



**International
Standard**

ISO 23402-3

**Dentistry — Portable dental
equipment for use in non-
permanent healthcare
environment —**

**Part 3:
Portable suction equipment**

*Médecine bucco-dentaire — Matériel dentaire portable utilisable
dans des environnements de soins de santé non permanents —*

Partie 3: Matériel d'aspiration portable

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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 document 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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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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).

A list of all parts in the ISO 23402 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

The ISO 23402 series aims to standardize requirements for portable dental equipment for use in non-permanent healthcare environments.

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Dentistry — Portable dental equipment for use in non-permanent healthcare environment —

Part 3: Portable suction equipment

1 Scope

This document specifies terminology, classification, requirements and test methods for portable suction equipment primarily intended to be used by dental professionals in non-permanent healthcare environments.

This document applies to portable suction equipment incorporated in a portable dental unit and free-standing portable suction equipment.

The requirements in this document focus on portability.

This document specifies requirements for information to be supplied by the manufacturer on the performance, operation and maintenance of portable suction equipment designed and constructed to be transported for use in non-permanent healthcare environments. This document also specifies requirements for the instructions to be supplied by the manufacturer on assembling, disassembling and packing for human transport between non-permanent healthcare environments.

This document does not apply to stationary dental equipment, wearable equipment (such as headlamps and loupes), mobile dental equipment or portable dental equipment that is not intended to be used in non-permanent healthcare environments or not designed to be disassembled, folded or packed for human transport between non-permanent healthcare environments. Also, requirements for stationary dental equipment that can be installed in a dental mobile medical facility (e.g. vehicular or containerized mobile dental clinic) are not considered in this document.

This document specifies requirements for portable suction equipment used to provide reduced pressure and flow at the cannula connector.

This document does not apply to portable suction equipment used for life support or for scavenging halogenated anaesthetic gases.

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

ISO 9687, *Dentistry — Graphical symbols for dental equipment*

ISO 11143, *Dentistry — Amalgam separators*

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ISO 23402-1:2020, *Dentistry — Portable dental equipment for use in non-permanent healthcare environment — Part 1: General requirements*

ISO 29463-1:2017, *High efficiency filters and filter media for removing particles from air — Part 1: Classification, performance, testing and marking*

IEC 60335-1, *Household and similar electrical appliances — Safety — Part 1: General requirements*

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

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

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

IEC 61000-6-2, *Electromagnetic compatibility (EMC) — Part 6-2: Generic standards — Immunity standard for industrial environments*

IEC 61000-6-3, *Electromagnetic compatibility (EMC) — Part 6-3: Generic standards — Emission standard for residential, commercial and light-industrial environments*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942, ISO 7494-2, ISO 23402-1, IEC 60335-1, IEC 60601-1 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

air separator

apparatus which separates liquids and solids from the suction system air flow

[SOURCE: ISO 10637:2018, 3.1]

3.2

cannula connector

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

[SOURCE: ISO 10637:2018, 3.2]

3.3

suction machine

suction equipment component that produces pressure that is lower than atmospheric pressure

EXAMPLE Pump, side channel blower.

3.4

patient environment

area contained within the walls of an operatory or in the absence of walls, within a 1,5 m radius of the patient

Note 1 to entry: The area within a 1,5 m radius of the patient's body has been defined as the patient environment. See IEC 60601-1:2005+AMD1:2012+AMD2:2020, Figure A.9.

4 Classification

4.1 Applicable classifications

Classifications are according to ISO 23402-1:2020, Clause 4, except those given in [4.2](#) and [4.3](#).

4.2 Classification according to the degree of integration and location

4.2.1 General

Portable suction equipment is classified according to the degree of integration into the dental unit and the distance from the patient.

4.2.2 Type A: Fully integrated

The suction machine, air separator, solids filter, suction operating hose and cannula connector are contained in the portable dental unit, which is located within the patient environment.

4.2.3 Type B: Remote

The suction machine is not contained in the portable dental unit and can be located outside the patient environment. The air separator and solids filter are integrated in either the portable dental unit or portable suction equipment or both.

4.2.4 Type C: Standalone

The suction machine, air separator, solids filter, suction operating hose and cannula connector are contained in a self-contained portable suction unit, which is located within the patient environment and separate from the portable dental unit.

