INTERNATIONAL STANDARD

**ISO 5467-2**

First edition
2022-09

# Dentistry — Mobile dental units and dental patient chairs —

## Part 2: Air, water, suction and wastewater systems

*Médecine bucco-dentaire — Units dentaires et fauteuils dentaires patient mobiles —*

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



Reference number
ISO 5467-2:2022(E)



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Published in Switzerland

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# Foreword

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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).

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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).

A list of all parts in the ISO 5467 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.

# Introduction

This document was developed in consideration of ISO 7494-2:2022, so as to be applicable to mobile dental units. The requirements in this document focus on certain technical aspects to be appropriate for international standardization. The requirements for microbiological aspects of the fluids transported by mobile dental units are acknowledged to be also worthy of standardization and requirements pertaining to the prevention, inhibition, and removal of mobile dental unit waterline biofilm are being developed.

# Dentistry — Mobile dental units and dental patient chairs —

# Part 2:
# Air, water, suction and wastewater systems

## 1 Scope

This document specifies the requirements and test methods for mobile dental units concerning:

a) the properties of mobile 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 mobile dental unit,

c) the quality for incoming water and air,

d) the performance of mobile dental unit suction system, and

e) the air, water, suction and wastewater properties of mobile dental unit connections to the interfaces to dental handpieces.

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

This document is only applicable to mobile 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 5167-1, *Measurement of fluid flow by means of pressure differential devices inserted in circular cross-section conduits running full — Part 1: General principles and requirements*

ISO 5467-1, *Dentistry — Mobile dental units and dental patient chairs —Part 1: General requirements*

ISO 7494-2:2022, *Dentistry — Stationary dental units and dental patient chairs — Part 2: Air, water, suction and wastewater systems*

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

ISO 10637, *Dentistry — Central suction source equipment*

ISO 22052, *Dentistry — Central compressed air source equipment*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942, ISO 5467-1, ISO 7494-2, ISO 10637, ISO 22052 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**
**mobile dental unit suction system**
components located between the facility suction pipeline connection point and the cannula connector that are part of the mobile dental unit which enable 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

Note 1 to entry: Suction source equipment can be included in a mobile dental unit, in which case no facility suction pipeline connection point exists.

**3.2**
**mobile dental unit suction source connection point**
port on the mobile dental unit for connection to a supply of dental suction

## 4 Classification

### 4.1 Classification of dental air supply

If the mobile dental unit is equipped with an integrated compressed air source equipment, the integrated compressed air source equipment shall be classified according to the type of compressor lubrication methods into the following types:

Type 1: oil-lubricated compressor heads

Compressor heads are oil-lubricated.

Type 2: non-oil-lubricated compressor heads

Compressor heads are not oil-lubricated.

### 4.2 Classification of suction system and suction air flow rate

ISO 7494-2:2022, Clause 4 shall apply.

## 5 Requirements

### 5.1 Connections from the mobile dental unit to dental handpiece

The requirements and the test methods specified in ISO 7494-2:2022, 5.1 and 7.2 shall apply by replacing stationary dental unit with mobile dental unit.

Test in accordance with 7.1.2.

## 5.2 Supply connections to the mobile dental unit

Technical description shall include the configuration of the supply connections for the mobile dental unit, if applicable.

NOTE Some mobile dental units do not have any supply connection other than an electrical power supply cable.

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 Incoming water and bottled water

Instructions for use and technical description shall specify the requirements either for the incoming water to be supplied to the mobile dental unit or for the bottled water to be used in the mobile dental unit, or both, including the following parameters:

a) water pressure limits, if applicable;

b) water flow rate limit, if applicable;

c) water hardness limit;

d) pH limits;

e) maximum particle size.

NOTE The following ranges are typical ranges:

a) water pressure limits (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.

### 5.3.2 Materials used for construction of procedural water systems within the mobile dental unit

The requirements including the NOTE specified in ISO 7494-2:2022, 5.3.3 shall apply by replacing stationary dental unit with mobile dental unit.

Test in accordance with 7.1.

### 5.3.3 Backflow prevention device for mobile dental units connected to the external drinking water supply

The requirements including the NOTE and the test methods specified in ISO 7494-2:2022, 5.3.4 and 7.3 shall apply by replacing stationary dental unit with mobile dental unit.

