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Dentistry — Stationary dental units and dental patient chairs —

Part 2: Air, water, suction and wastewater systems

Médecine bucco-dentaire — Units dentaires fixes et fauteuils dentaires patient —

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,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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

The main changes are as follows:

— the requirements in this document have been limited to stationary dental units;

— the requirements for connections from the stationary dental unit to dental handpieces have been added in 5.1;

— measurement procedures for air flow and water flow have been added in 7.2.2;

— requirements for treatment methods for dental unit waterline biofilm have been added in 5.3.11;

— the requirement for noise level for dental suction systems has been removed since that main contribution to noise comes from the cannula, which is outside of the scope of this document.

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 www.iso.org/members.html.

Dentistry — Stationary dental units and dental patient chairs —

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,

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.

This document also specifies requirements for instructions for use and technical description.

This document does not specify requirements or test methods for the effectiveness of stationary dental unit waterline biofilm control.

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

This document is only applicable 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 10637, *Dentistry — Central suction source equipment*

ISO 14457, *Dentistry — Handpieces and motors*

ISO 18397, *Dentistry — Powered scaler*

ISO 20608, *Dentistry — Powder jet handpieces and powders*

ISO 22569, *Dentistry — Multifunction handpieces*

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 terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://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 hinder *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
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

3.6
incoming dental air connection point
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 either stationary dental unit or dental patient chair, or both, in which case no facility suction pipeline connection point exists.

3.8
stationary dental unit suction source connection point
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 that 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

EXAMPLE 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
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.

3.16
retraction
re-entry of water, air, and/or other medium into the stationary dental unit or the dental handpiece due to flow reversal

EXAMPLE 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 1 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.

NOTE 2 Often referred to as “medium-volume suction systems”.

5 Requirements

5.1 Connections from the stationary dental unit to dental handpieces

5.1.1 General

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.

5.1.2 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 Air and water flowrate specifications for powered scalers according to ISO 18397 and typical values are as follows:

a) Air-powered and electrical powered scalers: A minimum water flowrate is specified in ISO 18397. An adjustable flow rate up to 25 ml/min at a pressure specified by the manufacturer is typical.

b) Air-powered scalers: An air flowrate of up to 66 Nl/min at a pressure of (300 ± 100) kPa is specified in ISO 18397. An air flow rate of 30 Nl/min at a pressure of 300 kPa is typical.

Test in accordance with 7.2.

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.

5.1.3 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 Air and water flowrate specifications for multifunction handpiece according to ISO 22569 and typical values are as follows:

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 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 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.

5.1.4 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 Air and water flowrate specifications for handpiece and motor according to ISO 14457 and typical values are as follows:

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 is specified in ISO 14457. An air flow rate of 55 Nl/min at a pressure of 300 kPa 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 is specified in ISO 14457. An air flow rate of 20 Nl/min at a pressure of 250 kPa to 500 kPa is typical.

c) A spray air flowrate of at least 1,5 Nl/min at a pressure of 250 kPa 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 is specified in ISO 14457 and is typical.

Test in accordance with 7.2.

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.

5.1.5 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 Air and water flowrate specifications for powder jet handpieces according to ISO 20608 and typical values are as follows:

a) A maximum drive air flowrate of 40 Nl/min at 250 kPa is specified in ISO 20608.

b) A water flowrate of at least 20 ml/min at 150 kPa is specified in ISO 20608 and is typical.

Test in accordance with 7.2.

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

5.1.6 Simultaneous use of more than one dental handpiece

Unless the simultaneous use of multiple dental handpieces is excluded by design or contraindicated in the instructions for use, the requirements for minimum water flow rate and minimum air flow rate specified in 5.1.1 to 5.1.5 shall be met when the multifunction handpiece is operated simultaneously with each of the other dental handpieces or motors.

