

SLOVENSKI STANDARD oSIST prEN ISO 7494-2:2021

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Zobozdravstvo - Stacionarne dentalne enote - 2. del: Sistemi za dovod zraka in vode, za sukcijo (aspiracijo) in odvod odpadne vode (ISO/DIS 7494-2:2021)

Dentistry - Stationary dental units - Part 2: Air, water, suction and wastewater systems (ISO/DIS 7494-2:2021)

Zahnheilkunde - Fest installierte dentale Behandlungseinheiten - Teil 2: Luft-, Wasser-, Absaug- und Abwassersysteme (ISO/DIS 7494-2:2021)

Médecine bucco-dentaire - Units dentaires fixes - Partie 2. Systèmes d'alimentation en air et en eau, d'aspiration et d'évacuation des eaux usées (ISO/DIS 7494-2:2021)

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Dentistry — **Stationary dental units** — Part 2: **Air, water, suction and wastewater systems**

Partie 2: Systèmes d'alimentation en air et en eau, d'aspiration et d'évacuation des eaux usées

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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 of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 106, Dentistry, Subcommittee SC 6, Dental equipment. <u>oSIST prEN ISO 7494-2:2021</u> https://standards.iteh.ai/catalog/standards/sist/9c75e5b7-a834-4d95-a85b-

This third edition cancels and replaces the second edition (ISO 7494-2:2015), which has been technically revised.

The main changes compared to the previous edition are as follows:

- clarification that requirements in this document are limited to stationary dental units;
- requirements for connections from the stationary dental unit to dental handpieces were added as subclause 5.1;
- measurement procedures for air flow and water flow were added in <u>7.2.2;</u>

A list of all parts in the ISO 7494 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at <u>www.iso.org/members.html</u>.

Introduction

This document specifies requirements and test methods pertaining to components of stationary dental units which convey air, water, suction, and wastewater. The requirements in this document focus on certain technical aspects to be appropriate for international standardization. The working group acknowledges that requirements for microbiological aspects of the fluids transported in the stationary dental units are also worthy of standardization and is working to develop requirements pertaining to the prevention, inhibition, and removal of stationary dental unit waterline biofilm. Additional projects to develop microbiological requirements for air, water, and/or suction may follow.

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Dentistry — Stationary dental units —

Part 2: Air, water, suction and wastewater systems

1 Scope

This document specifies requirements and test methods for stationary dental units concerning

- a) the properties of stationary 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 stationary dental unit,
- c) the quality for incoming water and air, and
- d) the performance of stationary dental unit suction system, and
- e) the air, water, suction and wastewater properties of stationary dental unit connections to the interfaces to dental handpieces. A DARD PREVIEW

This document also specifies requirements for in structions for use and technical description.

This document does not specify requirements or test methods for the effectiveness of stationary dental unit waterline biofilm control. https://standards.iteh.ai/catalog/standards/sist/9c75e5b7-a834-4d95-a85b-

NOTE Test methods for the effectiveness of stationary dental unit waterline biofilm control are specified in ISO 16954.

This document is limited to stationary dental units that are not used for oral surgery treatment requiring sterile air and water supplies. Amalgam separators are not included in this document.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 7494-1, Dentistry — Stationary dental units and dental patient chairs — Part 1: General requirements

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

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

ISO 10637, Dentistry — Central suction source equipment

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942, ISO 7494-1, ISO 10637, ISO 14457, ISO 18397, ISO 20608, ISO 22569 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at https://www.iso.org/obp
- IEC Electropedia: available at http://www.electropedia.org/

3.1

bacterial filter

filter designed to restrict the passage of bacteria and reduce bacteria in the *procedural water* (3.15) or in the compressed air

3.2

backflow

flow of water and/or another medium back into the external drinking water supply

3.3

backflow prevention device

safety device to prevent *backflow* (3.2)

3.4

bottled water system

water system of the stationary dental unit in which *procedural water* (3.15) is supplied by an included reservoir which is not connected to an external drinking water supply system and is manually filled with *procedural water* (3.15)

