

**Dentistry - Dental units - Part 1: General requirements
and test methods (ISO 7494-1:2011)**

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EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 7494-1:2011 sisaldab Euroopa standardi EN ISO 7494-1:2011 ingliskeelset teksti.

Standard on kinnitatud Eesti Standardikeskuse 31.08.2011 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.

Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 15.08.2011.

Standard on kättesaadav Eesti standardiorganisatsioonist.

This Estonian standard EVS-EN ISO 7494-1:2011 consists of the English text of the European standard EN ISO 7494-1:2011.

This standard is ratified with the order of Estonian Centre for Standardisation dated 31.08.2011 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.

Date of Availability of the European standard text 15.08.2011.

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ICS 11.060.20

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English Version

Dentistry - Dental units - Part 1: General requirements and test methods (ISO 7494-1:2011)

Médecine bucco-dentaire - Units dentaires - Partie 1:
Exigences générales et méthodes d'essai (ISO 7494-1:2011)

Zahnheilkunde - Zahnärztliche Behandlungseinheiten - Teil
1: Allgemeine Anforderungen und Prüfverfahren (ISO 7494-1:2011)

This European Standard was approved by CEN on 14 August 2011.

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 CEN-CENELEC Management Centre or to any CEN member.

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Foreword

This document (EN ISO 7494-1:2011) has been prepared by Technical Committee ISO/TC 106 “Dentistry” in collaboration with 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of an identical text or by endorsement, at the latest by February 2012, and conflicting national standards shall be withdrawn at the latest by February 2012.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 7494-1:2005.

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Endorsement notice

The text of ISO 7494-1:2011 has been approved by CEN as a EN ISO 7494-1:2011 without any modification.

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.