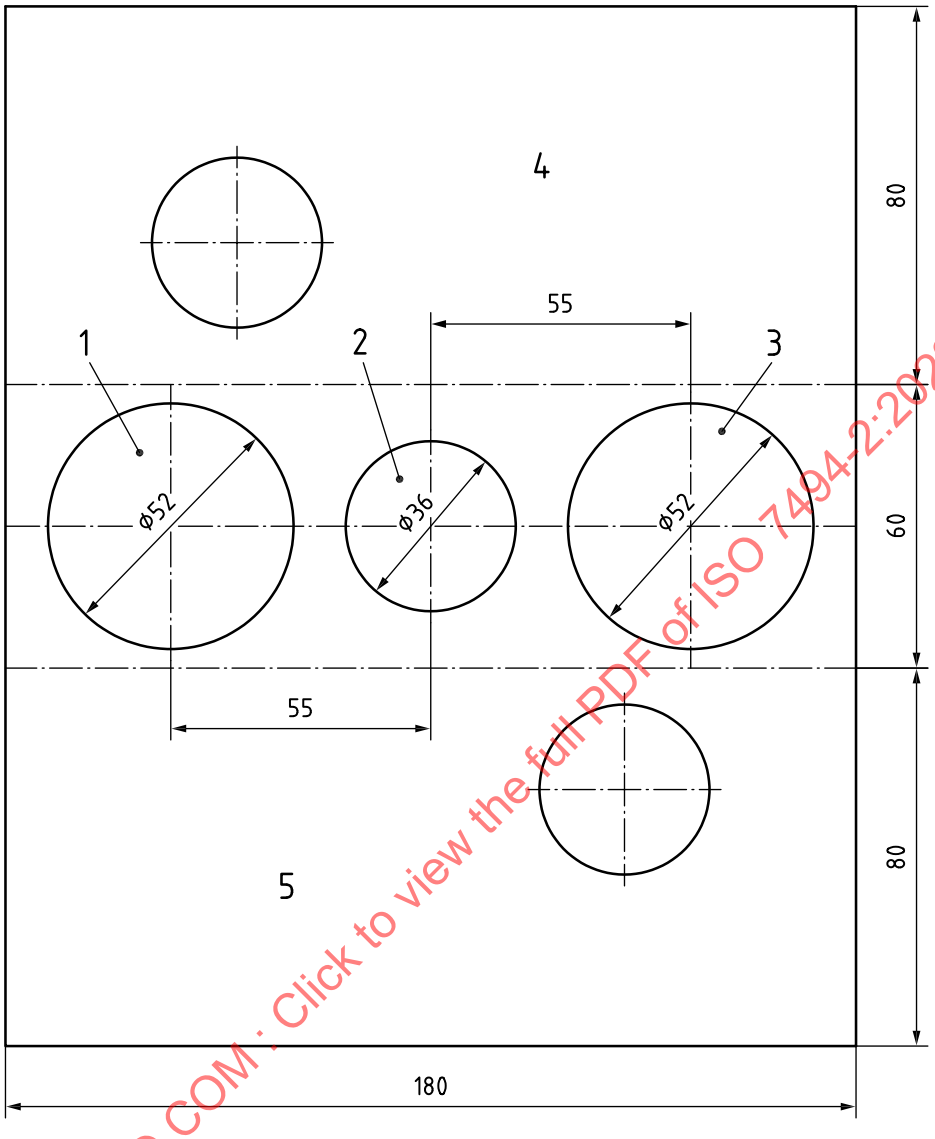
Test in accordance with 7.2.

5.2 Supply connections to the stationary dental unit

Technical description shall include the configuration of the supply connections for the stationary dental unit. The specified configuration of the supply connections shall be within a maximum area of 180 mm × 220 mm.

Technical description shall include detailed information of the position and the dimensions of supply connections (see Figure 1) for the stationary dental unit in the dental practice.

Dimensions in millimetres



Key

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

Figure 1 — Example of configuration of connection points and adjacent supply areas

In the dental practice, 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 Figure 1, keys 4 and 5) are given as maximum values.

Dimensions for plumbing holes (see Figure 1, key 1, 2, and 3) 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.

Test in accordance with 7.1.

5.3 Water and wastewater systems

5.3.1 General

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

5.3.2 Incoming water

If the stationary dental unit is intended to be directly connected to an external drinking water supply, the water supply shall be adjustable to provide the range of incoming water pressure specified by the manufacturer.

Instructions for use and technical description shall specify the requirements for the incoming water to be supplied to the stationary dental unit, including the following parameters:

a) water pressure limit;

b) water flow rate limit;

c) water hardness limit;

d) pH limits;

e) maximum particle size;

f) requirements for microbiological quality.

NOTE 1 Regional regulations can apply for drinking water.

NOTE 2 The following ranges are typical ranges:

a) water pressure limit (200 kPa to 600 kPa);

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

c) water hardness limit (less than 2,14 mmol/l;

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

e) maximum particle size (<100 µm).

Test in accordance with 7.1.

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

The materials used within the water path within the stationary dental unit shall be documented.

A risk assessment with respect to user, patient and third party shall be applied.

NOTE Treatments specified by the manufacturer of the stationary dental unit, such as the use of chemical agents in the procedural water system, could interact with the materials used in the procedural water system to affect the procedural water, which comes in contact with the patient's mucous membrane and wounds.

Test in accordance with 7.1.

5.3.4 Backflow prevention device for stationary dental units connected to the external drinking water supply

If the stationary dental unit is directly connected to the external drinking water supply, the technical description shall specify whether the stationary dental unit contains a backflow prevention device.

If the stationary dental unit contains a backflow prevention device, the backflow prevention device shall be at the incoming water connection point. If the backflow prevention device is an air gap, the air gap shall not be less than 20 mm.

NOTE Additional means of protection can be required by national or regional drinking water regulations.

If the stationary dental unit does not contain a backflow prevention device, the technical description shall include a reminder that the stationary dental unit must be installed in conformance with local backflow prevention regulations.

Test in accordance with 7.3.

5.3.5 Cuspidors

The point where the cuspidor rinse water is dispensed shall be at least 20 mm above the spill-over level of the cuspidor.

Test in accordance with 7.4.

5.3.6 Water venturi

Water venturi for suction of saliva and water 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 7.1.

5.3.7 Particle filter

A stationary dental unit directly connected to an external drinking water supply shall have at least one particle filter with an effective mesh size not greater than 100 µm installed at the incoming water connection point.

Test in accordance with 7.5.

5.3.8 Bacterial filter

If the stationary dental unit water supply is equipped with a filter intended to restrict the passage of bacteria, the bacterial filter shall be rated to restrict the passage of contaminants larger than 0,22 µm. The stationary dental unit manufacturer shall provide maintenance instructions and schedule for the bacterial filter.

Test in accordance with 7.1.

5.3.9 Bottled water system supplying procedural water or solution

These systems shall either be completely separated from the external drinking water supply system or shall have a backflow prevention device at the connection point with the external drinking water supply system.

