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**Dentistry — Dental units —**  
**Part 1:**  
**General requirements and test methods**

*Art dentaire — Units dentaires —*

*Partie 1: Exigences et méthodes d'essai générales*

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## Foreword

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International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 7494-1 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 6, *Dental equipment*.

This first edition of ISO 7494-1 cancels and replaces ISO 7494:1996, of which it constitutes a minor revision.

ISO 7494 consists of the following parts, under the general title *Dentistry — Dental units*:

- *Part 1: General requirements and test methods*
- *Part 2: Water and air supply*



# Dentistry — Dental units —

## Part 1: General requirements and test methods

### 1 Scope

This part of ISO 7494 specifies requirements and test methods for dental units, regardless of whether or not they are electrically powered.

It also specifies requirements for manufacturer's instructions, marking and packaging.

This part of ISO 7494 is one of a series of International Standards based on IEC 60601-1; in IEC 60601-1 (the "General Standard"), this type of International Standard is referred to as a "Particular Standard". As stated in IEC 60601-1:1988, 1.3, the requirements of this part of ISO 7494 take precedence over those of IEC 60601-1.

### 2 Normative references

The following referenced documents are indispensable for the application 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 6875, *Dental patient chair*

ISO 9687, *Dental equipment — Graphical symbols*

IEC 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety*

### 3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1 and ISO 1942 (some of which are repeated below for convenience) apply.

#### 3.1

##### **dental equipment**

furniture, machines, apparatus and accessories thereto, specially manufactured and/or presented for the use of authorized persons in the practice of dentistry and/or its associated procedures

[ISO 1942]

3.2

**dental unit**

item of dental equipment consisting of an assembly of interconnected sub-units of dental equipment and instruments providing a functional unit for dental use

[ISO 1942]

**4 Classification**

**4.1 According to type of protection against electric shock**

Dental units may be classified as follows.

**a) Class I equipment**

Equipment in which protection against electric shock does not rely on basic insulation only, but which includes an additional safety precaution in such a way that means are provided for the connection of accessible conductive parts to the protective (earth) conductor in the fixed wiring of the installation so that accessible conductive parts cannot become live in the event of a failure of the basic insulation.

**b) Class II equipment**

Equipment in which protection against electric shock does not rely on basic insulation only, but in which additional safety precautions such as double insulation or reinforced insulation are provided, there being no provision for protective earthing or reliance upon installation conditions.

**4.2 According to degree of protection against electric shock**

Dental units may be grouped by type as follows.

**a) Type B equipment**

Class I or II equipment or equipment with an internal electrical power source providing an adequate degree of protection against electric shock, particularly regarding

- allowable leakage currents;
- reliability of the protective earth connection (if present).

Type B equipment is, for example, suitable for intentional external and internal application to the patient, excluding direct cardiac application.

**b) Type BF equipment**

Type B equipment with an F-type isolated (floating) applied part.

**4.3 According to mode of operation**

Dental units are a type of equipment with intermittent operation.

## 5 Requirements and recommendations

### 5.1 General requirements

#### 5.1.1 Design

**5.1.1.1** Electrical requirements given in 5.3 are only applicable to electrically powered dental units. The general requirements referred to in IEC 60601-1:1988, are applicable to non-electrical dental units as well.

If the dental unit is an integral part of the dental patient chair, then ISO 6875 applies in addition.

**5.1.1.2** Dental units shall be designed, constructed and manufactured so that when properly transported, stored, installed, used and maintained according to the manufacturer's instructions, they cause no reasonably foreseeable danger to the patient, to the operating personnel or to the surroundings in normal use and in single-fault condition.

These requirements cannot be objectively assessed. They are considered as fulfilled if all the tests specified in Clause 7 are passed.

**5.1.1.3** Dental units shall have the strength and rigidity necessary to resist the stresses to which they may be subjected in normal dental practice without risk of introducing fire, electric shock or accident hazard.

These requirements cannot be objectively assessed. They are considered as fulfilled if all the tests specified in Clause 7 are passed.

**5.1.1.4** Any item of equipment recommended by the manufacturer for use in conjunction with the dental unit shall not render the unit unsafe.

These requirements cannot be objectively assessed. They are considered as fulfilled if all the tests specified in Clause 7 are passed.

**5.1.1.5** Edges and corners of components and parts of the unit accessible to the patient or personnel shall be finished so as to avoid injury to the patient or operator.

Compliance shall be checked by visual inspection.

**5.1.1.6** Instrument hoses connected to the unit shall be disconnectable for cleaning and disinfection.

The disconnectability shall be checked by manual inspection.

