
Dentistry — Mobile dental units and dental patient chairs —

Part 1: General requirements

*Médecine bucco-dentaire — Units dentaires et fauteuils dentaires
patient mobiles —*

Partie 1: Exigences générales

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Contents

Page

Foreword	iv
Introduction	v
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	2
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	5
5.3.1 General electrical requirements	5
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 Tipping and stability of mobile dental patient chair	6
8 Instructions for use	7
9 Technical description	8
10 Marking	8
11 Packaging	8
Annex A (informative) Example of a test report	9
Bibliography	13

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).

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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 5467 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 document was developed with consideration of ISO 7494-1:2018 to be applicable to mobile dental units and dental patient chairs by

- limiting the scope to mobile dental units and dental patient chairs,
- providing instability and rough handling requirements in [5.2.1.4](#) and [5.2.1.5](#),
- providing a requirement for locking in position in [5.2.1.6](#),
- providing a requirement for dimension in [5.2.1.7](#), and
- providing a requirement for impact to [5.2.1.8](#).

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Dentistry — Mobile dental units and dental patient chairs —

Part 1: General requirements

1 Scope

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

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

ISO 23402-1:2020, *Dentistry — Portable dental equipment for use in non-permanent healthcare environment — 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 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, IEC 80601-2-60 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

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

ISO 7494-1:2018, Clause 4 shall apply.

Test in accordance with 7.1.2.

5 Requirements

5.1 General requirements

5.1.1 Basic safety and essential performance

The requirements specified in ISO 7494-1:2018, 5.1.1 shall apply by replacing: dental unit and dental patient chair with mobile dental unit and mobile dental patient chair, IEC 60601-1:2005 + AMD1:2012 with IEC 60601-1:2005 + AMD1:2012 +AMD2:2020, and IEC 80601-2-60:2012 with IEC 80601-2-60:2019.

Test in accordance with 7.1.2.

5.1.2 Controls and indicators

The requirements including the NOTE specified in ISO 7494-1:2018, 5.1.2 shall apply by replacing IEC 60601-1:2005 + AMD1:2012 with IEC 60601-1:2005 + AMD1:2012 + AMD2:2020.

Test in accordance with 7.1.2.

5.1.3 Function stop system

The requirements including the EXAMPLE and the test methods specified in ISO 7494-1:2018, 5.1.3 and 7.3.2 shall apply by replacing dental patient chair with mobile dental patient chair.

Test in accordance with 7.1.2.

5.1.4 Usability

The requirements specified in ISO 7494-1:2018, 5.1.4 shall apply.

Test in accordance with 7.1.2.

5.1.5 Cleaning and disinfection

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

Test in accordance with [7.1.2](#).

5.1.6 Excessive temperatures

The requirements specified in ISO 7494-1:2018, 5.1.6 shall apply by replacing IEC 60601-1:2005 + AMD1:2012 with IEC 60601-1:2005 + AMD1:2012 + AMD2:2020 and IEC 80601-2-60:2012 with IEC 80601-2-60:2019.

Test in accordance with [7.1.2](#).

5.1.7 Biocompatibility

The requirements specified in ISO 7494-1:2018, 5.1.7 shall apply.

Test in accordance with [7.1.2](#).

5.1.8 Solids filter

The requirements and the test methods specified in ISO 7494-1:2018, 5.1.8 and 7.2.1 shall apply by replacing dental unit with mobile dental unit.

Test in accordance with [7.1.2](#).

5.1.9 Amalgam separator device

The requirements specified in ISO 7494-1:2018, 5.1.9 shall apply 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 ISO 7494-1:2018, 5.1.10.1 shall apply.

Test in accordance with [7.1.1](#).

5.1.10.2 Flammability

The requirements specified in ISO 7494-1:2018, 5.1.10.2 shall apply.

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 mobile dental units and dental patient chairs, ISO 5467-2 shall apply.