Test in accordance with 7.1.

5.3.10 Retraction

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

Test in accordance with 7.6.

5.3.11 Treatment method for biofilm

5.3.11.1 General

The manufacturer shall specify a treatment method either for preventing or inhibiting stationary dental unit waterline biofilm formation (see 5.3.11.2) or for removing stationary dental unit waterline biofilm (see 5.3.11.3), or both in the instructions for use or technical description.

If the treatment method includes a system for manually or automatically introducing a chemical agent to the stationary dental unit waterlines, the system shall either be completely separated from the external drinking water supply system or shall have a backflow prevention device at the connection point with the external drinking water supply system.

The manufacturer shall specify the required supplies (e.g. chemical treatment), instructions for use, maintenance procedures and maintenance frequency associated with the treatment method(s).

5.3.11.2 Treatment method for biofilm prevention or inhibition

The manufacturer shall specify one or more treatment method(s) for preventing or inhibiting stationary dental unit waterline biofilm formation to achieve acceptable microbiological water quality of the procedural water supplied by the stationary dental unit.

NOTE 1 Acceptable microbiological water quality complies with national or regional requirements or recommendations for stationary dental unit procedural water.

NOTE 2 Presently no International Standard for microbiological water quality of stationary dental unit procedural water lines exists.

Test in accordance with 7.8.

5.3.11.3 Treatment method for biofilm removal

The manufacturer shall specify one or more treatment method(s) for removal of stationary dental unit waterline biofilm to achieve acceptable microbiological water quality of the procedural water supplied by the stationary dental unit.

NOTE 1 Acceptable microbiological water quality complies with national or regional requirements or recommendations for stationary dental unit procedural water.

NOTE 2 Presently no International Standard for microbiological water quality of stationary dental unit procedural water lines exists.

Manufacturers can specify that these methods shall be performed by qualified personnel only.

Test in accordance with 7.9.

5.3.12 Water sampling connection point

For stationary dental units directly connected to the external drinking water supply, the technical description should include a recommendation to install a sampling point for incoming water at or near the incoming water connection point.

NOTE See Figure A.1, key 25.

If the instructions for use recommend installing a sampling point, the instructions for use shall give information about collecting samples of water and the technical description shall provide information about the installation and collection of water samples.

Test in accordance with 7.1.

5.3.13 Wastewater drain connection

The technical description shall specify the maximum wastewater flow rate from the stationary dental unit that the drain shall be capable of accommodating.

The technical description shall specify the minimum gradient of the wastewater lines.

Test in accordance with 7.1.

5.4 Air system

5.4.1 General

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

5.4.2 Incoming dental air

The instructions for use and the technical description shall specify requirements for the dental air to be supplied to the stationary dental unit, including the following parameters:

a) air pressure limit;

b) air flow rate limit;

c) purity class [2:4:2] in accordance with ISO 8573-1.

NOTE 1 The quality of dental air is specified in ISO 22052.

NOTE 2 The following ranges are typical:

a) air pressure limits (600 ± 100) kPa;

b) air flow rate limit (greater than 80 Nl/min at 300 kPa);

c) air purity-class [2:4:2] according to ISO 8573-1:

Particle class 2: The maximum number of particles per cubic metre as a function of particle size in the dental air are as follows:

Particle size	maximum number of particles per cubic meter
0,1 µm < d ≤ 0,5 µm	≤ 400 000
0,5 µm < d ≤ 1,0 µm	≤ 6 000
1,0 µm < d ≤ 5,0 µm	≤ 100

Humidity class 4: The pressure dewpoint is ≤+3 °C at 20 °C medium temperature and at 0,7 MPa constant system pressure (this is equivalent to an atmospheric dewpoint of ≤−21 °C).

Oil content class 2: The oil content of the dental air is ≤0,1 mg/m^3.

Test in accordance with 7.1. Test results shall conform to ISO 8573-1.

5.4.3 Particle filters

A particle filter with an effective mesh size not exceeding 50 µm shall be installed at the incoming dental air connection point of the stationary dental unit.

Test in accordance with 7.5.

5.4.4 Bacterial filters

If the stationary dental unit air supply is equipped with a filter intended to restrict the passage of bacteria, the bacterial filter shall be rated to restrict the passage of contaminants larger than 0,22 µm

with a retention of 99,99 %. The stationary dental unit manufacturer shall provide maintenance instructions and schedule for the bacterial filter.

Test in accordance with 7.1.

5.5 Stationary dental unit suction systems

5.5.1 General

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

5.5.2 Maximum suction pressure

The maximum suction pressure to be supplied to the stationary dental unit at the stationary dental unit suction source connection point under static conditions (i.e. no flow) shall be specified in the technical description.

If the maximum suction pressure under no air flow conditions exceeds 40 kPa, the manufacturer shall include in the stationary dental unit a device to limit the maximum suction pressure to 40 kPa, at the cannula connector.

If the stationary dental unit is equipped with a suction-limiting device, the manufacturer shall specify the maximum suction pressure available at the cannula connector under static conditions.

The stationary dental unit suction systems shall withstand the maximum suction pressure supplied to the stationary dental unit per manufacturer specifications without damage to its materials or components.

Test in accordance with 7.7.2.