#### 5.1.2 Moving parts

Moving parts that may constitute a hazard under normal working conditions shall be covered to prevent the risk of injury to the patient and personnel.

The distance between power-activated moving parts and counterparts accessible to the patient's and personnel's hands and fingers shall be less than 10 mm (i.e. < 10 mm) when fully opened or a minimum of 20 mm (i.e.  $\geq$  20 mm) when fully closed.

Safety features shall be provided to protect the patient and personnel from accessible power-activated moving parts. These can include safety switches, limit switches or controls requiring continuous activation.

All electrical cables and hydraulic tubes shall be adequately protected against wear, fracture and damage due to rubbing or strain incurred during normal operation of the unit.

Testing shall be carried out in accordance with 7.2.2.

### 5.1.3 Operating controls

Controls should be located to comply with ergonomic conditions and in such a position or be of such design that they cannot be accidentally activated.

Operating symbols in accordance with ISO 9687 shall be used where applicable.

Testing shall be carried out in accordance with 7.2.1.

### 5.1.4 Cleaning and disinfection

All exterior parts including instrument hoses shall be cleanable and disinfected, without deterioration of the surface or markings, by using agents recommended by the manufacturer.

Testing shall be carried out in accordance with 7.1.8.

### 5.1.5 Excessive temperatures

The requirements given in ISO 60601-1:1998, Clause 42 apply.

## 5.2 Mechanical requirements

### 5.2.1 Cuspidors

Cuspidor bowls, if provided, shall be of a material that is capable of undergoing repeated cleaning and disinfection in accordance with instructions provided by the manufacturer without signs of deterioration.

Testing shall be carried out in accordance with 7.2.3.

### 5.2.2 Solids collector

Dental units shall contain a solids collector in the waste system. The solids collector should be capable of retaining anything having a diameter of  $\geq 2$  mm.

Testing shall be carried out in accordance with 7.2.1.

### 5.2.3 Amalgam separator device

Dental units shall be capable of being equipped with or connected to an amalgam separator device in the waste system.

Testing shall be carried out in accordance with 7.2.1.

### 5.2.4 Bursting pressure

Pressure systems used in dental units shall be strong enough to withstand without bursting or leaking the pressures specified by the manufacturer.

Testing shall be carried out in accordance with 7.2.4.

### 5.2.5 Pressure relief

Dental units shall be equipped with a means for safe pressure relief for all parts in which pressure might be generated in the event of fire.

Pressure-relief devices, fused plugs, soldered joints, non-metal tubing or other suitable pressure-relief means or the equivalent may be employed to comply with this requirement.

Testing shall be carried out in accordance with 7.2.1.

#### **5.2.6 Stability in normal use**

The requirements given in IEC 60601-1:1988, Clause 24 apply.

### **5.3 Electrical requirements**

#### **5.3.1 Failsafe device**

In case of a single-fault condition, e.g. failure of a limit switch, additional protective means shall be provided such as mechanical limits to prevent injury to the patient and/or operating personnel.

The failsafe device shall also offer protection against hazards which might arise from any type of connection with a dental patient chair.

Testing shall be carried out in accordance with 7.3.2.

#### **5.3.2 Power input**

The requirements given in IEC 60601-1:1988, Clause 7 apply.

#### **5.3.3 Single-fault conditions**

The requirements given in IEC 60601-1:1988, 3.6 apply.

#### **5.3.4 Protection against electrical shock hazards**

The requirements given in IEC 60601-1:1988, Clause 13 apply.

#### **5.3.5 Requirements related to classification**

##### **5.3.5.1 Class I equipment**

The requirements given in IEC 60601-1:1988, 14.1 apply.

##### **5.3.5.2 Class II equipment**

The requirements given in IEC 60601-1:1988, 14.2 apply.

##### **5.3.5.3 Class I and II equipment**

The requirements given in IEC 60601-1:1988, 14.4 apply, limited to classes I and II.

##### **5.3.5.4 Types B and BF equipment**

The requirements given in IEC 60601-1:1988, 14.6 apply, limited to types B and BF.

#### **5.3.6 Limitation of voltage and/or energy**

The requirements given in IEC 60601-1:1988, Clause 15 apply, with the following additions.

- Voltage shall not exceed a nominal value of 25 V a.c. or 60 V d.c. safety extra-low voltage (SELV) at a rated supply voltage on the transformer or converter, between conductors in an earth-free circuit which is isolated from the supply mains by a safety transformer or by a device with an equivalent separation.
- Parts of the unit generating internal voltages higher than SELV shall be separated electrically from SELV. The measures required for this, such as protective shield or insulation, are an integral part of the unit and are tested together with this.
- Parts of the unit that are fed at SELV shall not generate any internal voltage higher than SELV, unless these voltages are separated electrically safe from SELV.

