INTERNATIONAL STANDARD

ISO 7494-2

Second edition
2015-04-01

Dentistry — Dental units —

Part 2: Air, water, suction and wastewater systems

Médecine bucco-dentaire — Units dentaires —

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

Reference number
ISO 7494-2:2015(E)

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Published in Switzerland

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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*

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.

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

3.2
bacterial filter
filter designed to restrict the passage of bacteria and reduce bacteria in the procedural water or in the compressed air

3.3
backflow
flow of water and/or another medium back into the external drinking water supply

3.4
backflow prevention device
safety device to prevent backflow

3.5
bottled water system
dental unit water system in which procedural water is supplied by an included reservoir which is not connected to an external drinking water supply system and is manually filled with incoming water or incoming solution

3.6
cannula connector
component at the end of the dental suction operating hose, which joins the cannula to the operating hose

3.7
dental air
compressed air supplied through the dental unit for powering, controlling, and/or assisting various dental instruments 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

3.8
dental treatment centre
combination of functional items for dental use which consist, for example, of dental unit, dental patient chair, and interconnected sub-units of dental equipment and instruments providing a functional environment for dental care

3.9
dental unit suction system
passive entity, including all the components from the dental unit suction source connection point through the cannula connector, which can induce air flow when connected to a suction source to evacuate solids, liquids, aerosols and gases from the oral cavity and immediate surrounding area during oral treatment procedures

3.10
dental unit suction source connection point
any port on the dental unit for connection to a supply of dental suction

3.11
filter
apparatus which restricts targeted constituents from passing through it

3.12
incoming air
compressed air supplied to the dental unit

3.13
incoming air connection point
any port on the dental unit for connection to an external compressed air supply

3.14
incoming solution
solution of substances specified by the manufacturer, and introduced in combination with, or in place of, the incoming water in order to improve or maintain the quality of the procedural water or for other reasons, such as coolant for cutting burs or medicament for oral cavity

3.15
incoming water
water supplied to the dental unit for procedural use or non-procedural use

3.16
incoming water connection point
any port on the dental unit for connection to an external drinking water supply

3.17
non-procedural water
water supplied by the dental unit for purposes other than use in the oral cavity

EXAMPLE Cuspidor bowl rinse water, water venturi supply water.

3.18
procedural water
water supplied by the dental unit for use in the oral cavity

EXAMPLE Handpiece coolant water, multifunction handpieces (syringes) water, scaler coolant water, cup fill water.

3.19
retraction
re-entry of water, air, and/or other medium into the dental unit or the dental instruments due to flow reversal, e.g. caused by momentary dynamic pressure variations during turning off the instruments

3.20
rinse water
water for cleaning

3.21
spill-over level
highest possible level of water or solution in a device above which the fluid will flow over the edge

3.22
suction system
active entity of dental equipment, including a suction source equipment, which enables an air flow to be induced which is designed to remove spray, liquids, and solids from the mouth of the dental patient during dental treatment

3.23
wastewater
solution that is discharged into the drainage system by way of the cuspidor drain, saliva ejector, air separator, amalgam separator, or other dental unit component or system

3.24
water disinfection system
system designed to reduce the microbiological contamination in a dental unit procedural water

3.25
water venturi
device using waterflow to produce a suction

3.26
wastewater connection point
port for the connection through which wastewater flows and is discharged into the drains

4 Classification

4.1 Classification of suction systems

According to ISO 10637:1999, suction systems are classified to the type of suction as follows:

a) dry system;

b) semi-dry system;

c) wet system.

4.2 Classification of suction air volume flow rate

According to ISO 10637:1999, suction systems are classified to the type of air volume flow rate as follows:

a) type 1: high-volume suction system, suction system with an air intake of more than 250 Nl/min[1)] at the suction cannula connector;

b) type 2: medium-volume suction system, suction system with an air intake between 90 Nl/min and 250 Nl/min[1)] at the suction cannula connector.

5 Requirements

5.1 Requirements for supply connections

The manufacturer's technical description shall include the configuration of the supply connections for the dental unit. The specified configuration of the supply connections shall lie within a maximum area of 180 mm × 220 mm.

The manufacturer's technical description shall include detailed information of the position and the dimensions of supply connections (see keys 1 to 5 in Figure 1) for the dental unit in the dental treatment centre.

In the dental treatment centre, often a core hole in the floor with a diameter of 160 mm is used. Therefore, it is recommended to place the supply connections within this diameter.

An example of the configuration and the connection points is given in Figure 1.

Dimensions for the connections for electricity and compressed air areas (see keys 4 and 5 in Figure 1) are given as maximum values.

Dimensions for plumbing holes (see keys 1, 2, and 3 in Figure 1) are given as minimum values. The diameters specify the free space required for tubes and hoses.

The holes without dimensions can be positioned anywhere inside the connection area.

Gas tubing, if required, shall not be located inside the areas specified in Figure 1.

The location of other utility connections which are not indicated shall be specified by the manufacturer.

This test is in accordance with 7.12.

5.2 Requirements for water and wastewater systems

NOTE A schematic diagram of possible water and wastewater systems is given as example in Figure A.1.