5.5.3 Suction pressure head loss

The manufacturer shall measure and report in the technical description the pressure head loss between the stationary dental unit suction source connection point and the atmospheric end of the cannula (with cannula recommended by the stationary dental unit manufacturer installed) at each of the following flow rates: 90 Nl/min, 170 Nl/min and 250 Nl/min.

NOTE 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 101,325 kPa].

Measurements shall be carried out in accordance with 7.7.3.

NOTE 2 This information helps parties responsible for specifying complete suction systems (i.e. suction source equipment, piping systems, and stationary dental unit suction systems) to meet the flow performance requirements specified by a dental clinic.

Measurements are not required at flow rates that require the suction pressure to exceed the maximum pressure specified by the manufacturer. Results at additional flow rates may be reported at the manufacturer's discretion in the technical description.

5.5.4 Configuration of cannula connectors and cannula

5.5.4.1 Nominal size of cannula

The manufacturer of the cannula connector shall state a nominal size of the connector and specify the requirements for cannula that can be used with the connector.

The manufacturer of the stationary dental unit shall describe in the technical description and in the instructions for use the required dimensions of cannula connection.

Test in accordance with 7.1.

5.5.4.2 Accessibility of cannula

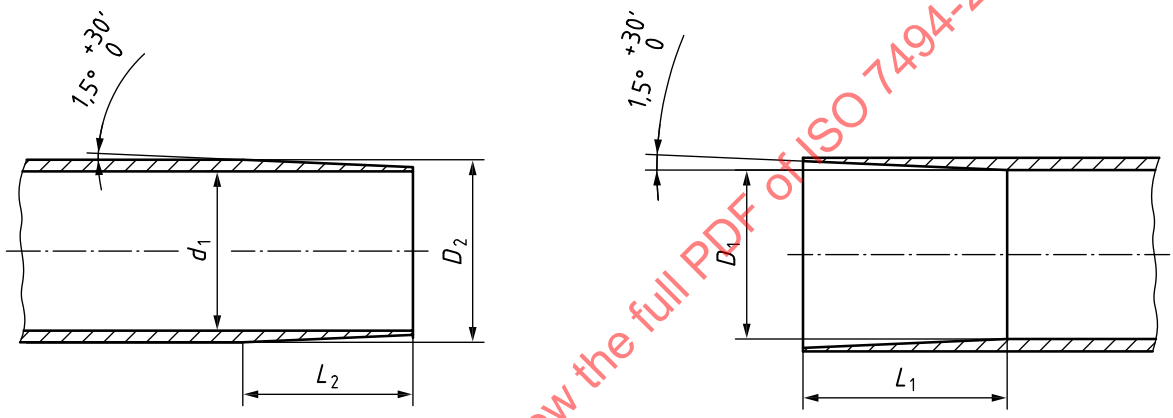
Cannula connectors shall allow access of the cannula to every part of the patient's mouth without causing distortion of the hoses.

Test in accordance with 7.1.

5.5.4.3 Dimension of cannula connection

The design of the connection between the cannula and cannula connector shall be at the discretion of the manufacturer. An example of a connection design is provided in Figure 2 and Table 1.

Dimensions in millimetres



a) Cannula **b) Cannula connector**

Key

d_1 nominal inside diameter of cannula
D_1 inside diameter of cannula connector
D_2 outside diameter of cannula
L_1 inside taper length of cannula connector
L_2 outside taper length of cannula

Figure 2 — Example of design of interface between cannula and cannula connector

Table 1 — Example of dimensions of interface between cannula and cannula connector

d_1 mm	D_1 mm	D_2 mm	L_1 mm	L_2 mm
15 ± 1	14,9 + 0,2	16,1 – 0,2	18 – 1	15 – 1
11 ± 1	10,9 + 0,2	12,1 – 0,2	18 – 1	15 – 1
≥6 Saliva ejector	Dimensions and tolerances given by the manufacturer			

The dimensions of cannula connection shall be described in the technical description and instructions for use.

Test in accordance with 7.1.

5.5.5 Operating hoses with cannula connectors

Operating hoses shall have an internally smooth surface and shall be flexible.

Test in accordance with 7.1.

5.5.6 Solids filter

Solids filter for stationary dental unit suction systems shall be located at the stationary dental unit in such a way to allow easy removal for maintenance.

If an air separator is included in the stationary dental unit, the solids filter shall be placed to ensure proper function of the air separator.

The solids filter shall have a mesh size either determined by the manufacturer or specified in the instructions for use and the technical description, or both.

Test in accordance with 7.1.

5.5.7 Air separator

The technical description shall include information about maintenance and replacement of the air separator, if applicable.

Test in accordance with 7.1.

5.5.8 Stationary dental unit suction source connection point

The technical description shall include the connection dimensions.

Test in accordance with 7.1.

5.6 Test report

A test report shall be prepared to report the results of all applicable tests and inspection requirements specified in this document. Annex C gives a template for the test report.

6 Sampling

One representative sample of the stationary dental unit water and air supply and stationary dental unit suction system being tested shall be selected.

7 Measurement and test methods

7.1 Visual inspection

7.1.1 Visual inspection of device

Visually inspect the device to determine conformity with the requirements.

7.1.2 Visual inspection of documentation or test reports

Visually inspect product documentation or test reports to determine conformity with the requirements.