### 5.3.7 Enclosures and protective covers

The requirements given in IEC 60601-1:1988, Clause 16 apply.

### 5.3.8 Spillage and ingress of liquids

The requirements given in IEC 60601-1:1988, 44.3 and 44.6 apply.

### 5.3.9 Leakage

The requirements given in IEC 60601-1:1988, 44.4 apply.

### 5.3.10 Separation

The requirements given in IEC 60601-1:1988, Clause 17 apply, with the following addition.

- Electrical non-insulated heating devices, e.g. hot-water syringes, which are in direct contact with water, as well as electrically operated low-voltage motors in the handpiece with basic insulation, shall be operated with safety extra-low voltage (SELV).

### 5.3.11 Protective earthing, functional earthing and potential equalization

The requirements given in IEC 60601-1:1988, Clause 18 a) to g) apply.

### 5.3.12 Continuous leakage currents and patient auxiliary currents

#### 5.3.12.1 General requirements

The requirements given in IEC 60601-1:1988, 19.1 apply.

#### 5.3.12.2 Single-fault conditions

The requirements given in IEC 60601-1:1988, 19.2 apply, with the following additions.

- In low-voltage electrical motors that do not fulfil the requirement given in 5.3.19, bridging over the working insulation against the housing is considered a first fault. In this case the values for the patient leakage current given in Table 1 shall not be exceeded.
- In syringes providing hot water in which the non-insulated heating element is in direct contact with water, one-sided grounding of the SELV is considered a first fault. In this case the values for the patient leakage current given in Table 1 shall not be exceeded.

Testing shall be carried out in accordance with 7.3.3.

### 5.3.12.3 Allowable values

The maximum allowable current values shall be as specified in Table 1.

Testing shall be carried out in accordance with 7.3.3.

**Table 1 — Maximum allowable values of continuous leakage currents and patient auxiliary currents**

Values in milliamperes

Current path	Type B		Type BF	
	NC <sup>a</sup>	SFC <sup>b</sup>	NC <sup>a</sup>	SFC <sup>b</sup>
Earth leakage current	0,5	1 <sup>c</sup>	0,5	1
Enclosure leakage current	0,1	0,5	0,1	0,5
Patient leakage current	0,1	0,5	0,1	0,5
Patient leakage current (mains voltage on the signal input part or signal output part)	—	5	—	—
Patient leakage current (mains voltage on the applied part)	—	—	—	5
Patient auxiliary current	d.c.	0,01	0,01	0,05
	a.c.	0,1	0,5	0,5

<sup>a</sup> NC: Normal condition.  
<sup>b</sup> SFC: Single-fault condition.  
<sup>c</sup> The only single-fault condition for the earth leakage current is the interruption of one supply conductor at a time; see IEC 60601-1:1988, 19.2 a) and Figure 16.

### 5.3.13 Dielectric strength

#### 5.3.13.1 General requirements for all types of dental units

The requirements given in IEC 60601-1:1988, 20.1 apply.

#### 5.3.13.2 Requirements for dental units with an applied part

The requirements given in IEC 60601-1:1988, 20.2 apply, with the following additions.

B-a) For hot-water syringes which have been tested according to 7.3.3, testing the dielectric strength is not applicable.

The feed current circuit is tested with SELV. The water column between the heating element and the patient is considered to be the protective impedance towards the patient.

B-b) This insulation shall be basic insulation.

B-e) If the application part of the type F contains voltages that are not larger than SELV, then the basic insulation is sufficient.

B-g) Parts standing in direct conductive contact with water must be insulated as if they had direct contact to the ground or protective ground wire.

This does not apply to parts for which the water column represents a protective impedance.

### 5.3.13.3 Values of test voltages

The requirements given in IEC 60601-1:1988, 20.3 apply, except as follows.

— For applied parts operated with SELV, the test voltage for all installations to be tested shall be 500 V.

Testing shall be carried out in accordance with 7.3.4.

### 5.3.14 Interruption of power supply

The requirements given in IEC 60601-1:1988, 49.1 to 49.3 apply.

### 5.3.15 Abnormal operation and fault conditions

The requirements given in IEC 60601-1:1988, Clause 52 apply.

### 5.3.16 Components and general assembly

The requirements given in IEC 60601-1:1988, 56.1 b) and d) apply.

The requirements given in IEC 60601-1:1988, 56.3 to 56.10 apply.

The requirements given in IEC 60601-1:1988, 56.11 b) apply.