4.3 Classification according to air flow rate

Portable suction equipment is classified according to the minimum air flow rate intended to be produced by the portable suction equipment under normal use conditions.

NOTE 1 This classification is intended to facilitate communication between parties involved in the specification, design, procurement, operation and maintenance of portable suction equipment.

NOTE 2 Reference conditions for normal litres (NI) are defined in [7.1.2](#).

— Type 1 portable suction equipment is intended to supply a minimum air flow rate of 250 NI/min at one suction cannula connector on the dental unit.

NOTE 3 Type 1 portable suction equipment is often commercially referred to as “high-volume suction” in certain regions of the world.

— Type 2 portable suction equipment is intended to supply a minimum air flow rate of 170 NI/min at one suction cannula connector on the dental unit.

— Type 3 portable suction equipment is intended to supply a minimum air flow rate of 90 NI/min at one suction cannula connector on the dental unit.

NOTE 4 Type 3 portable suction equipment is often commercially referred to as “medium-volume suction” in certain regions of the world.

These specified classifications do not restrict other specifications for minimum air flow rate that can be deemed appropriate in certain applications, regions or markets. In instances where none of the specified

classifications are applicable, an alternative value may be specified for the minimum air volume flow rate, to be supplied by the manufacturer.

NOTE 5 The target performance indicated for each of these types of portable suction equipment is intended to assist in communicating the performance requirements of complete portable suction equipment. See also ISO 10637:2018, 4.2.

5 Requirements

5.1 General

Requirements are according to ISO 23402-1:2020, Clause 5 except where superseded by [5.2](#) to [5.10](#).

5.2 Protection against electric shock

If applicable, portable suction equipment classified as Class I in accordance with IEC 60601-1 shall have an external protective earth terminal or conductor, and the instructions for use shall include instructions for the connection to the earth.

Devices with a voltage of alternating current (AC) 24 V or of direct current (DC) 34 V or less, can be used without an external protective earth terminal or conductor, when specified in the instructions for use.

5.3 Safety requirements

For the safety requirements, the following requirements shall be applied in accordance with the classification specified in [4.2](#).

- For portable suction equipment intended to be located within patient environment, the requirements of IEC 60601-1 shall apply.

Testing shall be carried out in accordance with IEC 60601-1.

- For type B portable suction equipment intended to be located outside of patient environment, the requirements of IEC 60335-1 shall apply.

Testing shall be carried out in accordance with IEC 60335-1.

5.4 Electromagnetic compatibility

For the electromagnetic compatibility (EMC), the following requirements shall be applied in accordance with the classification specified in [4.2](#).

- For portable suction equipment intended to be located within patient environment, the requirements of IEC 60601-1-2 shall apply.

Testing shall be carried out in accordance with IEC 60601-1-2.

- For type B portable suction equipment intended to be located outside of patient environment, the following requirements shall apply.

- Immunity requirements of IEC 61000-6-2 shall apply.

- Emission requirements of IEC 61000-6-3 shall apply.

- Testing shall be carried out in accordance with IEC 61000-6-2 and IEC 61000-6-3.

5.5 Utility requirements

5.5.1 Compressed air supply

If applicable, the manufacturer shall specify the characteristics of the compressed air in the instructions for use, that is to be supplied to the portable suction equipment, including pressure and flow rate.

Compliance shall be checked in accordance with [7.4.2](#).

5.5.2 Suction waste container

If a suction waste container is part of the portable suction equipment, the manufacturer shall specify in the instructions for use, the maximum volume of waste that the container can hold. Suction waste container should be capable of being easily emptied, cleaned and reprocessed as per applicable infection control requirements or guidelines.

Compliance shall be checked in accordance with [7.4.2](#).

5.6 Operational requirements

5.6.1 General

The requirements in [5.6](#) pertain to the operation of portable suction equipment for use in non-permanent healthcare environments.

5.6.2 Cleaning

5.6.2.1 Suction lines

Manufacturers shall provide instructions for cleaning the interior of the suction lines that convey gasses, liquids and particulates in the instructions for use.

The portable suction equipment suction lines shall be capable of withstanding the solutions for the cleaning process specified by the manufacturer, including any cleaner, sanitizer, disinfectant, neutralizer or other solutions specified for maintaining the cleanliness of the suction lines and components.

Conformity shall be checked in accordance with [7.5](#).