7.2 Dental handpiece connection test

7.2.1 Apparatus

The test apparatus shall include the following as depicted in Figure 3:

7.2.1.1 Volumetric measuring jar, with an accuracy of ±5 %, to measure water flow rate.

7.2.1.2 Water flowmeter, with an accuracy of ±5 %, to measure water flow rate.

7.2.1.3 Air flowmeter, with an accuracy of ±5 %, to measure air flow rate.

7.2.1.4 Water pressure gauge, with an accuracy of ±5 %, to measure the water supply pressure.

7.2.1.5 Air pressure gauge, with an accuracy of ±5 %, to measure the air supply pressure.

7.2.1.6 Adapter, with a hose connection on both sides to be fitted between hose and e.g. a turbine.

NOTE For air driven instruments, a hose connector according to ISO 9168 Type 3 is used.

7.2.1.7 Dental handpiece connection jig. Other adapters between hose and instrument shall be specified by the manufacturer.

NOTE The adapter in Figure B.1 and Figure B.2 is an example for air driven instruments in accordance with ISO 9168, Type 3.

7.2.1.8 Air regulator, with an accuracy of ±5 %, to regulate air pressure.

NOTE An example can be found in Annex B.

7.2.2 Procedure

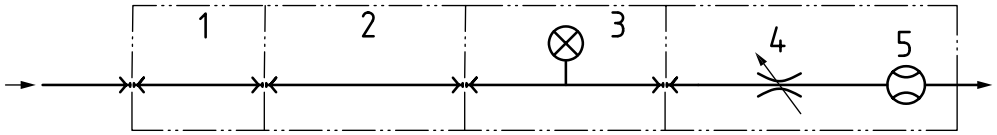
7.2.2.1 Measurement of air flow and pressure of pressurized air

Measure the pressure between hose and handpieces. Measure the air flow between hose and handpieces (as specified in 5.1.2 to 5.1.5) or at the incoming air connection point (as specified in 5.1.2 to 5.1.5). Connect the stationary dental unit to an incoming dental air supply that can be adjusted to provide the range of incoming dental air pressure specified by the manufacture with at least the minimum specified flow rate per 5.4.2.

For requirements that specify the incoming dental air supplied to the stationary dental unit is to be adjusted over the range of pressure specified by the manufacturer, perform measurements at least at the minimum and maximum pressure values for the incoming dental air specified by the manufacturer.

Adjust the pressure at the dental handpiece connection test apparatus by adjusting the attached air regulator to the values stated in 5.1.2 to 5.1.5 or to the pressure rated by the manufacturer. Measure and record the air flowrate when the dental handpiece is operated. If the flowrate varies depending on degree of operation (e.g. extent to which the foot control is operated), measure under operating conditions that produce the maximum flowrate.

If a range of pressures at the dental handpiece connection is specified, measure and record the air flowrate at least at the minimum and maximum pressure values specified.

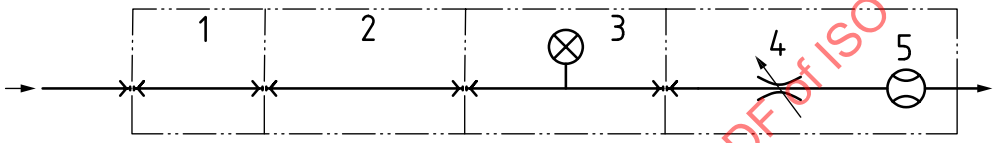


Key

1 stationary dental unit
2 hose
3 handpiece connection test jig
4 air regulator
5 air flowmeter

Figure 3 — Schematic diagram to measure air flow rate and pressure of pressurized air

7.2.2.2 Measurement of water flow rate and water pressure



Key

1 stationary dental unit
2 hose
3 handpiece connection test jig
4 water regulator
5 water flowmeter

Figure 4 — Schematic diagram to measure water flow rate and water pressure

If the stationary dental unit is intended to be directly connected to an external drinking water supply, connect the incoming water connection point to a water supply that can be adjusted to provide the range of incoming water pressure specified by the manufacturer with at least the minimum specified flow rate per 5.3.1.

If the stationary dental unit is supplied by a bottled water system, follow the manufacturer instructions for connecting the bottled water system.

For requirements that specify the incoming water supplied to the stationary dental unit is to be adjusted over the range of pressure specified by the manufacturer, perform measurements at least at the minimum and maximum pressure values for the incoming water specified by the manufacturer.

Unless otherwise specified, set the water flowrate adjustment of the stationary dental unit to the maximum flowrate setting.

Water flow rate and pressure shall be measured between hose and handpieces or at the incoming water connection point. See Figure 4.

Adjust the pressure at the dental handpiece connection test apparatus by adjusting the attached water regulator to the values stated in 5.1.1 to 5.1.5 or to the pressure rated by the manufacturer. Measure and record the water flowrate when the dental handpiece is operated. If the flowrate varies depending on degree of operation (e.g. extent to which the foot control is operated), measure under operating conditions that produce the maximum flowrate.

If a range of pressures at the dental handpiece connection is specified, measure and record the water flowrate at least at the minimum and maximum pressure values specified.

7.3 Systems directly connected to external drinking water supply test

Check by visual inspection whether a backflow prevention device or an air gap is installed at the incoming water connection point.

Measure the distance of the air gap, if applicable, with a readily available measuring device.

7.4 Cuspidor test

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 between the lowest point of the rinse water outlet and the spill-over level with a readily available measuring device.