Test in accordance with ISO 5467-2.

5.2 Mechanical requirements

5.2.1 General mechanical requirements

5.2.1.1 Moving parts

The requirements specified in ISO 7494-1:2018, 5.2.1.1 shall apply by replacing IEC 60601-1:2005 + AMD1:2012 with IEC 60601-1:2005 + AMD1:2012 + AMD2:2020.

Test in accordance with [7.1.2](#).

5.2.1.2 Pressure vessels and parts subject to pneumatic or hydraulic pressure

The requirements and the test methods specified in ISO 7494-1:2018, 5.2.1.2 and 7.2.2 shall apply by replacing: dental unit and dental patient chair with mobile dental unit and mobile dental patient chair; and IEC 60601-1:2005 + AMD1:2012 with IEC 60601-1:2005 + AMD1:2012 + AMD2:2020.

Test in accordance with [7.1.2](#).

5.2.1.3 Mechanical hazards associated with surfaces, corners and edges

The requirements specified in ISO 7494-1:2018, 5.2.1.3 shall apply by replacing IEC 60601-1:2005 + AMD1:2012 with IEC 60601-1:2005 + AMD1:2012 + AMD2:2020.

Test in accordance with [7.1.2](#).

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

IEC 60601-1:2005 + AMD1:2012 + AMD2:2020, 9.4.3.2 shall apply.

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.

Testing shall be carried out in accordance with IEC 60601-1:2005 + AMD1:2012 + AMD2:2020, 9.4.3.2.

5.2.1.7 Maximum dimension

The requirements including the NOTE specified in ISO 23402-1:2020, 5.2.4 shall apply by replacing portable dental equipment with mobile dental unit and mobile dental patient chair.

Test in accordance with [7.1.2](#).

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

For handpiece hoses, the requirements specified in ISO 7494-1:2018, 5.2.2.1 shall apply by replacing dental unit with mobile dental unit.

Test 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 including the Table 1 specified in ISO 7494-1:2018, 5.2.3.1 shall apply by replacing: dental patient chair with mobile dental patient chair, IEC 60601-1:2005 + AMD1:2012 with IEC 60601-1:2005 + AMD1+2012 + AMD2:2020, and IEC 80601-2-60:2012 with IEC 80601-2-60:2019.

Test in accordance with [7.1.2](#).

5.2.3.2 Stability of headrest

The requirements and the test methods specified in ISO 7494-1:2018, 5.2.3.2 and 7.2.3 shall apply by replacing IEC 60601-1:2005 + AMD1:2012 and IEC 80601-2-60:2012 with IEC 60601-1:2005 + AMD1:2012 + AMD2:2020 and IEC 80601-2-60:2019.

Test in accordance with [7.1.2](#).

5.2.3.3 Stability of armrests

The requirements and the test methods specified in ISO 7494-1:2018, 5.2.3.3 and 7.2.4 shall apply.

Test in accordance with [7.1.2](#).

5.2.3.4 Loading capacity and vertical lift

The requirements and the test methods specified in ISO 7494-1:2018, 5.2.3.4 and 7.2.5 shall apply by replacing dental patient chair with mobile dental patient chair.

Test in accordance with [7.1.2](#).

5.2.3.5 Tipping and stability

The requirements specified in ISO 7494-1:2018, 5.2.3.5 shall apply by replacing dental patient chair with mobile dental patient chair.

Test in accordance with [7.2](#).

5.3 Electrical requirements

5.3.1 General electrical requirements

The requirements specified in ISO 7494-1:2018, 5.3.1 shall apply by replacing: dental unit and dental patient chair with mobile dental unit and mobile dental patient chair, IEC 60601-1:2005 + AMD1:2012 with IEC 60601-1:2005 + AMD1:2012 + AMD2:2020, and IEC 80601-2-60:2012 with IEC 80601-2-60:2019.

Test in accordance with [7.1.2](#).