in 5.1.2 of ISO 7494-1:2018 applies.

Conformity shall be checked in accordance with IEC 60601-1:2005+AMD1:2012+AMD2:2020.

5.1.3 Function stop system

The requirements and EXAMPLE specified in 5.1.3 of ISO 7494-1:2018 applies by replacing dental unit and dental patient chair with mobile dental unit and mobile dental patient chair.

Test in accordance with [7.3.2.](#)

5.1.4 Usability

The requirements specified in 5.1.4 of ISO 7494-1:2018 applies.

Test in accordance with [7.1.2](#).

5.1.5 Cleaning and disinfection

The requirements specified in 5.1.5 of ISO 7494-1:2018 applies by replacing dental unit and dental patient chair with mobile dental unit and mobile dental patient chair.

Test in accordance with ISO 21530.

5.1.6 Excessive temperatures

The requirements specified in 5.1.6 of ISO 7494-1:2018 applies.

Test in accordance with IEC 60601-1:2005+AMD1:2012+AMD2:2020 and IEC 80601-2-60:2019.

5.1.7 Biocompatibility

The requirements specified in 5.1.7 of ISO 7494-1:2018 applies.

Biocompatibility shall be assessed in accordance with ISO 10993-1.

5.1.8 Solids filter

The requirements specified in 5.1.8 of ISO 7494-1:2018 applies by replacing dental unit with mobile dental unit.

Test in accordance with [7.2.1](#).

5.1.9 Amalgam separator device

The requirements specified in 5.1.9 of ISO 7494-1:2018 applies by replacing dental unit with mobile dental unit.

Test in accordance with [7.1.2](#).

5.1.10 Upholstery and padding

5.1.10.1 Resistance to liquid absorption

The requirements specified in 5.1.10.1 of ISO 7494-1:2018 applies.

Test in accordance with [7.1.1](#).

5.1.10.2 Flammability

The requirements specified in 5.1.10.2 of ISO 7494-1:2018 applies.

Conformity shall be checked in accordance with [7.1.1](#)

5.1.11 Air, water suction, and waste water systems

For air, water suction and waste water systems of the mobile dental units and dental patient chairs, ISO 5467-2 shall apply.

Test in accordance with ISO 5467-2.

ISO/DIS 5467-1:2021(E)

5.2 Mechanical requirements

5.2.1 General mechanical requirements

5.2.1.1 Moving parts

The requirements specified in 5.2.1.1 of ISO 7494-1:2018 applies.

Conformity shall be checked in accordance with IEC 60601-1:2005+AMD1:2012+AMD2:2020.

5.2.1.2 Pressure vessels and parts subject to pneumatic or hydraulic pressure

The requirements specified in 5.2.1.2 of ISO 7494-1:2018 applies by replacing dental unit and dental patient chair with mobile dental unit and mobile dental patient chair.

Test in accordance with [7.2.2](#).

5.2.1.3 Mechanical hazards associated with surfaces, corners and edges

The requirements specified in 5.2.1.3 of ISO 7494-1:2018 applies.

Conformity shall be checked in accordance with IEC 60601-1:2005+AMD1:2012+AMD2:2020.

5.2.1.4 Instability

IEC 60601-1:2005+AMD1:2012+AMD2:2020, 9.4 shall apply.

Conformity shall be checked in accordance with IEC 60601-1:2005+AMD1:2012+AMD2:2020.

5.2.1.5 Rough handling

IEC 60601-1:2005+AMD1:2012+AMD2:2020, 15.3.5 shall apply.

Conformity shall be checked in accordance with IEC 60601-1:2005+AMD1:2012+AMD2:2020.

5.2.1.6 Locking in position

Mobile dental unit and dental patient chair shall have a support system or means that can lock the position of the equipment to resist any further movement on the floor.

The locking system or means shall be capable of being engaged and disengaged.

Conformity shall be checked in accordance with [7.1.1](#).

5.2.1.7 Maximum dimension

Mobile dental unit and dental patient chair shall be able to fit through a door having a width of 0,8 m and a height of 2,0 m when moving the equipment to another location, and to be folded if necessary.

Test in accordance with [7.1.2](#).

NOTE This requirement is compatible with the minimum door sizes specified in the International Residential Code (IRC R311.4.2 Door Type and Size) and International Building Code (IBC 1008.1.1 Size of doors).

5.2.1.8 Impacts

IEC 60601-1:2005+AMD1:2012+AMD2:2020, 15.3.3 shall apply.

Conformity shall be checked in accordance with IEC 60601-1:2005+AMD1:2012+AMD2:2020.

5.2.2 Mechanical requirements for mobile dental units

5.2.2.1 Handpiece hoses

The requirements specified in 5.2.2.1 of ISO 7494-1:2018 applies by replacing dental unit with mobile dental unit.

Test out in accordance with [7.1.1](#).

5.2.3 Mechanical requirements for mobile dental patient chairs

5.2.3.1 Maximum patient mass and static loading

The requirements specified in 5.2.3.1 of ISO 7494-1:2018 applies by replacing dental patient chair with mobile dental patient chair and according to the [Table 1](#).

Table 1 — Patient mass distribution

Part of patient supported by mobile dental patient chair	Mass distribution %	Example: Mass distribution for 150 kg patient kg (rounded)
Head and neck	7,4	11
Upper trunk and upper arms	33,4	50
Lower trunk, lower arms and hands, thighs	40,7	61
Legs and feet	18,5	28
Total patient	100	150

Test in accordance with IEC 60601-1:2005+AMD1:2012+AMD2:2020 and IEC 80601-2-60:2019 under static load condition. <https://standards.iteh.ai/catalog/standards/sist/0f083a04-bf3b-4b9d-ae10-d5c66ebb1e23/osist-pren-iso-5467-1-2022>

5.2.3.2 Stability of headrest

The requirements specified in 5.2.3.2 of ISO 7494-1:2018 applies.

Test in accordance with [7.2.3](#).

5.2.3.3 Stability of armrests

The requirements specified in 5.2.3.3 of ISO 7494-1:2018 applies.

Test in accordance with [7.2.4](#).

5.2.3.4 Loading capacity and vertical lift

The requirements specified in 5.2.3.4 of ISO 7494-1:2018 applies by replacing dental patient chair with mobile dental patient chair.

Test in accordance with [7.2.5](#).

5.2.3.5 Tipping and stability

The requirements specified in 5.2.3.5 of ISO 7494-1:2018 applies by replacing dental patient chair with mobile dental patient chair when tested in accordance with [7.2.6](#).