7.5 Particle filter test

Check by visual inspection whether a particle filter is installed at the incoming water either at the incoming water or air connection points, or both. Check the instruction for use and the technical description 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 filter size requirement for water particle filters in 5.3.6 or for air particle filters in 5.4.2.

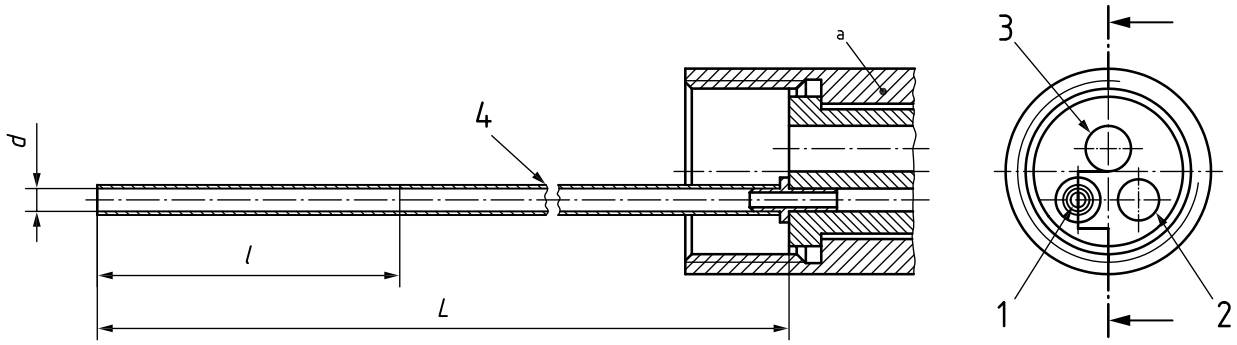
7.6 Retraction test

Connect the handpiece hose to the stationary dental unit. Then connect a transparent hose of (L = 150 ± 2) mm length and (d = 1,5 ± 0,1) mm internal diameter to the water fitting to which the handpiece is normally attached.

Measure the volume of retraction in the transparent hose.

The unconnected end of the transparent hose shall be squared off.

Operate the stationary dental unit's valve as it would usually be done when activating the water flow for the handpiece to ensure that the vertically held hose is completely filled. Operate the stationary dental unit's water valve as it would usually be done when shutting off the handpiece. The meniscus of the column of water in the hose shall not be more than a distance of l = 20 mm from the end of the hose when held vertically, with the open hose end extending upward. See Figure 5.



Key

1 water
2 exhaust
3 drive air
4 transparent hose
[a] Example of the type 4 hose connector from ISO 9168.
l retracted distance
L length of the transparent hose
d internal diameter of the transparent hose

Figure 5 — Configuration of retraction test apparatus in connection with a type 4 hose connector

7.7 Stationary dental unit suction systems test

7.7.1 General

Perform all tests at an ambient temperature of (23 ± 2) °C. Condition all test samples at ambient temperature for at least 4 h.

The connections of all measuring devices shall be leak-free.

Measure the suction pressures with a gauge having a measurement tolerance not greater than ±5 %.

7.7.2 Static suction pressure test

Connect a pressure gauge at the stationary dental unit suction source connection point capable of measuring the maximum suction supply pressure specified by the stationary dental unit manufacturer.

Plug or seal all cannula connectors in a leak-free manner.

If the stationary dental unit is equipped with a suction-limiting device, connect a second pressure gauge at the cannula connector on one of the operating hoses. Connect the second pressure gauge in a manner which allows it to measure the pressure within the suction system while the flow through the cannula connector is completely blocked.

Connect a suction source to the stationary dental unit suction source connection point and operate at the maximum suction pressure specified by the manufacturer, as measured by the pressure gauge at the stationary dental unit suction source connection point.

If the stationary dental unit is equipped with a suction-limiting device, allow it to operate normally. Check whether the pressure at the cannula connector does not exceed the maximum pressure specified by the manufacturer.

Maintain the maximum specified static suction pressure for 1 h. Then, turn off the suction source and examine all components of the stationary dental unit suction system for damage.

7.7.3 Suction pressure head loss test

7.7.3.1 Apparatus

The test apparatus shall include the following as depicted in Figure 6:

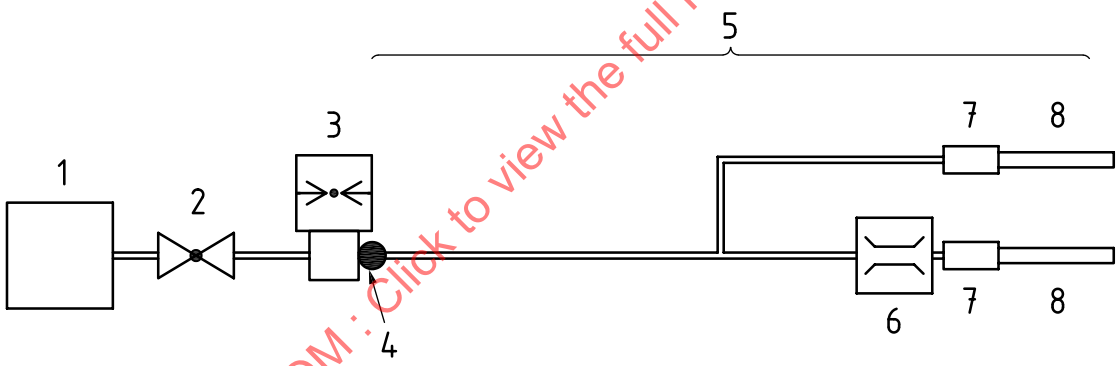
7.7.3.1.1 Suction source, as specified by the manufacturer.