### 5.3.17 Mains parts, components and layout

The requirements given in IEC 60601-1:1988, Clause 57 apply, with the following addition to 57.10.

— In the case of application parts which are operated within SELV, the creepage distances and air clearances according to IEC 60601-1:1988, Table XVI, column headed "Basic insulation between parts of opposite polarity" apply.

### 5.3.18 Protective earthing — Terminals and connections

The requirements given in IEC 60601-1:1988, Clause 58 apply.

### 5.3.19 Construction and layout

The requirements given in IEC 60601-1:1988, Clause 59 apply.

## 6 Sampling

Where possible, all type tests shall be made on one representative sample of the dental unit being tested.

## 7 Testing

### 7.1 General information for tests

#### 7.1.1 General provisions

The sequence of tests shall be conducted according to Annex A.

All tests described in this part of ISO 7494 are type tests. Type tests are made on one representative sample of the item being tested.

Do not repeat any of these tests.

Since some of the tests described are destructive tests, the dental unit tested shall not be used afterwards.

### **7.1.2 Ambient temperature, humidity, atmospheric pressure**

After the dental unit being tested has been set up for normal use, tests shall be carried out under operating conditions at

- a) an ambient temperature within the range 15 °C to 35 °C;
- b) a relative humidity within the range 45 % to 75 %;
- c) an atmospheric pressure within the range 860 mbar to 1 060 mbar (645 mmHg to 795 mmHg).

The equipment shall be protected from draughts which might affect the validity of the tests.

### **7.1.3 Other conditions**

The requirements given in IEC 60601-1:1988, 4.6 a), b) and d) apply.

### **7.1.4 Supply and test voltages, type of current, nature of supply, frequency**

The requirements given in IEC 60601-1:1988, 4.7 apply.

### **7.1.5 Preconditioning**

The requirements given in IEC 60601-1:1988, 4.8 apply.

### **7.1.6 Repairs and modifications**

The requirements given in IEC 60601-1:1988, 4.9 apply.

### **7.1.7 Humidity preconditioning treatment**

The requirements given in IEC 60601-1:1988, 4.10 apply.

### **7.1.8 Cleaning and disinfection**

Cleaning and disinfection tests shall be in accordance with IEC 60601-1:1988, 4.7.

## **7.2 Mechanical tests**

### **7.2.1 Visual inspection**

Visually inspect the equipment to determine compliance with the requirements.

### **7.2.2 Moving parts**

Measure the distances between the moving parts and counterparts and visually inspect the equipment to determine compliance with the requirements.

### **7.2.3 Cuspidor**

Treat the cuspidor 20 times with disinfecting agents recommended by the manufacturer before visual inspection to determine compliance with the requirements.

#### 7.2.4 Bursting pressure

Subject two samples of each of the pressure systems to a hydrostatic pressure as follows.

- Remove or disable any pressure-relief system prior to conducting the burst test.
- Connect the system to a suitable hydraulic pump. Raise the pressure gradually to 40 % of the final test pressure (three times the working pressure specified by the manufacturer) and hold at that pressure for 1 min. Then increase the pressure to the final test pressure and hold at that pressure for 3 min. The results are unacceptable if the sample either bursts or leaks.

### 7.3 Electrical tests

#### 7.3.1 Power supply

Dental units shall be designed for connection to a mains supply having the following characteristics:

- a) rated voltage not exceeding 250 V single-phase;
- b) maximum internal impedance of 0,1  $\Omega$ ;
- c) voltage fluctuations generally not exceeding  $\pm 10$  % of the nominal voltage, not including short-time fluctuations (for example, of duration less than 1 s), at irregular intervals such as those caused by operation of X-ray generators or similar equipment;
- d) voltages which are sinusoidal in shape and form a near-symmetrical supply system in case of polyphase supply;
- e) frequency which does not deviate by more than 1 Hz from the nominal value up to 100 Hz and by more than 1 % from 100 Hz to 1 kHz;
- f) protective measures to be specified in a future IEC Standard on electrical installations in hospitals and in medically used rooms outside hospitals.

Testing shall be carried out using readily available measuring instruments.

#### 7.3.2 Failsafe device

On dental units which are power-activated and controlled by limit switches, such limit switches shall be purposely bypassed, one at a time while the dental unit operates through its full range of motion, without resulting in collapse of the dental unit that would be harmful to the patient and/or operating personnel.