Test in accordance with 7.1.2.

### 5.3.4 Cuspidors

If the mobile dental unit is equipped with a cuspidor, the requirements and the test methods specified in ISO 7494-2:2022, 5.3.5 and 7.4 shall apply by replacing stationary dental unit with mobile dental unit.

Test in accordance with 7.1.2.

### 5.3.5 Water venturi

If the mobile dental unit uses water venturi for suction of saliva and wastewater, the requirements specified in ISO 7494-2:2022, 5.3.6 shall apply.

Test in accordance with 7.1.

### 5.3.6 Particle filter

The requirements specified in ISO 7494-2:2022, 5.3.7 shall apply by replacing stationary dental unit with mobile dental unit.

Test in accordance with 7.2.

### 5.3.7 Bacterial filter

The requirements specified in ISO 7494-2:2022, 5.3.8 shall apply by replacing stationary dental unit with mobile dental unit.

Test in accordance with 7.1.

### 5.3.8 Bottled water system supplying procedural water or solution

If the mobile dental unit is equipped with a bottled water system, the requirements specified in ISO 7494-2:2022, 5.3.9 shall apply.

Test in accordance with 7.1.

### 5.3.9 Retraction

The requirements and the test methods specified in ISO 7494-2:2022, 5.3.10 and 7.6 shall apply by replacing stationary dental unit with mobile dental unit.

Test in accordance with 7.1.2.

### 5.3.10 Treatment method for biofilm

The requirements including the NOTE and the test methods specified in ISO 7494-2:2022, 5.3.11, 7.8 and 7.9 shall apply by replacing stationary dental unit with mobile dental unit.

Test in accordance with 7.1.2.

### 5.3.11 Water sampling connection point

If the mobile dental unit is intended to be connected to an external drinking water supply, the requirements specified in ISO 7494-2:2022, 5.3.12 shall apply by replacing stationary dental unit with mobile dental unit.

Test in accordance with 7.1.

#### 5.3.12 Wastewater drain connection

If the mobile dental unit is intended to be connected to an external wastewater line, the requirements specified in ISO 7494-2:2022, 5.3.13 shall apply by replacing stationary dental unit with mobile dental unit.

Test in accordance with 7.1.

#### 5.3.13 Wastewater container

If the mobile dental unit is equipped with a wastewater container, the instructions for use and the technical description shall specify the capacity.

Test in accordance with 7.1.

### 5.4 Air system

#### 5.4.1 Incoming dental air

If the mobile dental unit is intended to be connected to an external compressed air source equipment, the requirements specified in ISO 7494-2:2022, 5.4.2 shall apply by replacing stationary dental unit with mobile dental unit.

Test in accordance with 7.1.

#### 5.4.2 Purity class of dental air supplied by an integrated compressed air source equipment

If the mobile dental unit is equipped with an integrated compressed air source equipment, the purity class of dental air supplied by the equipment shall be [2:4:2] in accordance with ISO 8573-1.

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

#### 5.4.3 Particle filters

A filter with an effective mesh size not exceeding 50 µm shall be installed at the incoming dental air connection point of the mobile dental unit or at the connection point to the integrated compressed air source equipment.

Test in accordance with 7.2.

#### 5.4.4 Bacterial filters

If the mobile dental unit air supply is equipped with a filter intended to restrict the passage of bacteria, the requirements specified in ISO 7494-2:2022, 5.4.4 shall apply by replacing stationary dental unit with mobile dental unit.

Test in accordance with 7.1.

#### 5.4.5 Condensate drain

The mobile dental unit shall be equipped with a means to drain off a condensate water, if necessary.

Test in accordance with 7.1.

#### 5.4.6 Compressed air filter

If an air dryer is installed to the mobile dental unit, the grade of filtration for dryer system shall be ≤ 5 µm.

Test in accordance with 7.1.

#### 5.4.7 Sound level of compressed air source equipment

If the mobile dental unit is equipped with an integrated compressed air source equipment, IEC 60601-1:2005 + AMD1:2012 + AMD2:2020, 9.6.2 shall apply.

Testing shall be carried out in accordance with IEC 60601-1:2005 + AMD1:2012 + AMD2:2020.

