INTERNATIONAL STANDARD

ISO 7494-2

First edition
2003-03-01

Dentistry — Dental units —

Part 2: Water and air supply

Art dentaire — Units dentaires —

Partie 2: Alimentation en eau et en air

Reference number
ISO 7494-2:2003(E)

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Published in Switzerland

Contents

Page

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 first edition of ISO 7494-2, together with ISO 7494-1, cancels and replaces ISO 7494:1996, which has been technically revised.

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

— *Part 2: Water and air supply*

The following part is under preparation:

— *Part 1: General requirements*

Introduction

The requirements for water and air supply of dental units have been discussed extensively in TC 106/SC 6/WG 2, and it was concluded that the technical specifications for the water and air lines within dental units are sufficiently defined while the microbiological side of the problem is not addressed.

The formulation of criteria in order to avoid or reduce biofilm on the surfaces in water and air lines was considered difficult. Because the current technical state of the art does not provide an all-inclusive solution, no agreement could be reached. Therefore it was agreed to publish first the general technical requirements for the water and air lines as an International Standard. In the next step it is envisaged to find a solution for the microbiological problems, including evaluation criteria for controlling or removing dental waterline biofilm.

Dentistry — Dental units —

Part 2: Water and air supply

1 Scope

This part of ISO 7494 specifies requirements and test methods for the materials, design and construction of the water and air supply within dental units in order to ensure that the compressed water and air supplied via the dental unit are of appropriate quality. It includes provisions for the prevention of retraction of oral fluids into the water supply of the dental unit.

This part of ISO 7494 does not address prevention of contamination and/or proliferation of hazardous micro-organisms (for example bacteria, viruses) in the dental unit.

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 7494:1996, *Dental units*

ISO 11144, *Dental equipment — Connections for supply and waste lines*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
procedural water
water supplied by the dental unit for use in the oral cavity

EXAMPLE Handpiece coolant water, syringe water, scaler coolant water or rinse cup water.

3.2
non-procedural water
water supplied by the dental unit for purposes other than use in the oral cavity

EXAMPLE Cuspidor bowl rinse water or water venturi supply water.

3.3
incoming water
water supplied to the dental unit for procedural or non-procedural use

3.4
incoming solution
solution of substances defined 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

NOTE Other reasons may be as coolant for cutting burs, medicament for oral cavity, etc.

3.5
bottled water system
water supply system that is based on a reservoir supplying procedural water or solution separately from the incoming water from the municipal water supplier

3.6
outgoing water
water emerging from the dental unit

3.7
outgoing solution
solution of substances, defined by the manufacturer, emerging from the dental unit in combination with, or in place of, the outgoing water

3.8
retraction
re-entry of water, air and/or other medium into the dental unit or the dental instruments due to flow reversal

NOTE Retraction may be caused e.g. by momentary dynamic pressure variations during turning off the instruments.

3.9
backflow
flow of water, air and/or another medium back into the municipal water supply via the dental unit

3.10
wastewater
any solution that is discharged into the drainage system from the dental operatory

NOTE Wastewater may be discharged from e.g. the cuspidor, saliva ejector, water separator, amalgam separator.

3.11
incoming-water connection point
any port on the dental unit for connection to a municipal water supply

3.12
wastewater connection point
port for the connection through which wastewater flows and is discharged into the drains

3.13
incoming air
compressed air supplied to the dental unit

3.14
incoming-air connection point
any port on the dental unit for connection to a compressor

3.15
backflow-prevention device
device to prevent backflow

EXAMPLE Pipe disconnector or air gap.

3.16
cleaning system for suction or wastewater lines
system for cleaning the suction or wastewater lines configured in such a way that the suction or wastewater tubes are connected to the procedural water supply for flushing

3.17
rinse water
water for cleaning

3.18
spill-over level
highest possible level of water or solution in a device above which the fluid spills over the edge

3.19
water venturi
device using water flow to produce a vacuum

3.20
water-disinfection system
system intended to reduce the number of colony-forming units of bacteria per millilitre of water or solution

3.21
antibacterial filter
filter intended to trap and reduce bacteria in the procedural water or in the compressed air

3.22
dental air
common ambient air available in the dental office, used for dental procedures in the oral cavity of the patient

NOTE This air is different from medical air used for anaesthetic purposes or for surgical purposes (e.g. during endoscopy).

