INTERNATIONAL STANDARD

ISO 7494-1

Second edition
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Dentistry — Dental units —

Part 1: General requirements and test methods

Médecine bucco-dentaire — Units dentaires —

Partie 1: Exigences générales et méthodes d'essai

Reference number
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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 second edition cancels and replaces the first edition (ISO 7494-1:2004), which has been technically revised.

The following changes were made:

a) the requirements were aligned with IEC 60601-1:2005;

b) the mass distributions for the maximum loads were aligned with ISO 6875;

c) the requirements for the technical description and the labelling were updated.

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*

Introduction

Specific qualitative and quantitative test methods for freedom from biological hazard are not included in this International Standard. However, it is recommended that, for the assessment of possible biological hazards, reference be made to ISO 10993-1.

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 the manufacturer's instructions, marking and packaging.

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 4073, *Dentistry — Information system on the location of dental equipment in the working area of the oral health care provider*

ISO 6875, *Dentistry — Patient chair*

ISO 9687, *Dental equipment — Graphical symbols*

ISO 11144, *Dental equipment — Connections for supply and waste lines*

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

IEC 60601-1:2005, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 62366, *Medical devices — 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, *Medical electrical equipment — Part 2-60: Particular requirements for basic safety and essential performance of dental equipment*[1)]

1) To be published.

3 Terms and definitions

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

3.1
dental equipment
furniture, machines, apparatus and accessories made for use in the practice of dentistry and/or its associated procedures

NOTE Adapted from ISO 1942:2009, definition 2.68.

3.2
dental unit
combination of interconnected dental equipment and dental instruments constituting a functional assembly for use in the provision of dental treatment

[ISO 1942:2009, definition 2.86]

3.3
dental handpiece
hand-held instrument used in dentistry for patient treatment, which is connected to the dental unit

3.4
high frequency surgery device
HF surgery device
electrosurgical device
hand-held medical electrical instrument designed to transmit high frequency electrical current to biological tissue for the purpose of cutting or modifying the tissue in a surgical procedure

4 Classification

4.1 General

This classification applies to electrically operated dental units only.

4.2 According to type of protection against electric shock

Dental units are classified in accordance with IEC 60601-1 as follows:

a) Class I equipment, see IEC 60601-1:2005, 3.13.

b) Class II equipment, see IEC 60601-1:2005, 3.14.

4.3 According to degree of protection against electric shock

If a dental unit has an applied part, the applied part shall be grouped as Type B (see IEC 60601-1:2005, 3.132).

High frequency surgery devices incorporated in the dental unit are exempt from this classification.

4.4 According to mode of operation

IEC 60601-1:2005, 6.6 applies.

5 Requirements

5.1 General

Electrical requirements are only applicable to electrically operated dental units. There are, however, general requirements referred to in IEC 60601-1 which are applicable to non-electrical dental units as well.

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

IEC 60601-1 and IEC 80601-2-60 apply.

5.1.1 Handpiece hoses

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

The disconnectability shall be checked by manual inspection.

5.1.2 Moving parts

The requirements given in IEC 60601-1:2005, 9.2 apply.

Testing shall be carried out in accordance with 7.2.1.

5.1.3 Operating controls

Operating controls shall be designed and located to minimize accidental activation. Graphical symbols for operating controls shall be in accordance with ISO 9687.

IEC 60601-1:2005, 15.1 applies.

5.1.4 Usability

Testing shall be carried out in accordance with IEC 62366.

5.1.5 Cleaning and disinfection

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

Testing shall be carried out in accordance with ISO 21530.

5.1.6 Excessive temperatures

The requirements given in IEC 60601-1:2005, 11.1 apply.

5.1.7 Biocompatibility

The requirements given in IEC 60601-1:2005, 11.7 apply.

Compliance is checked by inspection of the information provided by the manufacturer.

5.1.8 Connections for supply and waste lines

All connections shall be in accordance with ISO 11144.

5.2 Mechanical requirements

5.2.1 Solids collector

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

Testing shall be carried out in accordance with 7.1. Measurement shall be carried out using readily available measuring instruments.

5.2.2 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 7.1.

5.2.3 Bursting pressure

Pressure systems used in dental units shall be strong enough to withstand, without bursting or leaking, the pressures specified in 7.2.2.

Testing shall be carried out in accordance with 7.2.2.

5.3 Electrical requirements

IEC 60601-1 and IEC 80601-2-60 apply.

5.3.1 Failsafe device

In case of a single-fault condition, e.g. failure of a limit switch, additional protective means (failsafe device) 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.

5.3.2 Test point

In order to perform the service requirement specified in IEC 62353, the dental unit shall have a connector/plug for the power supply.

Testing shall be carried out in accordance with 7.1.

6 Sampling

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

7 Testing

7.1 Visual inspection

Visually inspect the equipment to determine compliance with the requirements.

7.2 Mechanical tests

7.2.1 Moving parts

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

7.2.2 Pressure vessels and parts subject to pneumatic and hydraulic pressure

Test in accordance with IEC 60601-1:2005, 9.7.

7.3 Electrical tests

IEC 60601-1 and IEC 80601-2-60 apply.

7.3.1 Failsafe device

On dental units which are power-activated and controlled by limit switches, deliberately bypass such limit switches one by one (single-fault condition). Then operate the test piece through its full range of 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.

8 Manufacturer's instructions

8.1 General

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

IEC 60601-1: 2005, 7.9.1 applies.

8.2 Instructions for use

IEC 60601-1: 2005, 7.9.2 applies.

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

If mounting equipment 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

IEC 60601-1:2005, 7.9.3.1, 7.9.3.2 and 7.9.3.3 apply.

In addition, the following information shall also 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.), electrical supplies and other services;

d) information on the assembly and mounting of the dental unit;

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

f) air and water input requirements (pressure and flow rate) and output characteristics, including diagram of piping for air, water, suction and waste water, if applicable;

g) step-by-step procedures for operation and routine maintenance of the dental unit, including illustrations showing the location of and explanation of each control;

h) instructions for use, which shall also include warning statements on the use of the dental unit in conjunction with other equipment that may move;

i) instructions for cleaning and disinfecting the dental unit;

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

k) maximum allowable load of non-chair-mounted units;

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

m) standard attachments that the dental unit is designed to accept and loading capabilities for these attachments;

n) full fluid characteristics for the input and output connections to the dental unit;

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

p) minimum space requirements and recommendations for unit installation within the dental operatory;

q) working pressures of pressure systems used in the dental unit;

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

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

t) information on waste disposal and recycling.

9 Marking

IEC 60601-1:2005, Clause 7 applies.

Symbols used for controls and performance shall be in accordance with ISO 9687.

Compliance is checked by visual inspection.

10 Packaging

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

If several packages are supplied, they shall be marked on the outside to facilitate the assembly and installation in accordance with IEC 60601-1:2005, 7.2.17.

Bibliography

[1] ISO 6385, *Ergonomic principles in the design of work systems*

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

[3] ISO 11226, *Ergonomics — Evaluation of static working postures*

[4] ISO 17664, *Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices*

[5] IEC 60601-1-4, *Medical electrical equipment — Part 1-4: General requirements for safety — Collateral standard: Programmable electrical medical systems*

[6] IEC 62304, *Medical device software — Software life cycle processes*

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