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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

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).

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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 third edition of ISO 7494-1 cancels and replaces ISO 7494-1:2011 and ISO 6875:2011, which has been technically revised.

A list of all parts in the ISO 7494 series can be found on the ISO website.

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.

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 7494-2, *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*

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]

4 Classification

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

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

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.

5.1.7 Biocompatibility

ISO 10993-1 shall apply.

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.

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.

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.

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.

5.2.3.2 Stability of headrest

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.

5.3 Electrical requirements

5.3.1 General electrical requirements

Electrical requirements are only applicable to electrically operated dental units and dental patient chairs.

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

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

5.3.2 Test points for periodic safety checks

In order to perform the safety checks specified in IEC 62353, dental units and dental patient chairs shall have a connector/plug for the power supply.

Testing shall be carried out in accordance with 7.1.1.

NOTE To simplify the periodic safety checks a plug is preferred.

5.3.3 Position limiting of dental patient chair

In case of a single-fault condition of a limit switch or other means controlling dental patient chair movement, additional protective means shall be provided.

EXAMPLE Mechanical limits to prevent injury to the patient and/or operating personnel.

Testing shall be carried out in accordance with 7.3.1

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.

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 the dental unit and/or dental patient chair 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 Mechanical tests

7.2.1 Measurement of solids filter

Check the solids filter mesh size with readily available measuring instruments.

7.2.2 Pressure vessels and parts subject to pneumatic or hydraulic pressure

All pressure vessels and parts subject to pneumatic or hydraulic pressure shall be tested in accordance with IEC 60601-1:2005 + AMD1:2012, 9.7.

The parts of a pneumatic or hydraulic system that are used as a support system for the dental patient chair shall be tested regardless of the pressure and volume of the pressurized system in accordance with 9.7.5 of IEC 60601-1:2005 + AMD1:2012 (independent of the two conditions specified in the first paragraph of 9.7.5).

7.2.3 Headrest of dental patient chair

Position the dental patient chair in the fully reclined position with the headrest fully extended. Apply a force at the centre of the headrest in a vertically downward direction corresponding to 7,4 % of the maximum patient mass (see Table 1, head and neck) and the weight of the headrest itself, applying the relevant safety factors given in IEC 60601-1:2005 + AMD1:2012, 9.8.2 and IEC 80601-2-60:2012, Table 201.102

Test in accordance with IEC 60601-1:2005 + AMD1:2012, 9.8 and IEC 80601-2-60:2012, 201.9.8.2.

7.2.4 Armrest of dental patient chair

If the armrest is designed to be moveable, adjust it to the position for use with a seated patient receiving dental treatment.

At the most critical location on the armrest, apply a force of 670 N vertically downwards for 1 min and subsequently apply a force of 440 N horizontally, in the inward and outward directions for 1 min in each direction.

7.2.5 Vertical lift of dental patient chair

Subject the test piece to a mass distributed in accordance with Table 1, plus the additional mass of items mounted on the dental patient chair as specified by the manufacturer as maximum lifting capability.

Activate the test piece for three uninterrupted up-and-down movements. Then operate the test piece intermittently three times using the control switch, performing three further complete up-and-down movements and position the seat of the test piece in a middle position.

Measure the height of the seat. Leave the test piece under load in the same position for 1 h. Then measure the height of the seat again and calculate the distance by which it has sunk.

7.2.6 Tipping and stability of dental patient chair

A test fixture is required which has a vertical post that can be securely attached to the seat of the 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 dental patient chair under the conditions specified below. See Figure 1.

Install the dental patient chair according to the manufacturer's instructions. Attach the test fixture to the seat of the 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) 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