5.6.2.2 Water and wastewater removal prior to transport or storage

The portable suction equipment shall include a means for purging procedural water, non-procedural water and wastewater from the equipment, in accordance with the infection control requirements, before packing for transport or storage, to prevent stagnation or freezing.

Conformity shall be checked in accordance with [7.4.2](#).

5.7 Characterization of portable suction equipment flow rate performance

The manufacturer of portable suction equipment shall measure and report the flow rate of the equipment.

Measurements shall be carried out in accordance with [7.2.1.1](#) or [7.2.1.2](#).

5.8 Maximum suction pressure

The maximum suction pressure under no air flow conditions shall not exceed 40 kPa when the pressure limiting valve (if included as a part of the portable suction equipment) is operating as intended by the manufacturer.

Testing shall be carried out in accordance with [7.2.2](#) or [7.2.3](#).

5.9 Amalgam separator

If the portable suction equipment includes an amalgam separator as an integral part, it shall conform to ISO 11143.

Testing shall be carried out in accordance with ISO 11143.

5.10 Bacterial filter

If included, 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 portable suction equipment manufacturer shall provide maintenance instructions and a schedule for the bacterial filter.

Testing shall be carried out in accordance with [7.3](#).

6 Sampling

One representative sample of the portable suction equipment being tested shall be selected.

7 Measurement and test methods

7.1 General

7.1.1 General provisions for tests

Measurement and test methods are according to ISO 23402-1:2020, Clause 7, except where superseded by the following.

- Unless otherwise specified, do not repeat tests.
- Where a component or equipment part has specified ratings exceeding those appropriate to its use in the equipment, it may be tested for such a wider range.

Conformity is considered to be achieved if all relevant tests of this document are passed successfully.

7.1.2 Reference conditions (air flow rates)

Air flow rates shall be reported as normalized air flow rates using the following reference conditions:

- air temperature 20 °C;
- absolute air pressure 100 kPa = [1 bar](a);
- relative water vapour pressure 65 %.

The air flow rate unit is normal litres per minute (Nl/min).

7.1.3 Atmospheric conditions

After the portable suction equipment being tested has been set up for normal use, carry out tests under the following atmospheric test conditions:

- a) ambient temperature within the range from 20 °C to 25 °C;
- b) relative humidity within the range from 45 % to 75 %;
- c) atmospheric pressure within the range 860 hPa to 1 060 hPa.

Protect the equipment from draughts which can affect the validity of the tests.

After the measurement, all values shall be calculated to reference conditions as specified in [7.1.2](#).

7.1.4 Other conditions

For portable suction equipment intended to be located within patient environment, conditions specified in IEC 60601-1 shall apply.

For type B portable suction equipment intended to be located outside of patient environment, conditions specified in IEC 60335-1 shall apply.

7.2 Performance tests

7.2.1 Measurement of flow rate performance

7.2.1.1 Types A and C of portable suction equipment

Measure the air flow rate of the portable suction equipment in accordance with ISO 5167-1 or by using an equivalent, with a measurement tolerance of $\pm 5\%$. 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.

The flow rate measurement shall be made without a cannula inserted in the cannula connector. Turn on the remote suction equipment and adjust to maximum flow. When steady-state flow has been reached, measure and report the flow rate.

7.2.1.2 Type B of portable suction equipment

If the remote suction machine is not supplied as part of the portable dental unit or portable suction equipment, the manufacturer shall specify the minimum air flow rate of the type B portable suction equipment.

Connect type B portable suction equipment to a mock conduit that simulates a head-loss specified by the manufacturer of the portable suction equipment. Turn on the remote suction equipment and adjust to maximum flow. When steady-state flow has been reached, measure and report the flow rate.

7.2.2 Measurement of maximum suction pressure of portable suction equipment types A and C

Refer to manufacturer's instructions before adjusting any suction pressure limiting valve or mechanism.

NOTE Subjecting operating portable suction equipment to strong suction pressure in excess of factory allowable maximum suction during no air flow conditions can cause equipment damage.

The following steps shall be applied.

- a) Switch off suction equipment power.
- b) Install a suction pressure measuring device, with measuring tolerance of $\pm 5\%$, in the cannula connector.
- c) Ensure other cannula connectors are fully closed.
- d) Operate the portable suction equipment at its factory allowable maximum suction strength.
- e) If the suction pressure measuring device reading exceeds 40 kPa, use the manufacturer's instructions required by [8.3 n](#)) to limit the no air flow suction pressure to no more than 40 kPa.
- f) The test is passed if the maximum suction pressure does not exceed 40 kPa.

