

SLOVENSKI STANDARD oSIST prEN ISO 7494-2:2013

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Zobozdravstvo - Zobozdravstvene enote - 2. del: Medijski kanali in priključki (ISO/DIS 7494-2:2013)

Dentistry - Dental units - Part 2: Media channels and connections (ISO/DIS 7494-2:2013)

Zahnheilkunde - Zahnärztliche Behandlungseinheiten - Teil 2: Medienkanäle und Anschlüsse (ISO/DIS 7494-2:2013)

Médecine bucco-dentaire - Units dentaires - Partie 2: Alimentation en eau et en air (ISO/DIS 7494-2:2013)

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11.060.20 Zobotehnična oprema Dental equipment

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EUROPEAN STANDARD NORME EUROPÉENNE EUROPÄISCHE NORM

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Will supersede EN ISO 11144:1996, EN ISO 7494-2:2003

English Version

Dentistry - Dental units - Part 2: Media channels and connections (ISO/DIS 7494-2:2013)

Médecine bucco-dentaire - Units dentaires - Partie 2: Alimentation en eau et en air (ISO/DIS 7494-2:2013)

Zahnheilkunde - Zahnärztliche Behandlungseinheiten - Teil 2: Medienkanäle und Anschlüsse (ISO/DIS 7494-2:2013)

This draft European Standard is submitted to CEN members for parallel enquiry. It has been drawn up by the Technical Committee CEN/TC 55.

If this draft becomes a European Standard, 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.

This draft European Standard was established by CEN 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 CEN-CENELEC Management Centre has the same status as the official versions.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

prEN ISO 7494-2:2013 (E)

Contents	Pag
_	
Foreword	

iTeh STANDARD PREVIEW (standards.iteh.ai)

<u>SIST EN ISO 7494-2:2015</u> https://standards.iteh.ai/catalog/standards/sist/e90c953a-9a8c-4c0b-86e1 f4a6543b36b0/sist-en-iso-7494-2-2015

prEN ISO 7494-2:2013 (E)

Foreword

This document (prEN ISO 7494-2:2013) 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 document is currently submitted to the parallel Enquiry.

This document will supersede EN ISO 11144:1996, EN ISO 7494-2:2003.

Endorsement notice

The text of ISO/DIS 7494-2:2013 has been approved by CEN as prEN ISO 7494-2:2013 without any modification.

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DRAFT INTERNATIONAL STANDARD ISO/DIS 7494-2

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INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION

Dentistry — Dental units —

Part 2:

Media channels and connections

Médecine bucco-dentaire — Units dentaires —

Partie 2: Alimentation en eau et en air

[Revision of first edition (ISO 11144:1995) and first edition of ISO 7494-2:2003]

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SIST EN ISO 7494-2:2015

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO-lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five-month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.

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ISO/DIS 7494-1

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Contents		Page	
Forewo	ord	v	
Introdu	uction	vi	
1	Scope	7	
2	Normative references		
_			
3	Terms and definitions		
4	Classification		
4.1	Classification of suction systems		
4.2	Classification of suction air volume flow rate	10	
5	Requirements	11	
5.1	Requirements for supply connections		
5.2	Requirements for the water supply		
5.2.1	Water quality		
5.2.2	Materials used for construction of procedural water systems within the dental unit		
5.2.3	Backflow prevention device for dental units using external drinking-water		
5.2.4 5.2.5	CuspidorsWater venturi		
5.2.5 5.2.6	Particle filter		
5.2.7	Antibacterial filters		
5.2.8	Bottled water system supplying incoming water or solution		
5.2.9	Retraction		
5.2.10	Water disinfection systems		
5.2.11	Water sampling connection point.M.I.S.O7404.2.2045		
5.2.12	Waste water drain connection		
5.3	Requirements for the air supply		
5.3.1	Air quality (dental air)		
5.3.2	Particle filters		
5.3.3	Antibacterial filters		
5.4	Requirements for suction devices		
5.4.1 5.4.2	Maximum static vacuum pressureFlow performance		
5.4.2	Air separators		
5.4.4	Requirements for accessories	16	
5.4.5	Noise level		
5.4.6	Suction connection point		
	•		
6	Sampling		
7	Tests	_	
7.1	Cuspidors		
7.2	Water venturi		
7.3	Systems using municipal water	18	
7.4	Bottled water system supplying procedural water or solution		
7.5 7.6	RetractionParticle filters		
7.6 7.7	Antibacterial filters		
7. <i>1</i> 7.8	Water disinfection systems		
7.9	Tests for dental unit suction devices		
7.9.1	Static vacuum pressure test		
7.9.2	Flow characterization test		
7.9.3	Measurement of noise level		

