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BSI Standards Publication

Dentistry — Dental units

Part 2: Air, water, suction and wastewater systems (ISO 7494-2:2015)

bsi.

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This British Standard is the UK implementation of EN ISO 7494-2:2015. It supersedes BS EN ISO 11144:1997 and BS EN ISO 7494-2:2003 which are withdrawn.

The UK participation in its preparation was entrusted by Technical Committee CH/106, Dentistry, to Subcommittee CH/106/4, Dental Instruments and Equipment.

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Dentistry - Dental units - Part 2: Air, water, suction and wastewater systems (ISO 7494-2:2015)

Médecine bucco-dentaire - Units dentaires - Partie 2:
Systèmes d'alimentation en air et en eau, d'aspiration et
d'évacuation des eaux usées (ISO 7494-2:2015)

Zahnheilkunde - Zahnärztliche Behandlungseinheiten - Teil
2: Luft-, Wasser-, Absaugungs- und Abwassersysteme (ISO
7494-2:2015)

This European Standard was approved by CEN on 10 January 2015.

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CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

This document (EN ISO 7494-2:2015) 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of an identical text or by endorsement, at the latest by October 2015, and conflicting national standards shall be withdrawn at the latest by October 2015.

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 7494-2:2003 and EN ISO 11144:1996.

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

Endorsement notice

The text of ISO 7494-2:2015 has been approved by CEN as EN ISO 7494-2:2015 without any modification.

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: [Foreword - Supplementary information](#)

The committee responsible for this document is ISO/TC 106, *Dentistry*, Subcommittee SC 6, *Dental equipment*.

This edition of ISO 7494-2 cancels and replaces ISO 7494-2:2003 and ISO 11144, of which it constitutes a technical revision, while only replacing certain requirements specific to dental units given in ISO 10637. In addition, it consolidates and updates requirements formerly specified in

- ISO 10637:1999, *Dental equipment — High- and medium-volume suction systems*, and
- ISO 11144:1995, *Dental equipment — Connections for supply and waste lines*.

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

- *Part 1: General requirements and test methods*
- *Part 2: Air, water, suction and wastewater systems*

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Introduction

This part of ISO 7494 specifies requirements and test methods pertaining to components of the dental unit which convey air, water, suction, and wastewater. 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 biofilm. Additional projects to develop microbiological requirements for air, water, and/or suction may follow.

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Dentistry — Dental units —

Part 2:

Air, water, suction and wastewater systems

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 wastewater drain plumbing,
- b) the materials, design, and construction of the compressed air and water system within the dental unit,
- c) the quality for incoming water and air, and
- d) the performance of dental unit suction system.

This part of ISO 7494 also specifies requirements for instructions for use and technical description.

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 International Standard.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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 7494-1:2011, *Dentistry — Dental units — Part 1: General requirements and test methods*

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

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

ISO 10637:1999, *Dental equipment — High- and medium-volume suction systems*

ISO 14971, *Medical devices — Application of risk management to medical devices*

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 ISO 7494-1 and the following apply.

3.1

air separator

apparatus which separates liquids and solids from the suction air