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Dentistry — Stationary dental units and dental patient chairs —

Part 1: General requirements

Médecine bucco-dentaire — Units dentaires fixes et fauteuils dentaires patient —

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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This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 6, *Dental equipment*.

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Dentistry — Stationary dental units and dental patient chairs —

Part 1: General requirements

1 Scope

This document specifies requirements and test methods for stationary dental units, dental patient chairs, and combinations of both 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, 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.

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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*

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ISO 7494-2, *Dentistry — Dental units — Part 2: Air, water, suction and wastewater systems*

ISO 8191-1, *Furniture — Assessment of the ignitability of upholstered furniture — Part 1: Ignition source: smouldering cigarette*

ISO 9168, *Dentistry — Hose connectors for air driven dental handpieces*

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

ISO 11143, *Dentistry — Amalgam separators*

ISO 17664, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices*

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

IEC 60601-1:2005+AMD1:2012, *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 62353, *Medical electrical equipment — Recurrent test and test after repair of medical electrical equipment*

IEC 80601-2-60:2012, *Medical electrical equipment — Part 2-60: Particular requirements for basic safety and essential performance of dental equipment*

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3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942, ISO 4073, IEC 60601-1:2005 + AMD1:2012 and IEC 80601-2-60:2012 and the following apply.

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

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at https://www.iso.org/obp

3.1
dental unit
assembly of devices 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
dental patient chair
device designed to support and position the patient for treatment and therefore provided with a range of movements

3.3
dental handpiece
handheld instrument used in dentistry for use in patient treatment and connected to the *dental unit* (3.1)

[SOURCE: IEC 80601-2-60:2012, 201.3.203]

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4 Classification

Classification according to IEC 60601-1:2005 + AMD1:2012 and IEC 80601-2-60:2012 shall apply.

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5 Requirements

5.1 General requirements

5.1.1 Basic safety and essential performance

IEC 60601-1:2005 + AMD1:2012 and IEC 80601-2-60:2012 shall apply to dental units, to electrical dental patient chairs and to non-electrical dental patient chairs.

Conformity shall be checked in accordance with IEC 60601-1:2005 + AMD1:2012 and IEC 80601-2-60:2012.

5.1.2 Controls and indicators

Controls and indicators shall be designed and located to minimize accidental activation. For arrangement of controls and indicators IEC 60601-1:2005 + AMD1:2012, 15.1 shall apply.

NOTE Standardized graphical symbols for controls and indicators are specified in ISO 9687.

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

5.1.3 Function stop system

Electrically powered dental patient chairs shall incorporate at least one function stop system which is located so that it can be easily activated by the operating personnel and which, when activated, instantly

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stops all powered movements of the dental patient chair that could be hazardous to the patient and/or the operating personnel.

EXAMPLE A foot control capable of immediately stopping all powered movements of the dental patient chair is a suitable function stop system.

Testing shall be carried out in accordance with 7.3.2.

5.1.4 Usability

Usability evaluation shall be carried out following the process described in IEC 62366-1.

Testing shall be carried out in accordance with IEC 62366-1.

5.1.5 Cleaning and disinfection

All materials used for external and touchable surfaces of the dental unit and dental patient chair which can be contaminated by aerosols, splatters and droplets in normal use shall be capable to be cleaned and disinfected without deterioration or discoloration when tested in accordance with ISO 21530 and using the relevant cleaning agents and disinfectant agents recommended by the manufacturer.

Testing shall be carried out in accordance with ISO 21530.

5.1.6 Excessive temperatures

IEC 60601-1:2005 + AMD1:2012, 11.1 and IEC 80601-2-60:2012, 201.11 shall apply.

Testing shall be carried out in accordance with IEC 60601-1:2005 + AMD1:2012 and IEC 80601-2-60:2012.

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5.1.7 Biocompatibility

ISO 10993-1 shall apply.

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

5.1.8 Solids filter

Dental units with a waste water system shall contain a solids filter. The solids filter shall be capable of retaining solid particles with a diameter of ≥ 2 mm.

Testing shall be carried out in accordance with 7.2.1.

