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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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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. $\geqslant 20$ 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 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 $\geqslant$ 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 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 [a]	SFC [b]	NC [a]	SFC [b]
Earth leakage current	0,5	1 [c]	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	0,05	0,01	0,05
a.c.	0,1	0,5	0,1	0,5

[a] NC: Normal condition.

[b] SFC: Single-fault condition.

[c] 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.