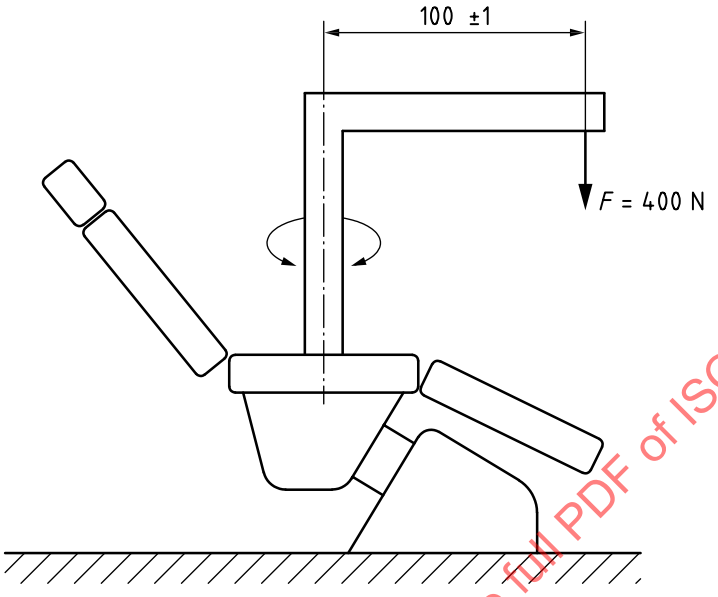

Figure 1 — Example of test fixture (rotatable around the vertical post)

Observe whether the dental patient chair overbalances and measure whether the maximum distance that the base edge 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.

7.3 Electrical tests

7.3.1 Position limiting of dental patient chair

If the dental patient chair is power-activated and controlled by limit switches or other active means, deliberately bypass such means one by one (single-fault condition). Then operate the test piece through its full range of power-activated motion to ensure that it does not result in collapse of the test piece or damage to the test piece that would be harmful to the patient or to the operating personnel.

7.3.2 Function stop system

For each function that induces electrically powered movement of the dental patient chair that can be hazardous to the patient and/or the operating personnel, activate the function and then the function stop system. Confirm that the movement stops instantly.

8 Manufacturer's instructions

8.1 General

Instructions for use and/or other technical descriptions can be provided in printing and/or electronic form, if electronic form is permissible under local law where the product is placed.

Documents, if applicable, shall be provided containing at least the information specified in 8.2 to 8.3.

IEC 60601-1:2005 + AMD1:2012, 7.9.1 shall apply.

Conformity shall be checked in accordance with 7.1.2.

8.2 Instructions for use

IEC 60601-1:2005 + AMD1:2012, 7.9.2 and IEC 80601-2-60: 2012, 201.7.9.2 shall apply.

In addition and if applicable, the manufacturer shall provide the following information in the instructions for use:

a) instructions as specified in ISO 17664 for cleaning, disinfection and sterilization;

b) the maximum patient mass;

c) warning statements for the use of dental units and/or dental patient chairs in conjunction with other equipment that can move;

d) maximum loading capabilities for third party equipment attachments on dental units;

e) explanations for all symbols used in the product marking;

f) step-by-step procedures for operation, routine maintenance and basic trouble shooting with explanations of each control, indicator and any other feature relevant for the intended use and safe operation of the dental unit and/or dental patient chair.

Conformity shall be checked in accordance with 7.1.2.

8.3 Technical description

IEC 60601-1:2005 + AMD1:2012, 7.9.3.1, 7.9.3.2 and 7.9.3.3 shall apply.

If applicable, the manufacturer shall provide the following additional information:

a) overall dimensions;

b) overall dimensions of the base plate and service location interfaces;

c) minimum space requirements and recommendations for installation within the dental treatment room;

d) overall movements, including the maximum range of rotation for all swivel arms;

e) details of interface surfaces and methods of retention (e.g. bolts), electrical supplies and other services;

f) information on the assembly and mounting;

g) mass;

h) maximum support and/or lifting capability: if the dental unit or the dental patient chair is intended to carry additional items, the maximum mass of such items shall be indicated;

i) electrical characteristics including wiring diagram, input requirements (e.g. voltage and frequency), fuse values and output characteristics;

j) air and water input requirements (e.g. pressure and flow rate) and output characteristics, including diagram of piping for air, water, suction and waste water;

k) maximum allowable load and maximum movement of the dental unit and its accessories in the most unfavourable position;

l) maximum allowable load of non-chair-mounted dental units;

m) maximum allowable load of the working surface in its most unfavourable position;

n) standard attachments that the dental unit and the dental patient chair are designed to accept and loading capabilities for these attachments;

o) full fluid characteristics for the input and output connections if applicable;

p) list of spare parts that are required in general use;

q) working pressures of pressure systems;

r) transport and storage conditions (e.g. humidity, temperature and air pressure);

s) operating environment conditions (including at least humidity, temperature conditions and air pressure);

t) information on waste disposal and recycling of the dental unit and the dental patient chair;

u) maximum torque capability for accessory mountings: if the dental patient chair is intended to carry additional items, the maximum mass of such items shall be indicated;

v) The full range of motion for dental patient chairs.

