SLOVENSKI STANDARD
SIST EN ISO 7494-1:2005

01-december-2005

Zobozdravstvo – Dentalne enote – 1. del: Splošne zahteve in preskusne metode (ISO 7494-1:2004)

Dentistry - Dental units - Part 1: General requirements and test methods (ISO 7494-1:2004)

Zahnheilkunde - Zahnärztliche Behandlungsgeräte - Teil 1: Allgemeine Anforderungen und Prüfverfahren (ISO 7494-1:2004)

Art dentaire - Units dentaires - Partie 1: Exigences et méthodes d'essai générales (ISO 7494-1:2004)

Ta slovenski standard je istoveten z: **EN ISO 7494-1:2005**

ICS:

11.060.20	Zobotehniļna oprema	Dental equipment

SIST EN ISO 7494-1:2005 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 7494-1

August 2005

ICS 11.060.20

English Version

Dentistry - Dental units - Part 1: General requirements and test methods (ISO 7494-1:2004)

Art dentaire - Units dentaires - Partie 1: Exigences et méthodes d'essai générales (ISO 7494-1:2004)

Zahnheilkunde - Zahnärztliche Behandlungsgeräte - Teil 1: Allgemeine Anforderungen und Prüfverfahren (ISO 7494-1:2004)

This European Standard was approved by CEN on 4 August 2005.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

Ref. No. EN ISO 7494-1:2005: E

Foreword

The text of ISO 7494-1:2004 has been prepared by Technical Committee ISO/TC 106 "Dentistry" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 7494-1:2005 by Technical Committee CEN/TC 55 "Dentistry", the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by February 2006, and conflicting national standards shall be withdrawn at the latest by February 2006.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Endorsement notice

The text of ISO 7494-1:2004 has been approved by CEN as EN ISO 7494-1:2005 without any modifications.

INTERNATIONAL STANDARD

ISO 7494-1

First edition
2004-11-01

Dentistry — Dental units —

Part 1: General requirements and test methods

Art dentaire — Units dentaires —

Partie 1: Exigences et méthodes d'essai générales

Reference number
ISO 7494-1:2004(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

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.

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. $\geqslant 20$ 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.