3.5

dental air

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compressed air supplied through the stationary dental unit for powering, controlling, and/or assisting various dental handpieces and equipment, as well as for assisting practitioners with procedures in the oral cavity, but not for procedures requiring medical air or sterile air, such as endoscopy, oral surgery, analgesia, and life support <u>oSIST prEN ISO 7494-2:2021</u>

3.6

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incoming dental air connection point

any port on the stationary dental unit for connection to an external compressed air supply

3.7

stationary dental unit suction system

components located between the facility suction pipeline connection point and the cannula connector that are part of the stationary dental unit which enable an air flow to be induced which is designed to remove liquids, solids, and airborne liquid or solid particulates from the mouth of the dental patient during dental treatment

Note 1 to entry: Suction source equipment may be included in stationary dental unit and/or dental patient chair, in which case no facility suction pipeline connection point exists.

3.8

stationary dental unit suction source connection point

any port on the stationary dental unit for connection to a supply of dental suction

3.9

exhaust air

dental air discharged from an air motor or turbine after being used to power the air motor or turbine

3.10

filter

apparatus which restricts targeted constituents from passing through it

3.11

incoming solution

solution of substances specified by the manufacturer, and introduced in combination with, or in place of, the *incoming water* (3.12) in order to improve or maintain the quality of the *procedural water* (3.15) or for other reasons, such as coolant for cutting burs or medicament for oral cavity

3.12

incoming water

water supplied to the stationary dental unit for procedural use or non-procedural use

3.13

incoming water connection point

any port on the stationary dental unit for connection to an external drinking water supply

3.14

non-procedural water

water supplied by the stationary dental unit for purposes other than use in the oral cavity

EXAMPLE Cuspidor bowl rinse water, *water venturi* (3.20), supply water

3.15

procedural water

water supplied by the stationary dental unit for use in the oral cavity

EXAMPLE Handpiece coolant water, multifunction handpiece (syringe) water, scaler coolant water, cup fill water

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3.16 retraction

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re-entry of water, air, and/or other medium into the stationary dental unit or the dental handpiece due to flow reversal <u>oSIST prEN ISO 7494-2:2021</u>

EXAMPLE https://standards.iteh.ai/catalog/standards/sist/9c75e5b7-a834-4495-a85b-Momentary dynamic pressure variations during turning off the handpiece.

3.17

spill-over level

highest possible level of water or solution in a device above which the fluid will flow over the edge

3.18

wastewater

solution that is discharged into the drainage system by way of the cuspidor drain, saliva ejector, air separator, amalgam separator, or other component or system of the stationary dental unit

3.19

water disinfection system

system designed to reduce the microbiological contamination in a stationary dental unit *procedural* water (3.15)

3.20

water venturi

device using waterflow to produce a suction

3.21

wastewater connection point

port for the connection through which *wastewater* (3.18) flows and is discharged into the drains

4 Classification

4.1 Classification of suction systems

According to ISO 10637, suction systems are classified to the type of suction as follows:

- a) Dry-suction system;
- b) Semi-dry-suction system;
- c) Wet-suction system.

4.2 Classification of suction air flow rate

According to ISO 10637, suction systems are classified to the type of air flow rate as follows:

Type 1: Suction system intended to supply a minimum air flow rate of 250 NL/min at one suction cannula connector on the stationary dental unit.

NOTE Often referred to as "High-volume suction systems".

Type 2: Suction system intended to supply a minimum air flow rate of 170 NL/min at one suction cannula connector on the stationary dental unit.

Type 3: Suction system intended to supply a minimum air flow rate of 90 NL/min at one suction cannula connector on the stationary dental unit TANDARD PREVIEW

NOTE Often referred to as "Medium-volume suction systems" teh.ai)

5 Requirements

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5.1 Connections from the stationary dental unit to dental handpieces

Technical description shall include the configuration of the air and water connections to the applicable dental handpieces.