### 5.5 Mobile dental unit suction systems

#### 5.5.1 Maximum suction pressure

If the mobile dental unit is intended to be connected to an external suction machine, the requirements and the test methods specified in ISO 7494-2:2022, 5.5.2 and 7.7.2 shall apply by replacing stationary dental unit with mobile dental unit.

Test in accordance with 7.1.2.

#### 5.5.2 Suction pressure head loss

If the mobile dental unit is intended to be connected to an external suction machine, the requirements and the test methods specified in ISO 7494-2:2022, 5.5.3 and 7.7.3 shall apply by replacing stationary dental unit with mobile dental unit.

Test in accordance with 7.1.2.

#### 5.5.3 Configuration of cannula connectors and cannula

The requirements, figure and table specified in ISO 7494-2:2022, 5.5.4 shall apply by replacing stationary dental unit with mobile dental unit.

Test in accordance with 7.1.

#### 5.5.4 Operating hoses with cannula connectors

The requirements specified in ISO 7494-2:2022, 5.5.5 shall apply.

Test in accordance with 7.1.

#### 5.5.5 Solids filter

The requirements specified in ISO 7494-2:2022, 5.5.6 shall apply by replacing stationary dental unit with mobile dental unit.

Test in accordance with 7.1.

#### 5.5.6 Air separator

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

Test in accordance with 7.1.

#### 5.5.7 Mobile dental unit suction source connection point

The technical description shall include the connection dimensions, if applicable.

Test in accordance with 7.1.

#### 5.5.8 Suction flow rate

If the mobile dental unit is equipped with an internal suction machine, the flow rate at the cannula connector of the mobile dental unit shall not be less than type 1: 250 Nl/min, type 2: 170 Nl/min or type 3: 90 Nl/min.

NOTE 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].

Test in accordance with 7.3.

#### 5.5.9 Bacterial filter

If the mobile dental unit is equipped with a bacterial filter, the bacterial filter shall be rated to restrict the passage of contaminants larger than 0,3 µm and have an efficiency of at least 99,95 %. The mobile dental unit manufacturer shall provide maintenance instructions and schedule for the bacterial filter.

Test in accordance with 7.1.

### 5.6 Test report

A test report shall be prepared to report the results of all applicable testing and inspection requirements specified in this document.

The test report shall at least include the following information:

— the standard used, i.e. ISO 5467-2:2022;

— the method used (if the standard includes several);

— the result(s), including a reference to the clause which explains how the results were calculated;

— if present, any deviations from the procedure;

— if present, any unusual features observed;

— the date of the test.

An example for a test report template is given in Annex A.

## 6 Sampling

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

## 7 Measurement and test methods

### 7.1 Visual inspection

#### 7.1.1 Visual inspection of equipment

Visually inspect the equipment to determine whether it conforms to the requirements.

#### 7.1.2 Visual inspection of documentation or test reports

Visually inspect product documentation or test reports to determine whether it conforms to the requirements.

### 7.2 Particle filters test

Check by visual inspection whether a particle filter is installed at either the incoming water or air connection points, or both, or at the connection point of the integrated compressed air source equipment. Check the instructions 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 5.4.3.

### 7.3 Suction flow rate test

Measure the suction flow rate of the mobile dental unit in accordance with ISO 5167-1 or by using an equivalent, with a measurement tolerance of ±5 %. If another method is used, the manufacturer shall provide a methodology description complete enough that it can be duplicated by a competent interested party, so that its accuracy equivalency to ISO 5167-1 can be independently verified.

Performance for the mobile dental unit shall be measured at the maximum air flow rate at the cannula connector.

## 8 Instructions for use

Mobile dental units shall be accompanied by documents containing relevant information as specified in ISO 5467-1 and ISO 7494-2 by replacing stationary dental unit with mobile dental unit, if applicable. In addition, the following information shall be provided:

a) maintenance instructions and schedule of the bacterial filter for the mobile dental unit suction systems, if applicable;

b) drainage method, if applicable;

c) capacity of the wastewater container, if applicable;

d) type of integrated compressed air source equipment in accordance with 4.1, if applicable.

## 9 Technical description

Mobile dental units shall be accompanied by documents containing relevant information as specified in ISO 5467-1 and ISO 7494-2 by replacing stationary dental unit with mobile dental unit, if applicable. In addition, the following information shall be provided:

a) drainage method, if applicable;

b) maintenance instructions and schedule for the bacterial filter, if applicable;

c) capacity of the wastewater container, if applicable.