5.1.9 Amalgam separator device

If the dental unit is equipped with or capable to be equipped with an amalgam separator device, this device shall conform to ISO 11143.

Testing shall be carried out in accordance with 7.1.2.

5.1.10 Upholstery and padding

5.1.10.1 Resistance to liquid absorption

Covering upholstery materials shall be resistant to liquid absorption.

Testing shall be carried out in accordance with 7.1.1.

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5.1.10.2 Flammability

Testing shall be carried out in accordance with ISO 8191-1.

When tested, the upholstery and padding shall not ignite. Resultant charring, if any, shall be not greater in length than 30 mm in any direction measured from the nearest point of the test cigarette.

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 dental units and dental patient chairs ISO 7494-2 shall apply.

Testing shall be carried out in accordance with ISO 7494-2.

5.2 Mechanical requirements

5.2.1 General mechanical requirements

5.2.1.1 Moving parts

IEC 60601-1:2005 + AMD1:2012, 9.2 shall apply.

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

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5.2.1.2 Pressure vessels and parts subject to pneumatic or hydraulic pressure

Pressure vessels and parts subject to pneumatic or hydraulic pressure used in dental units and dental patient chairs shall be capable of withstanding, without bursting or leaking, the pressure test specified in 7.2.2.

5.2.1.3 Mechanical hazards associated with surfaces, corners and edges

IEC 60601-1:2005 + AMD1:2012, 9.3 shall apply.

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

5.2.1.4 Stability of support systems

IEC 60601-1:2005 + AMD1:2012, 9.4 and 9.8 shall apply.

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

5.2.2 Mechanical requirements for dental units

5.2.2.1 Handpiece hoses

Handpiece hoses connected to the dental unit should be disconnectable for cleaning and disinfection.

For hoses for air driven dental handpieces ISO 9168 shall apply.

For hoses for other dental handpieces the hose connector is determined by the manufacturer.

Testing shall be carried out in accordance with 7.1.1.

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5.2.3 Mechanical requirements for dental patient chairs

5.2.3.1 Maximum patient mass and static loading

The maximum patient mass shall be specified by the manufacturer and shall be at least 150 kg. The mass distribution to be used in testing shall be in accordance with Table 1.

If the patient chair is intended to support a patient mass greater than 150 kg, the mass distribution shall be distributed proportionally according to the %-values given in Table 1.

Table 1 — Patient mass distribution

Part of patient supported by 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

The static loading requirements of IEC 60601-1:2005 + AMD1:2012, 9.8 and IEC 80601-2-60:2012, 201.9 shall apply when the dental patient chair is in the most unfavourable position.

Testing shall be carried out in accordance with IEC 60601-1:2005 + AMD1:2012 and IEC 80601-2-60:2012 under static load condition.

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5.2.3.2 Stability of headrest

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The headrest shall be capable of withstanding the force specified in 7.2.3 without failure and without risk to the patient or operating personnel. This force simulates unintentional movements and the weight of the patient's head, including any additional load applied by the operating personnel and the force imparted to the headrest by the patient due to arching of his/her body.

Testing shall be carried out in accordance with 7.2.3.

5.2.3.3 Stability of armrests

Armrests, if provided, shall be capable of withstanding, without failure or permanent deformation the force specified in 7.2.4. Armrests designed to be movable horizontally or vertically shall be capable of withstanding the loads specified in 7.2.4 without their function becoming permanently impaired.

Testing shall be carried out in accordance with 7.2.4.

5.2.3.4 Loading capacity and vertical lift

Dental patient chairs shall be capable of supporting and lifting the maximum patient mass specified by the manufacturer, distributed according to Table 1, plus the movable mass of additional mounted items, plus any accessory devices specified by the manufacturer as additional lifting capability. The dental patient chair shall not sink more than 10 mm in 1 h.

Testing shall be carried out in accordance with 7.2.5.

5.2.3.5 Tipping and stability

The dental patient chair shall not overbalance and no part of the base edge shall lift off of the ground by more than 5 mm when tested in accordance with 7.2.6.

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