4 Requirements for the water supply

4.1 General

All connections shall be in accordance with ISO 11144. A schematic diagram of possible water connections in dental units is given in Figure 1.

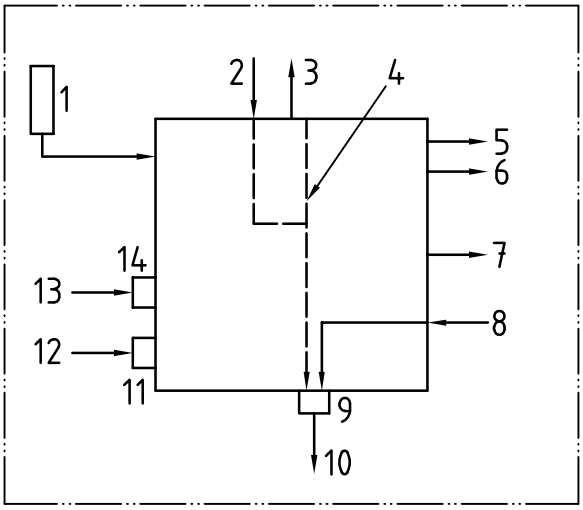
4.2 Materials used for construction of procedural water systems within the dental unit

The dental unit shall be designed and constructed so that the materials which come into contact with procedural water or solutions, or that are likely to come into contact with them, do not cause any adverse effects on the quality of the procedural water or solution.

For the construction of procedural water or solution lines, only materials which have been approved by water quality authorities, if available, shall be used.

The materials used within the water path shall be listed together with the respective International Standard with which they comply, if applicable.

Test in accordance with Clause 7.



Key

1 incoming water or procedural solution from a bottled water system
2 wastewater outlet from the cuspidor
3 non-procedural water for the cuspidor
4 wastewater lines within the dental unit
5 procedural water for the cup filler
6 procedural water for dental instruments
7 air for dental instruments
8 water outlet from the suction device
9 wastewater connection point
10 wastewater line
11 incoming-air connection point
12 incoming air
13 incoming water from the municipal water supply
14 incoming-water connection point

Figure 1 — Examples of possible water and air connections in dental units

4.3 Backflow prevention for systems using municipal water

A system using municipal water as procedural water for the dental unit (e.g. for dental instruments, cup fillers), for cleaning suction or wastewater supply lines and for water-disinfection systems, shall have a backflow-prevention device at the point of connection with the municipal water supply or an air gap of no less than 20 mm.

Test in accordance with 6.3.

4.4 Cuspidor

The distance of the air gap between the point at which the rinse water for the cuspidor is dispensed and the spill-over level of the cuspidor with a blocked drain shall be at least 20 mm.

Test in accordance with 6.1.

4.5 Water venturi

Water venturis for suction of saliva and wastewater shall only be used if an additional backflow-prevention device is installed at the connection point of the water venturi device.

Test in accordance with 6.2.

4.6 Particle filter

Except in the case of a bottled water supply, at least one particle filter with an effective mesh size not exceeding 90 µm shall be installed at the incoming-water connection point in the dental unit in order to prevent the entry of solid particles from the municipal water supply into the water system.

Test in accordance with 6.6.

4.7 Bottled water system supplying incoming water or solution

These systems shall either be completely separate from the municipal water supply system or shall have a backflow-prevention device at the point of connection with the municipal water supply system.

Test in accordance with 6.4.

4.8 Retraction

The volume of the retraction of procedural water or solution shall not exceed 40 mm^3 (= 0,04 ml).

Test in accordance with 6.5.

4.9 Water-disinfection systems

These systems shall either be completely separate from the municipal water supply system or shall have a backflow-prevention device at the point of connection with the municipal water supply system.

If a water-disinfection system is installed in a dental unit, it shall be tested in accordance with 6.8.

5 Requirements for the air supply

5.1 General

All connections shall be in accordance with ISO 11144.

A schematic diagram of possible air connections in dental units is given in Figure 1.

5.2 Particle filters

A filter with an effective mesh size not exceeding 25 µm shall be installed at the incoming-air connection point of the dental unit.

Test in accordance with 6.6.

