INTERNATIONAL STANDARD

ISO 7494

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Dental units

Units dentaires

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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.

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.

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

This second edition cancels and replaces the first edition (ISO 7494:1990), of which it constitutes a technical revision.

Annex A forms an integral part of this International Standard.

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Dental units

1 Scope

ISO 7494 is one of a series of International Standards based on IEC 601-1; in IEC 601-1 (the "General Standard"), this type of International Standard is referred to as a "Particular Standard". As stated in 1.3 of IEC 601-1:1988, the requirements of this International Standard take precedence over those of IEC 601-1.

This International Standard specifies requirements and test methods for dental units, regardless of their construction and regardless of whether or not they are electrically powered.

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

NOTE 1 For dental patient chairs see ISO 6875, and for dental operating lights see ISO 9680.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 1942-4:1989, *Dental vocabulary — Part 4: Dental equipment.*

ISO 6875:1995, *Dental patient chair.*

ISO 9680:1993, *Dental operating light.*

ISO 9687:1993, *Dental equipment — Graphical symbols.*

IEC 601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety.*

3 Definitions

For the purposes of this International Standard, the definitions given in IEC 601-1 apply, as appropriate, and the following definitions from ISO 1942-4.

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 1942-4]

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]

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

Electrical requirements given in 5.3 are only applicable to electrically powered dental units. The general requirements referred to in IEC 601-1:1988, 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.

5.1.1.1 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 following tests are passed.

5.1.1.2 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 following tests are passed.

5.1.1.3 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 following tests are passed.

5.1.1.4 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.

5.1.1.5 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 patient's and personnel's hands and fingers shall be less than 10 mm (i.e. 0 to < 10 mm) when fully opened or a minimum of 20 mm (i.e. ⩾ 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 disinfectable, 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 clause 42 of IEC 601-1:1988 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 $\geqslant$ 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 clause 24 of IEC 601-1:1988 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 clause 7 of IEC 601-1:1988 apply.

5.3.3 Single-fault conditions

The requirements given in subclause 3.6 of IEC 601-1:1988 apply.

5.3.4 Protection against electrical shock hazards

The requirements given in clause 13 of IEC 601-1:1988 apply.

5.3.5 Requirements related to classification

5.3.5.1 Class I equipment

The requirements given in subclause 14.1 of IEC 601-1:1988 apply.

5.3.5.2 Class II equipment

The requirements given in subclause 14.2 of IEC 601-1:1988 apply.

5.3.5.3 Classes I and II equipment

The requirements given in subclause 14.4 of IEC 601-1:1988 apply, limited to classes I and II.

5.3.5.4 Types B and BF equipment

The requirements given in subclause 14.6 of IEC 601-1:1988 apply, limited to types B and BF.

5.3.6 Limitation of voltage and/or energy

The requirements given in clause 15 of IEC 601-1:1988 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 may 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 clause 16 of IEC 601-1:1988 apply.

5.3.8 Spillage and ingress of liquids

The requirements given in subclauses 44.3 and 44.6 of IEC 601-1:1988 apply.

5.3.9 Leakage

The requirements given in subclause 44.4 of IEC 601-1:1988 apply.

5.3.10 Separation

The requirements given in clause 17 of IEC 601-1:1988 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 clause 18 items a) to g) of IEC 601-1:1988 apply.

5.3.12 Continuous leakage currents and patient auxiliary currents

5.3.12.1 General requirements

The requirements given in subclause 19.1 of IEC 601-1:1988 apply.

5.3.12.2 Single-fault conditions

The requirements given in subclause 19.2 of IEC 601-1:1988 apply, with the following additions:

In low-voltage electrical motors that do not fulfill the requirement according to 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 [1]	SFC [2]	NC [1]	SFC [2]
Earth leakage current		0,5	1 [3]	0,5	1 [3]
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	0,05	0,01	0,05
	a.c.	0,1	0,5	0,1	0,5

1) NC: Normal condition.

2) SFC: Single-fault condition.

3) The only single-fault condition for the earth leakage current is the interruption of one supply conductor at a time; see subclause 19.2 a) and figure 16 of IEC 601-1:1988.

5.3.13 Dielectric strength

5.3.13.1 General requirements for all types of dental units

The requirements given in subclause 20.1 of IEC 601-1:1988 apply.

5.3.13.2 Requirements for dental units with an applied part

The requirements given in subclause 20.2 of IEC 601-1:1988 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 subclause 20.3 of IEC 601-1:1988 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 subclauses 49.1 to 49.3 of IEC 601-1:1988 apply.

5.3.15 Abnormal operation and fault conditions

The requirements given in clause 52 of IEC 601-1:1988 apply.

5.3.16 Components and general assembly

The requirements given in subclauses 56.1 b) and d) of IEC 601-1:1988 apply.

The requirements given in subclauses 56.3 to 56.10 of IEC 601-1:1988 apply.

The requirements given in subclause 56.11 b) of IEC 601-1:1988 apply.

5.3.17 Mains parts, components and layout

The requirements given in clause 57 of IEC 601-1:1988 apply, with the following addition to subclause 57.10:

> In the case of application parts which are operated within SELV, the creepage distances and air clearances according to table 16 of IEC 601-1:1988, column headed "Basic insulation between parts of opposite polarity", apply.

5.3.18 Protective earthing — Terminals and connections

The requirements given in clause 58 of IEC 601-1:1988 apply.

5.3.19 Construction and layout

The requirements given in clause 59 of IEC 601-1:1988 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 International Standard 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 subclause 4.6, items a), b) and d) of IEC 601-1:1988 apply.

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

The requirements given in subclause 4.7 of IEC 601-1:1988 apply.

7.1.5 Preconditioning

The requirements given in subclause 4.8 of IEC 601-1:1988 apply.

7.1.6 Repairs and modifications

The requirements given in subclause 4.9 of IEC 601-1:1988 apply.

7.1.7 Humidity preconditioning treatment

The requirements given in subclause 4.10 of IEC 601-1:1988 apply.

7.1.8 Cleaning and disinfection

Cleaning and disinfection tests shall be in accordance with subclause 44.7 of IEC 601-1:1988.

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 for compliance with the requirement.

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) internal impedance of 0,1 Ω max.

c) voltage fluctuations generally not exceeding ± 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 clause 7 of IEC 601-1:1988;

b) after the humidity preconditioning treatment as described in subclause 4.10 of IEC 601-1:1988. 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 requires a fine metal mesh pressed against the water outlet opening (mesh aperture max. 0,3 mm and wire diameter min. 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 subclause 19.4 of IEC 601-1:1988.

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 subclauses 20.1 and 20.2 of IEC 601-1:1988 and according to table V of IEC 601-1:1988

a) immediately after warming up to operating temperature and switching off the equipment, and for