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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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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).

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).

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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 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.

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 80601-2060:2019.

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.

5.3.2 Test points for periodic safety checks

The requirements including the NOTE specified in ISO 7494-1:2018, 5.3.2 shall apply by replacing dental unit and dental patient chair with mobile dental unit and mobile dental patient chair.

Test in accordance with 7.1.1.

5.3.3 Position limiting of mobile dental patient chair

The requirements including the EXAMPLE and the test methods specified in ISO 7494-1:2018, 5.3.3 and 7.3.1 shall apply by replacing dental patient chair with mobile dental patient chair.

Test in accordance with 7.1.2.

5.4 Test report

A test report shall be prepared to report the results of all applicable testing and inspection requirements specified in this document.

The test report shall at least include the following information:

— the standard used, i.e. ISO 5467-1:2022;

— the method used (if the standard includes several);

— the result(s), including a reference to the clause which explains how the results were calculated;

— if present, any deviations from the procedure;

— if present, any unusual features observed;

— the date of the test.

An example for a test report template is given in Annex A.

6 Sampling

Where possible, all type tests shall be carried out with one representative sample of either the mobile dental unit or dental patient chair, or both being tested.

7 Testing

7.1 Visual inspection

7.1.1 Visual inspection of device

Visually inspect the device to determine conformity with the requirements.

7.1.2 Visual inspection of documentation or test reports

Visually inspect product documentation or test reports to determine conformity with the requirements.

7.2 Tipping and stability of mobile dental patient chair

A test fixture is required which has a vertical post that can be securely attached to the seat of the mobile dental patient chair and a rigid arm extending horizontally from the vertical post capable of supporting a 400 N downward load applied 100 cm ± 1 cm from the vertical post. The vertical post shall be sufficiently long to allow the horizontal arm to be positioned at 45° increments in the horizontal

plane, starting along the longitudinal axis of the mobile dental patient chair under the conditions specified below. See Figure 1.

Place in position and lock the position of the mobile dental patient chair on the floor according to the manufacturer's instructions. Attach the test fixture to the seat of the mobile dental patient chair where the patient sits when the backrest is in the fully upright position.

The test shall be performed at each 45° increment of the horizontal arm position with an unloaded (i.e. no patient load) mobile dental patient chair positioned in the most adverse (i.e. unstable) position. Any movable parts, such as support arms, shall be loaded with their maximum load and adjusted to the most adverse position. Apply a load of 400 N vertically downward to the horizontal post of the test fixture at 1 m from the vertical post.

Dimensions in centimetres

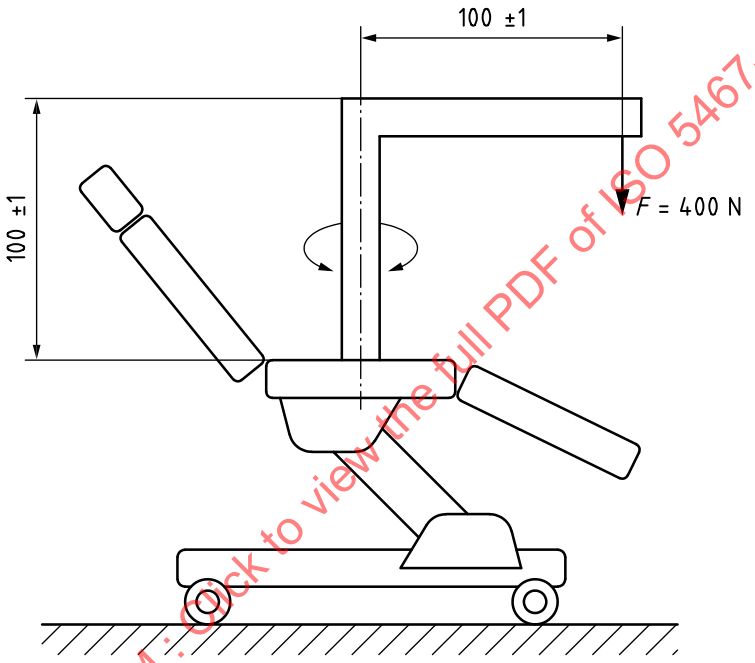

Figure 1 — Example of a test fixture (rotatable around the vertical post)

Observe whether the mobile dental patient chair overbalances and measure whether the maximum distance that the part specified in 5.2.1.6 lifts off the ground around its perimeter exceeds 5 mm.