5.3 Antibacterial filters

If antibacterial filters are installed in a dental unit, they shall be tested in accordance with 6.7 and Clause 7 e).

6 Tests

6.1 Cuspidors

Check by visual inspection whether the rinse water is dispersed above the spill-over level of the wastewater. Then measure the distance of the air gap with a measuring device.

6.2 Water venturi

Check by visual inspection that a backflow-prevention device is installed at the connection point of the water venturi device.

6.3 Systems using municipal water

Check by visual inspection whether a backflow-prevention device or an air gap is installed at the point of connection with the municipal water supply. Measure the distance of the air gap with a measuring device.

6.4 Bottled water system supplying procedural water or solution

Check by visual inspection if the bottled water system is separate from the municipal water supply. If not, check by visual inspection if a backflow-prevention device is installed at the point of connection with the municipal water supply.

6.5 Retraction

To measure the extent of retraction occurring beyond the connection point of the handpiece tubing, connect a transparent tube of (150 ± 2) mm length and (1,5 ± 0,1) mm internal diameter to the fitting to which the water tube of the handpiece hose is normally attached. Square off the unconnected end of the transparent tube. Operate the unit's water valve as would normally be done when shutting off the handpiece. The meniscus of the column of water in the tube shall not be more than 20 mm from the end of the tube when held vertically, with the open tube end extending upward.

The use of test tubing with an internal diameter, d, in the range of 0,8 mm to 2,0 mm is also permitted. In these cases measure the distance l, in millimetres, from the meniscus to the open end of the tube. Then calculate the volume V, in cubic millimetres, of retracted fluid using the following formula:

$$V = \frac{\left(\pi d^2 l\right)}{4}$$

where

V is the volume of retracted fluid, in cubic millimetres;

d is the inside diameter of the test tube, in millimetres;

l is the length from the meniscus to the open end of the test tube, in millimetres.

6.6 Particle filters

Check by visual inspection whether a particle filter is installed at the incoming-water and/or -air connection points. Check the accompanying documents to ensure that all information specified is provided, including information on the size of the filter mesh.

Check if the specified filter size meets the requirement for water filters in 4.5 or for air filters in 5.2.

6.7 Antibacterial air filters

Check by visual inspection whether antibacterial filters are installed. Check the accompanying documents to ensure that all information specified is provided.

6.8 Water-disinfection systems

Check by visual inspection whether water-disinfection systems are installed. Check the accompanying documents to ensure that all information specified is provided.

7 Manufacturer's instructions and information for use

Dental units shall be accompanied by documents containing relevant information as specified in ISO 7494:1996, Clause 8. In addition, the following information shall be provided by the manufacturer:

a) a description of the required quality of the incoming water for the dental unit, including the hardness range of the water;

b) a statement drawing the user's attention to the existence of national regulations, if available, concerning the quality of water for human use;

c) if a bottled water system is provided, information about decontamination of the reservoir and water lines or replacement of disposable ones, and information about connecting the water system to the dental unit;

d) the effective filter size and materials of particle filters and instructions for maintenance;

e) if antibacterial air filters are used, information about the method to be used for testing efficacy;

f) if antibacterial air filters are included in the air system of the dental unit, information concerning the technique for maintenance and replacement of the antibacterial filters;

g) if no water-disinfection system is installed into the dental unit, instructions for maintaining the water system to ensure that disinfection of the dental unit does not adversely affect the water quality, including the recommended rinsing and maintenance frequencies;

h) if the dental unit does not prevent the retraction of procedural water into the dental unit, a statement that only instruments which include anti-retraction devices are to be used together with the dental unit;

i) a statement drawing the user's attention to the existence of applicable regulations regarding backflow prevention and, if applicable, which provisions for such prevention have been made in the dental unit;

j) a specification of the required quality of the incoming dental air (e.g. free from oil, water, bacteria);

k) a statement drawing the user's attention to the existence of national regulations, if available, concerning the quality of dental air;

l) if a disinfection system is included in the dental unit, information concerning efficacy and the method to be used for testing efficacy and instructions on how to use the water-disinfection system.

In addition, information about the materials used for the water path (e.g. a list of materials) shall be made available to the user on request.

Bibliography

[1] ISO 1942-4, *Dental vocabulary — Part 4: Dental equipment*

ICS 11.060.20

Price based on 8 pages