7.7.3.1.2 Flow throttling valve, such as a common ball valve.

7.7.3.1.3 Suction source pressure gauge, capable of ±5 % accuracy, plus necessary items to connect the gauge to the stationary dental unit suction source connection point in a manner that has negligible impact on pressure readings and flow.

7.7.3.1.4 Flow measuring device, capable of ±5 % accuracy, that will impact the measured flow by no more than 5 %.

7.7.3.1.5 Pressure gauge, for measuring atmospheric pressure, capable of ±5 % accuracy.



Key

1 suction source
2 flow throttling valve
3 suction source pressure gauge assembly
4 stationary dental unit suction source connection point
5 stationary dental unit suction system (key 1 and 2 can be part of stationary dental unit, in which case key 4 does not exist)
6 flow measuring device (can also be placed between 7 and 8)
7 cannula connector
8 cannula

Figure 6 — Example of a configuration of typical head loss test apparatus

7.7.3.2 Procedure

Install the suction source pressure gauge assembly to the stationary dental unit suction source connection point. Connect the throttling valve on the inlet of the suction source gauge assembly. Connect the suction source device to the inlet of the throttling valve.

Install the flow measuring device at a point at which it is capable of measuring flow through one of the suction hoses with any flow control attached to that hose set fully open. Insert the manufacturer's recommended standard cannula into the cannula connector.

Any additional suction hoses shall be either unobstructed or shut off, according to the manufacturer's instructions for normal use.

Turn on the suction source device and adjust the throttling valve until the measuring device indicates the required flow rate.

Measure and record the pressure values at the suction source pressure gauge and the atmospheric pressure gauge. Calculate the head loss.

Repeat to obtain data for all specified flow rates for all suction hoses.

7.8 Treatment method for the prevention or inhibition of biofilm formation

Check by visual inspection whether the manufacturer has specified one or more treatment method(s) for controlling against stationary dental unit waterline biofilm formation.

Check the instructions for use to ensure that all information specified in 5.3.11.2 is provided.

7.9 Treatment method for biofilm removal

Check by visual inspection whether the manufacturer has specified one or more treatment method(s) for removing biofilm in stationary dental unit waterlines.

Check the instructions for use or technical description to ensure that all information specified in 5.3.11.3 is provided.

8 Instructions for use

Stationary dental units shall be accompanied by documents containing relevant information as specified in ISO 7494-1. In addition, the following information shall be provided:

a) type of suction system regarding air volume flow rate (type 1: 250 Nl/min, type 2: 170 Nl/min or type 3: 90 Nl/min) with which the stationary dental unit is intended to be used, if applicable;

b) specifications of pressure and flow rate of procedural water and dental air supplied to dental handpieces;

c) if the stationary dental unit is equipped with either particle filters or bacterial filters, or both for either air or water, or both, the filter specification, the information on replacement filters, the maintenance procedure(s) and schedule;

d) 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 bottled water system to the stationary dental unit;

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

f) required supplies for specified treatment method(s) for preventing or inhibiting stationary dental unit waterline biofilm formation (e.g. chemical treatment) and for removing stationary dental unit waterline biofilm formation, instructions for use, maintenance procedures and maintenance frequency associated with the treatment method(s);

g) information about the location and operation of the water sampling connection point, if applicable;

h) requirements for the incoming water;

i) if air separators are included in the stationary dental unit, information concerning the technique for maintenance, and replacement of the air separators;

j) nominal size of the cannula connector and specifications for cannula that can be used with the connector;

k) procedures for shutting down the stationary dental unit for an extended period with consideration for preventing biofilm formation;

l) specifications for the suction system solids filter and procedures and schedule for its maintenance and replacement.

9 Technical description

Stationary dental units shall be accompanied by documents containing relevant information as specified in ISO 7494-1. In addition, the following information shall be provided by the manufacturer:

a) information about whether the stationary dental unit suction system is compatible with wet, semi-dry, or dry suction systems;

b) type(s) of suction system regarding air volume flow rate (type 1: type 2: or type 3) with which the stationary dental unit is intended to be used, if applicable;

c) configuration of the air and water connections to the applicable dental handpieces;

d) specifications of pressure and flow rate of procedural water and dental air used to supply dental handpieces;

e) dimensions and location of connections for supply and waste lines for the stationary dental unit;

f) requirements for the incoming water;

g) information about the installation of a sampling point for incoming water at or near the incoming water connection point, if applicable;

h) information about the location and operation of the sampling point for incoming water for collecting incoming samples for bacterial tests or other testing, if applicable;

i) maximum wastewater flow rate from the stationary dental unit that the drain shall be capable of accommodating;

j) description of the minimum gradient of the wastewater lines;

k) requirements for the dental air;

l) maximum static suction pressure at the stationary dental unit suction source connection point and information about the suction connection dimensions;

m) table or graph providing typical pressure head loss of the stationary dental unit suction system from the point of the suction source connection point up to the atmospheric end of the cannula;

n) dimension of cannula connection;

o) specification for the suction system solids filter, including rated mesh size and compatibility with air abrasives, and information about maintenance and replacement of the solids filter, if applicable;

p) if an air separator is included in the stationary dental unit, information about maintenance and replacement of the air separator;

q) dimensions of the stationary dental unit suction source connection point;