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1) Nl/min indicates *normal litres per minute*, the amount of air that flows through a pipe calculated back to "normal" conditions [0 °C and 1 atm or 1,01325 bar (1 bar = 0,1 MPa = 0,1 N/mm^2 = 10^5 N/m^2)].

5.2.1 Incoming water

The manufacturer's instructions for use and technical description shall specify the requirements for the incoming water to be supplied to the dental unit, including the following parameters.

The following values are recommendations:

a) water pressure limits (2 bar to 6 bar);

b) water flow rate limit (greater than 5 l/min);

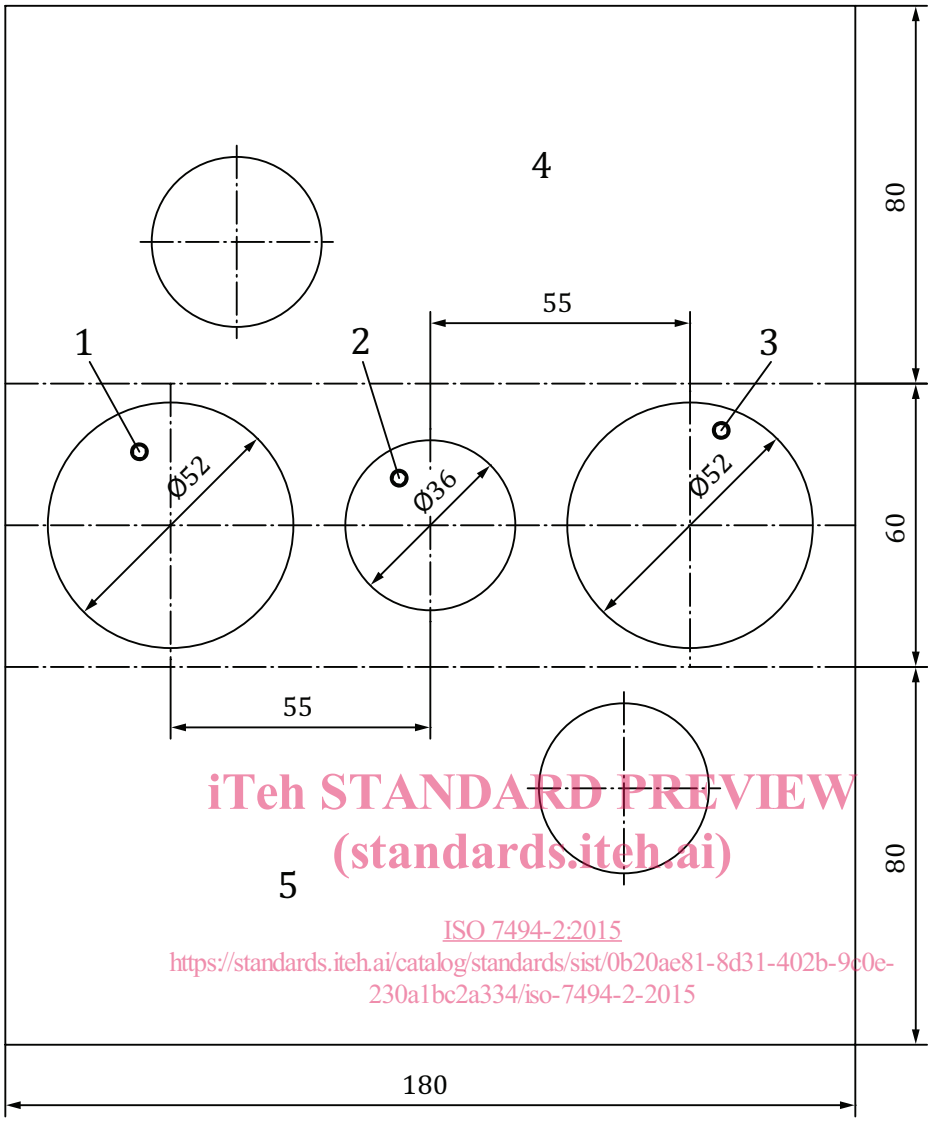
c) water hardness limit [less than 2,14 mmol/l (<12 °dH)];

d) pH limits (6,5 to 8,5);

e) maximum particle size (<100 µm);

f) conformance to local drinking water regulations.

This test is in accordance with 7.11.



Key

1 wastewater connection point
2 incoming water connection point
3 dental unit suction source connection point
4 connection area for electricity and telecommunication
5 connection area for incoming air

Figure 1 — Configuration example of connection points and adjacent supply areas

5.2.2 Materials used for construction of procedural water systems within the dental unit

The dental unit shall be designed and constructed in such a way that the materials which come into contact with the procedural water or solutions or that are likely to come into contact with them do not cause an unacceptable risk to the quality of the procedural water or solution.

The materials used within the water path shall be documented by the manufacturer. The materials used shall be evaluated by risk analysis to ensure that they do not cause an unacceptable risk to the quality of procedural water or solution.

Manufacturers shall document this risk analysis in accordance with ISO 14971.