Repeat the test at each of the 45° increments of the horizontal arm position (eight positions). It is permitted to exclude positions of the horizontal arm that are known to be less adverse than other positions with justification.

Testing without upholstery is permitted, but the mass of the upholstery shall be considered.

8 Instructions for use

The requirements specified in ISO 7494-1:2018, 8.1 and 8.2 shall apply by replacing: dental unit and dental patient chair with mobile dental unit and 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.

In addition, and if applicable, the manufacturer shall provide the following information in the instructions for use: precautions regarding the movement of either the mobile dental unit or dental patient chair, or both.

Conformity shall be checked in accordance with 7.1.2.

9 Technical description

The requirements specified in ISO 7494-1:2018, 8.1 and 8.3 shall apply by replacing: dental unit and dental patient chair with mobile dental unit and dental patient chair, and IEC 60601-1:2005 + AMD1: 2012 with IEC 60601-1:2005 + AMD1:2012 + AMD2:2020.

Conformity shall be checked in accordance with 7.1.2.

10 Marking

The requirements specified in ISO 7494-1:2018, Clause 9 shall apply by replacing IEC 60601-1:2005 + AMD1:2012 with IEC 60601-1:2005 + AMD1:2012 + AMD2:2020.

Conformity shall be checked in accordance with 7.1.2.

11 Packaging

The requirements specified in ISO 7494-1:2018, Clause 10 shall apply by replacing: dental units and dental patient chairs with mobile dental units and dental patient chairs, and IEC 60601-1:2005 + AMD1: 2012 with IEC 60601-1:2005 + AMD1:2012 + AMD2:2020.

Conformity shall be checked in accordance with 7.1.2.

Annex A
(informative)

Example of a test report

Table A.1 — Test report (cover page)

Test report no.:	
Name of product:	
Name and address of the applicant/client:	
Name and address of the manufacturer:	
Name and address of the factory/manufacturing site:	
Brand/Trademark (if applicable):	
Model/Type no.:	
Rated values and principal characteristics:	
Applied International Standard, which a sample of the product was tested and in conformity with:	ISO 5467-1:2022
Additional information (if necessary):	
Information about modifications:	
This test report was issued by: (name and address of the test house/certification body/manufacturer)	
Date:	
Test by: (name and signature)	
Approved by: (name and signature)	

Table A.2 — Test report (check list)

ISO 5467-1:2022		TEST REPORT REFERENCE NUMBER:			
CLAUSE NO.	REQUIREMENTS/DESCRIPTION	CONFORMITY/VERDICT			
		PASS	FAIL	N/A	Results, observations, notes, or comments
6	The test device under testing is a representative sample?				
4	Is the test device classified according to IEC 60601-1:2005 + AMD1:2012 + AMD2: 2020, 6 and IEC 80601-2–60:2019, 201.6?				
5.1.1	Positive test report according to IEC 60601-1:2005 + AMD1:2012 + AMD2: 2020 and IEC 80601-2–60:2019 available?				
5.1.2	Positive test report according to IEC 60601-1:2005 + AMD1:2012 + AMD2: 2020, 15.1 available?				
5.1.3	Instant stop of movement for all test conditions?				
5.1.4	Usability documentation according to IEC 62366-1 available?				
5.1.5	Positive test report according to ISO 21530 available?				
5.1.6	Positive test report according to IEC 60601-1:2005 + AMD1:2012 + AMD2: 2020, 11.1 and IEC 80601-2–60:2019, 201.11 available?				
5.1.7	Positive test report according to ISO 10993-1 available?				
5.1.8	Does the solids filter retain particles with a diameter of ≥ 2 mm?				
5.1.9	Positive test report for the amalgam separator according to ISO 11143 available?				
5.1.10.1	Is the covering upholstery resistant to liquid absorption?				
5.1.10.2	Does the upholstery and padding not ignite and is the charring not greater in length than 30 mm in any direction measured from the nearest point of the test cigarette?				
5.1.11	Positive test report according to ISO 5467-2 available?				
5.2.1.1	Positive test report according to IEC 60601-1:2005 + AMD1:2012 + AMD2: 2020, 9.2 available?				
5.2.1.2	Pressure vessels and parts subject to pneumatic and hydraulic pressure withstand test conditions without bursting or leaking?				
5.2.1.3	Positive test report according to IEC 60601-1:2005 + AMD1:2012 + AMD2: 2020, 9.3 available?				
5.2.1.4	Positive test report according to IEC 60601-1:2005 + AMD1:2012 + AMD2: 2020, 9.4 available?				