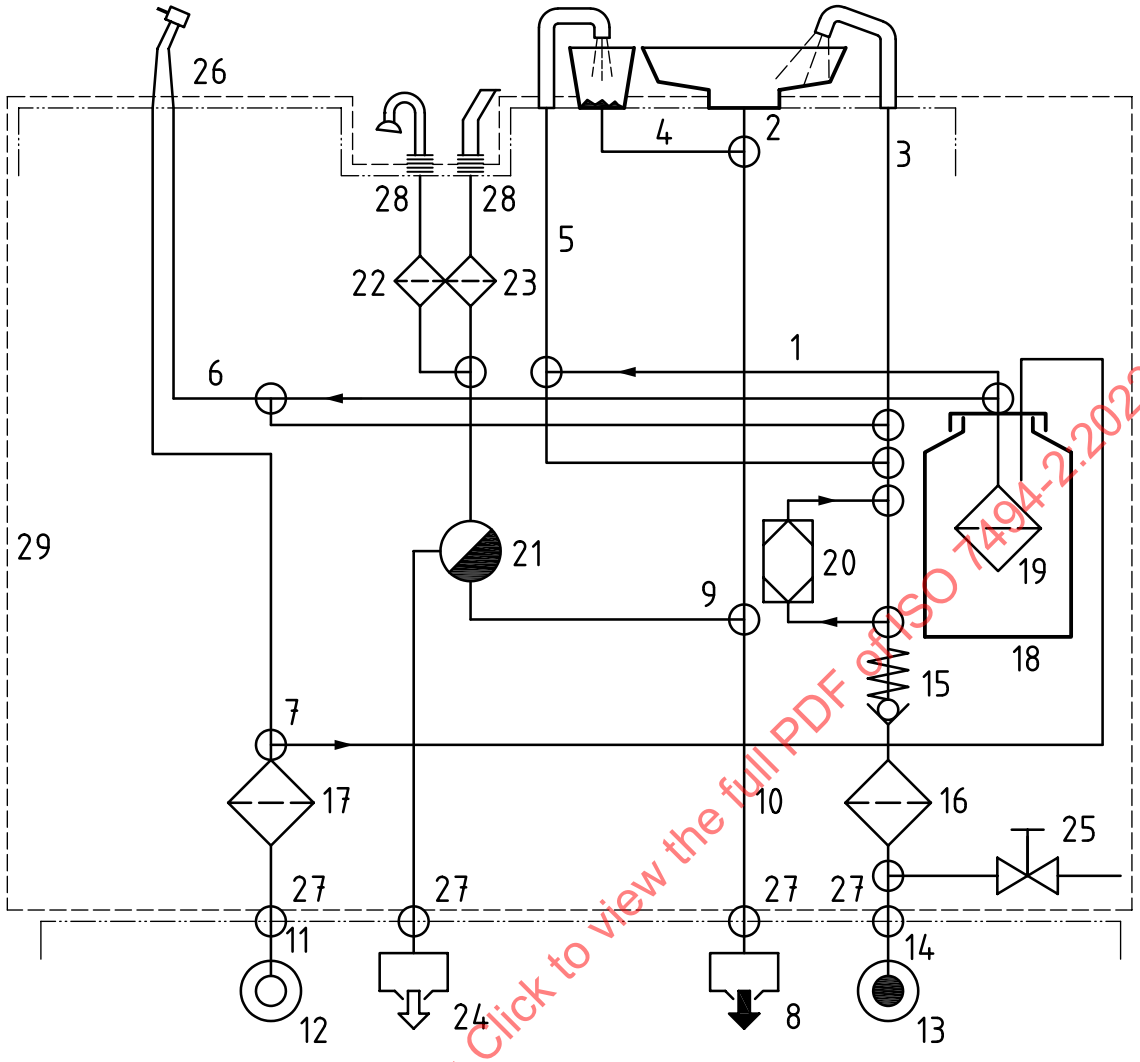
r) schematic diagram showing tubing, components and connections in the stationary dental unit, if applicable (see Figure A.1);

s) description of method(s) for preventing or inhibiting biofilm formation in stationary dental unit waterlines;

t) description of methods used to remove biofilm from stationary dental unit waterlines.

Annex A
(informative)

Example of schematic diagram of components and connections in a stationary dental unit



Key

1 procedural water or incoming solution supplied by the bottled water system reservoir
2 wastewater outlet from the cuspidor
3 non-procedural water supplied to the cuspidor
4 wastewater lines within the stationary dental unit
5 procedural water supplied to the cup filler
6 procedural water supplied to dental handpieces
7 dental air for dental handpieces and supplied to bottled water systems
8 wastewater drain
9 wastewater connection point
10 wastewater line
11 dental air connection point
12 dental air
13 incoming water from an external drinking water supply
14 incoming water connection point
15 backflow prevention device
16 water particle filter
17 air particle filter
18 bottled water system reservoir
19 bottled water system particle filter (optional)
20 water disinfection system
21 air separator (if required)
22 suction solids filter
23 suction solids filter
24 stationary dental unit suction source connection point
25 incoming water sampling connection point
26 dental handpiece with water and air supply
27 connection points
28 cannula connector
29 system boundary of stationary dental unit

Figure A.1 — Example of schematic diagram of components and connections in a stationary dental unit