oSIST prEN ISO 7494-2:2013

ISO/DIS 7494-2

7.9.4	Water sampling connection point	22
7.10	Air supply quality (dental-air)	
7.11	Supply connections	
8	Manufacturer's instructions for use	22
9	Technical description	23
Annex	A (informative) Schematic diagram of possible devices and connections in dental units (example)	24
Annex	B (informative) Test sequences	26
Bibliog	graphy	8
_	• •	

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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.

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 7494-2 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 6, *Dental equipment*.

This second edition cancels and replaces the first edition (ISO 7494-2:2003, ISO 11144:1995), which have been technically revised.

ISO 7494 consists of the following parts, under the general title *Dentistry* — *Dental units*:

- Part 2: Part 1: General requirements and test methods
- Part 2: Media channels and connections

ISO/DIS 7494-2

Introduction

This part of ISO 7494 is a combination of the following two International Standards:

ISO 7494-2:2003-03, Dentistry - Dental units - Part 2: Water and air supply

ISO 11144:1995-05-01, Dental equipment – Connections for supply and waste lines

This part of ISO 7494 specifies requirements and test methods pertaining to components of the dental unit which deliver air, water, suction and waste, as well as the effects that these components have on the delivery of air, water, suction and waste. This revision consolidates and updates requirements, which formerly were specified in the following three standards:

ISO 7494-2:2003 Dentistry – Dental units – Part 2: Water and air supply

ISO 10637:1999 Dental equipment – High- and medium-volume suction systems

ISO 11144:1995 Dental equipment – Connections for supply and waste lines

This revision entirely replaces ISO 7494-2:2003 and ISO 11144:1995, while it only replaces certain requirements specific to dental units in ISO 10637.

The requirements in this part of ISO 7494 focus on certain technical aspects regarded by the working group to be appropriate for international standardization. The working group acknowledges that requirements for microbiological aspects of the fluids transported by dental units are also worthy of standardization and is working to develop requirements pertaining to the prevention, inhibition and removal of dental unit waterline bio film. Additional projects to develop microbiological requirements for air, water and/or suction may follow.

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Dentistry — Dental units — Part 2: Media channels and connections

1 Scope

This part of ISO 7494 specifies requirements and test methods concerning:

- a) The configuration of dental unit connections to the compressed air supply, water supply, suction supply and waste water drain plumbing.
- b) The materials, design and construction of the compressed air and water supply within the dental unit.
- c) The quality for incoming water and air.
- d) The performance of dental unit suction devices in a dental unit.

This part of ISO 7494 also specifies requirements for instructions for use, marking, packaging and technical description that is to be provided by the manufacturer.

This part of ISO 7494 is limited to dental units that are not used for life support treatment of ambulatory patients or for oral surgery treatment requiring sterile air and water supplies. Amalgam separators are not included in this Standard.

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 / Note: Corrected and reprinted in 2010-03-01

ISO 7494-1, Dentistry — Dental units — Part 1: General requirements and test methods

ISO 8573-1:2010, Compressed air — Part 1: Contaminants and purity classes

ISO 9168, Dentistry — Hose connectors for air driven dental handpieces

ISO 10637, Dental equipment — High- and medium volume suction systems

IEC 61672-1, Electroacoustics — Sound level meters — Part 1: Specifications

IEC 62366, Medical devices — Application of usability engineering to medical devices

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 and the following apply.

3.1

accessories

cannula, manifold, filter and/or mobile support