NOTE This information helps dentists to select dental handpieces that perform clinically as expected.

5.1.1 Powered scaler

The flowrate and pressure for air and water supplied by the stationary dental unit at the connection to the powered scaler shall meet the specifications of the manufacturer.

NOTE For reference, air and water flowrates for powered scalers according to ISO 18397 and typical values:

a) Air-powered and electrical powered scalers:

A water flowrate of at least 20 ml/min at a pressure specified by the manufacturer is specified in ISO 18397. An adjustable flow rate up to 25 ml/min at a pressure of 250 kPa is typical.

b) Air powered scalers:

An air flowrate of up to 66 Nl/min at a pressure of (300 ± 100) kPa [$(3,0 \pm 1,0)$ bar] is specified in ISO 18397. An air flow rate of 30 Nl/min is typical.

Test in accordance with <u>7.2</u>.

The manufacturer's specification for air and water flowrate and pressure at the connection to the powered scaler shall be provided in the technical description and in the instructions for use.

5.1.2 Multifunction handpiece

The flowrate and pressure for air and water supplied by the stationary dental unit at the connection to the multifunction handpiece shall meet the specifications of the manufacturer.

NOTE For reference, air and water flowrates for multifunction handpiece according to ISO 22569 and typical values:

- a) An air flowrate of at least 10 Nl/min at a pressure specified by the manufacturer is specified in ISO 22569. An air flowrate of 10 Nl/min at a pressure of 300 kPa [3,0 bar] is typical.
- b) A water flowrate of at least 50 ml/min at a pressure specified by the manufacturer is specified in ISO 22569. A water flow rate of 50 ml/min at a pressure of 140 kPa [1,4 bar] is typical.

Test in accordance with 7.2.

The manufacturer's specification for air and water flowrate and pressure at the connection to the multifunction handpiece shall be provided in the technical description and in the instructions for use.

5.1.3 Handpiece and motor

The flowrate and pressure for air and water supplied by the stationary dental unit at the connection to the handpiece or motor shall meet the specifications of the manufacturer.

NOTE For reference, air and water flowrates for handpiece and motor according to ISO 14457 and typical values:

- a) For high-speed air turbine handpieces, air motors, handpieces with integrated air motor and prophy handpieces with integrated air motor a maximum air flow rate of 80 Nl/min at a pressure of (300 ± 100) kPa [(3,0 ± 1, 0) bar] is specified in ISO 14457. An air flow rate of 55 Nl/min is typical for a wide range of high speed air turbine handpieces.
- b) For electrical motors equipped with an air-cooling system a maximum air supply with 40 NL/min at a pressure range of 250 kPa to 500 kPa (2,5 bar to 5,0 bar) is specified in ISO 14457. An air flow rate of 20 Nl/min is typical.
- c) A spray air flowrate of at least 1,5 Nl/min at a pressure of 250 kPa [2,5 bar] is specified in ISO 14457 and is typical.
- d) A water flow rate of at least 50 ml/min at a pressure of 250 kPa [2,5 bar] is specified in ISO 14457 and is typical.

The stationary dental unit should conduct exhaust air from the connection to the handpiece to the atmospheric outlet in such a way as to keep air flow resistance in the exhaust line as low as practical.

Test in accordance with <u>7.2</u>.

The manufacturer's specification for air and water flowrate and pressure at the connection to the handpiece or motor shall be provided in the technical description and in the instructions for use.

5.1.4 Powder jet handpiece

The flowrate and pressure for air and water supplied by the stationary dental unit at the connection to the powder jet handpiece shall meet the specifications of the manufacturer.

NOTE For reference, air and water flowrates for powder jet handpieces according to ISO 20608 and typical values:

- a) A maximum drive air flowrate of 40 Nl/min at 250 kPa [2,5 bar] is specified in ISO 20608.
- b) A water flowrate of at least 20 ml/min at 150 kPa [1,5 bar] is specified in ISO 20608 and is typical.

Test in accordance with <u>7.2</u>.