Conformity shall be checked in accordance with 7.1.2.

9 Marking

9.1 Product marking

IEC 60601-1:2005 + AMD1:2012, Clause 7 shall apply.

Symbols used for controls and performance should be in accordance with ISO 9687 and ISO 15233-1 if applicable.

If appropriate symbols are not found in ISO 9687, other symbols are permissible.

Conformity shall be checked in accordance with IEC 60601-1:2005 + AMD1:2012, Clause 7.

9.2 Marking of packaging

All packages shall be marked on the outside to facilitate the assembly and installation.

IEC 60601-1:2005 + AMD1:2012, 7.2.17 shall apply.

Conformity shall be checked in accordance with IEC 60601-1:2005 + AMD1:2012, 7.2.17.

10 Packaging

Dental units and dental patient chairs shall be packaged for transportation at the discretion of the manufacturer in such a way that no damage can occur during anticipated transport conditions.

IEC 60601-1:2005 + AMD1:2012, 7.2.17 shall apply.

Conformity shall be checked in accordance with IEC 60601-1:2005 + AMD1:2012, 7.2.17.

Annex A
(informative)

Example of a test report

Test report no.:	
Product:	
Name and address of the applicant/client:	
Name and address of the manufacturer:	
Name and address of the factory:	
Brand (if any):	
Model/Type ref.:	
Rating and principal characteristics:	
A sample of the product was tested and found to be in conformity with the International Standard:	ISO 7494-1
Additional information (if necessary):	
Information about modifications:	
This test report is issued by testing/certification institute:	
Name and address:	
Date:	
Test by: (name + signature)	
Approved by: (name + signature)	

ISO 7494-1:2018		TEST REPORT REFERENCE NUMBER:			
CLAUSE NO.	REQUIREMENTS/DESCRIPTION	CONFORMITY/VERDICT			
		PASS	FAIL	N/A	Results, observations, notes, or comments
6.	The product under testing is a representative sample?				
4.	Is the product classified according to IEC 60601-1:2005 + AMD1:2012 and IEC 80601-2–60:2012, 201.11?				
5.1.1	Positive test report according to IEC 60601-1:2005 + AMD1:2012 and IEC 80601-2–60:2012 available?				
5.1.2	Positive test report according to IEC 60601-1:2005 + AMD1:2012, 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, 11.1 and IEC 80601-2–60:2012, 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 7494-2 available?				
5.2.1.1	Positive test report according to IEC 60601-1:2005 + AMD1:2012, 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, 9.3 available?				
5.2.1.4	Positive test report according to IEC 60601-1:2005 + AMD1:2012, 9.4 and 9.8 available?				
5.2.2.1	Handpiece hoses can be disconnected from the dental unit?				
5.2.2.1	Positive test report according to ISO 9168 available for hand piece hoses?				
5.2.3.1	Maximum patient mass specified by the manufacturer and at least 150 kg?				
5.2.3.1	Product can support maximum patient mass specified by the manufacturer under test conditions?				
5.2.3.1	Product can withstand static loading in most unfavourable position under requirements of IEC 60601-1:2005 + AMD1:2012, 9.8 and IEC 80601-2–60:2012, 201.9?				
5.2.3.2	Headrest can withstand a force corresponding to 7,4 % of the maximum patient mass under test conditions?				
5.2.3.3	Armrests can withstand a force of 670N vertically downwards for 1 min under test conditions?				
5.2.3.3	Armrests can withstand a force of 440N horizontally for 1 min under test conditions?				
5.2.3.4.	Products are capable to support and lift the maximum patient weight plus additional specified masses under test conditions?				
5.2.3.5	Product does not overbalance or no part of the base edge lifts of the ground by more than 5 mm under test conditions?				
5.3.1	Positive test report according to IEC 60601-1:2005 + AMD1:2012 and IEC 80601-2–60:2012 for electrical requirements available?				
5.3.2	Product does have a connector/plug for power supply?				
5.3.3	Product does not collapse or is damaged if tested under test conditions in a way that is harmful to patients or operating personnel?				
8.1	Positive test report according to IEC 60601-1:2005 + AMD1:2012, 7.9.1 available?				
8.2	Instructions for use for the product available?				