# Annex A
(informative)

# Test report

**Table A.1 — Test report (cover page)**

| | |
|---|---|
| Test report no. | |
| Name of product | |
| Name and address of the applicant/client | |
| Name and address of the manufacturer | |
| Name and address of the factory/manufacturing site | |
| Brand/Trademark (if applicable) | |
| Model/Type no. | |
| Rated values and principal characteristics | |
| Classification of dental air supply | |
| Classification of suction system | |
| Classification of suction air flow rate | |
| Applied International Standard, which a sample of the product was tested and in conformity with: | ISO 5467-2:2022 |
| Additional information (if necessary) | |
| Information about modifications | |
| This test report was issued by: (name and address of the test house/ certification body/manufacturer) | |
| Date: | |
| Test by: (name and signature) | |
| Approved by: (name and signature) | |

**Table A.2 — Test report (check list)**

| **ISO 5467-2:2022** | | **Test report reference number:** …… | | | |
|---|---|---|---|---|---|
| **Clause no** | **Requirements/description** | **Compliance/verdict** | | | **Results, observations, notes, comments** |
| | | **PASS** | **FAIL** | **N/A** | |
| 6 | Sampling: Is the test device a representative sample of the mobile dental unit? | | | | |
| 5.1 | Connections from the mobile dental unit to dental handpieces | | | | |
| | Do the instructions for use and technical description include the ranges? | | | | |
| 5.2 | Supply connections to the mobile dental unit | | | | |
| 5.3 | Water and waste water systems | | | | |
| 5.3.1 | Do the instructions for use and the technical description include the relevant requirements either for incoming water or for bottled water, or for both? | | | | |

**Table A.2** *(continued)*

| ISO 5467-2:2022 | | Test report reference number: …… | | | |
|---|---|---|---|---|---|
| Clause no | Requirements/description | Compliance/verdict | | | Results, observations, notes, comments |
| | | PASS | FAIL | N/A | |
| 5.3.2 | Is there an ISO 14971 risk analysis report about the materials used in the water path of mobile dental unit available? | | | | |
| 5.3.3 | Does the test device include a backflow prevention device in accordance with the requirements? | | | | |
| 5.3.4 | If a cuspidor is equipped, is the air gap distance between rinse water outlet and cuspidor spill over level at least 20 mm? | | | | |
| 5.3.5 | If a water venturi device is used, is an additional backflow prevention device available? | | | | |
| 5.3.6 | Does the test device directly connected to an external drinking water supply or a bottled water system have a particle filter with an effective mesh size not exceeding 100 µm? | | | | |
| 5.3.7 | If a bacterial filter is installed in the test device, does the mesh size not exceed 0,22 µm? | | | | |
| 5.3.8 | Is the installation of a bottled water system equipped with a backflow prevention device or is it separated from the external drinking water supply system? | | | | |
| 5.3.9 | Is the retraction of procedural water or solutions in the test device ≤ 40 $mm^3$? | | | | |
| 5.3.10 | Do the instructions for use and the technical description include the relevant requirements specified in ISO 7494-2:2022, 5.3.11? | | | | |
| 5.3.11 | Do the instructions for use and the technical description include a recommendation? | | | | |
| 5.3.12 | Does the technical description include information about the maximum wastewater flow rate and minimum gradient of the wastewater lines? | | | | |
| 5.3.13 | Do the instructions for use and the technical description include a capacity of wastewater container? | | | | |
| 5.4.1 | Do the instructions for use and the technical description include the relevant requirements for air? | | | | |
| 5.4.2 | Is the purity class of dental air [2:4:2] in accordance with ISO 8573-1? | | | | |
| 5.4.3 | Is a particle filter with an effective mesh size not exceeding 50 µm in the incoming airline installed? | | | | |
| 5.4.4 | If a bacterial filter is installed in the mobile dental unit, does the mesh size not exceed 0,22 µm? | | | | |
| 5.4.5 | Does the test device equip a means to drain off a condensate water? | | | | |
| 5.4.6 | Is the grade of filtration for dryer system not more than 5 µm? | | | | |