#### 7.3.3 Continuous leakage currents and patient auxiliary currents

The earth leakage current, the enclosure leakage current, the patient leakage current and the patient auxiliary current shall be tested

- a) after the dental unit has been brought to normal operating temperature, in accordance with the requirements of IEC 60601-1:1988, Clause 7;
- b) after the humidity preconditioning treatment as described in IEC 60601-1:1988, 4.10. The measurements shall be carried out with equipment located outside the humidity cabinet and shall commence 1 h after equipment has been taken out of this cabinet and has been placed in an environment with a temperature less than or equal to the temperature of the humidity cabinet.

In the case of water syringes, the leakage current measurement required a fine metal mesh pressed against the water outlet opening (maximum mesh aperture 0,3 mm and minimum wire diameter 0,1 mm). This metal mesh serves as contact point to the application part and shall be connected during the measurement with the mechanical parts of the syringe that can be touched, and the water shall be turned on.

For measuring arrangements and measuring devices, see IEC 60601-1:1988, 19.4.

### 7.3.4 Dielectric strength

The test voltage for single-phase equipment and for three-phase equipment (to be tested as single-phase equipment) shall be applied during 1 min to the insulation parts as described in 20.1 and 20.2 of IEC 60601-1:1988 and according to IEC 60601-1:1988, Table V

- a) immediately after warming up to operating temperature and switching off the equipment, and for heating elements by application of the circuit shown in IEC 60601-1:1988, Figure 28, and
- b) immediately after the humidity preconditioning treatment (as described in IEC 60601-1:1988, 4.10) with the equipment de-energized during the test and kept in the humidity cabinet, and
- c) after any required sterilization procedure with the equipment de-energized (see IEC 60601-1:1988, 44.7).

Initially, not more than half the prescribed voltage shall be applied, then it shall be raised over a period of 10 s to the full test voltage value, which shall be maintained for 1 min.

On low-voltage electrical motors, the working insulation of which simultaneously represents the basic insulation, the following test shall be performed.

- Operate the motor at maximum speed (according to directions for use of the manufacturer) and under the conditions given in IEC 60601-1:1988, Clause 8 for 5 h in intermittent operation. Afterwards subject the motor to the dielectric strength test according to 7.3.4 a), b) and c).

## 8 Manufacturer's instructions

### 8.1 General

The requirements given in IEC 60601-1:1988, 6.8.1 and in 8.2 to 8.4 of this part of ISO 7494 apply.

Information should be available in the language of the country where the product is to be used.

### 8.2 Instructions for use

The requirements given in IEC 60601-1:1988, 6.8.2 apply.

In addition, the full range of motion shall be quoted.

If mounting accommodation for other manufacturers' attachments is provided, the manufacturer shall stipulate the maximum loading capabilities for those attachments in the instructions for use included with each dental unit.

### 8.3 Technical description

The requirements given in IEC 60601-1:1988, 6.8.3 a), b) and c) apply.

In addition, the following information shall be provided by the manufacturer:

- a) overall dimensions of the dental unit;
- b) overall dimensions of the baseplate and service location interfaces, if applicable;
- c) details of interface surfaces and methods of retention (bolts, etc.) and electrical supplies and other services;
- d) information on the assembly and mounting of the dental unit;

- e) electrical characteristics (voltage, frequency, fuse values);
- f) step-by-step procedures for operation and routine maintenance of the dental unit, including illustrations showing the location of and explanation of each control and other features relating to safety consideration in the intended use;
- g) instructions for use, which shall also include warning statements on the use of the dental unit in conjunction with other equipment that may move;
- h) directions for cleaning and disinfecting the dental unit;
- i) data on the mass (loading limit) and maximum movement of the unit and its accessories generated at the mounting position, with the unit and accessories in the most unfavourable position;
- j) mass (loading limit) of non-chair-mounted units;
- k) maximum safe load capabilities of the working surface in its most unfavourable position;
- l) standard attachments that the dental unit is designed to accept and loading capabilities for these attachments;
- m) colour code of the tubing used in the dental unit;
- n) full fluid characteristics for the input and output connections to the dental unit;
- o) list of spare parts that would be required in general use;
- p) schematic wiring diagrams;
- q) minimum spare requirements and recommendations for unit installation within the dental operator;
- r) working pressures of pressure systems used in the dental unit.

#### 8.4 Check

The accompanying documents shall be checked to ensure that all information specified in 8.1 to 8.3 is provided.

### 9 Marking

#### 9.1 Marking on outside of mains-operated units

##### 9.1.1 General

Mains-operated dental units, including separable components thereof which have a mains part, shall be provided at least with permanently affixed and clearly legible markings on the outside of the major part of the dental units.

Markings, except for warning notes, which are attached underneath a cover which can be easily removed without tools shall also fulfil these requirements.

##### 9.1.2 Indication of origin

The requirements given in IEC 60601-1:1988, 6.1 e) apply.