7.2.3 Measurement of maximum suction pressure of type B portable suction equipment

If the remote suction machine is not supplied as part of the portable dental unit or portable dental unit, the manufacturer shall specify the maximum suction pressure of the type B portable suction machine.

Operate the type B portable suction equipment in accordance with the manufacturer's instructions for use and measure the maximum suction pressure at the connector of the equipment to a portable dental unit. The test has been passed if the maximum suction pressure measured does not exceed 40 kPa.

7.2.4 Measures to prevent excessive suction pressure

Check the technical description [8.3 n\)](#) to ensure that all information specified is provided.

7.3 Bacterial filters

Check by visual inspection whether bacterial filters are installed.

If bacterial filters are installed, check the specifications of the bacterial filter at a minimum in accordance with ISO 29463-1:2017, class ISO H35, or using similar test procedures that can confirm the filter efficiency is at least 99,95 % at a maximum particle size of 0,3 μm .

7.4 Visual inspection

7.4.1 Visual inspection equipment

Visually inspect the equipment to determine compliance with the requirements.

7.4.2 Visual inspection of documentation

Visually inspect the documentation provided by the manufacturer to determine compliance with the requirements.

7.5 Resistance to solutions for the cleaning process

7.5.1 Principle

This test method is based on inspection of test specimens of the materials used in the suction system after immersion in the solutions for the cleaning process specified by the manufacturer. Two separate immersion procedures are specified. The selection of which immersion procedure to use depends on whether the use of a single solution or the sequence use of multiple solutions for the cleaning process is specified by the manufacturer.

All data and observations shall be recorded.

7.5.2 Test specimens

Test specimens of all materials used in the suction system that are exposed to cleaning agent(s) shall be tested.

Three replicate test specimens shall be tested. If the manufacturer specifies more than one option for the solution for the cleaning process, a separate set of test specimens shall be tested with each solution for the cleaning process. If the manufacturer specifies a cleaning process involving a sequence of multiple solutions for the cleaning process, the same set of test specimens shall be tested with the entire sequence of solutions for the cleaning process.

One additional test specimen shall be used as a reference specimen.

7.5.3 Test conditions

The temperature of the test laboratory and all test materials and apparatus shall be $(23 \pm 2) ^\circ\text{C}$. Unless otherwise specified by the manufacturer's instructions for use, the temperature of the solution(s) for the cleaning process shall be $(23 \pm 2) ^\circ\text{C}$.

7.5.4 Solution(s) for the cleaning process

The solution(s) for the cleaning process specified by the manufacturer shall be prepared in accordance with the manufacturer's instructions.

7.5.5 Immersion procedure

7.5.5.1 General

If the cleaning process specified by the manufacturer specifies using a single solution for the cleaning process immerse the test specimens in accordance with 7.5.5.2. If the cleaning process specified by the manufacturer specifies using a sequence of multiple solutions for the cleaning process, immerse the test specimens in accordance with 7.5.5.3.

7.5.5.2 Immersion procedure for use of a single solution for the cleaning process

Place each test specimen in a separate glass container. Add a sufficient volume of the solution for the cleaning process to completely immerse the test specimen. Cover the containers with an air-tight lid or film.

Replace the solution for the cleaning process with a freshly prepared solution for the cleaning process every weekday (i.e. Monday through Friday) for a total of 14 days of immersion.

7.5.5.3 Immersion procedure for sequence use of multiple solutions for the cleaning process

Place each test specimen in a separate glass container. Add a sufficient volume of the first solution for the cleaning process to completely immerse the test specimen. After the contact time specified by the manufacturer's instructions for the first solution for the cleaning process, transfer the solution for the cleaning process test specimens to clean glass containers and add a sufficient volume of the second solution for the cleaning process to completely immerse the test specimen. After the contact time specified by the manufacturer's instructions for the second solution for the cleaning process, remove the test specimens from the containers. If additional solutions for the cleaning process are specified by the manufacturer's instructions, continue the sequence of transferring the test specimens to clean glass containers and immersing in the next solution(s) for the cleaning process for the contact time specified by the manufacturer's instructions until the complete sequence of solutions for the cleaning process specified by the manufacturer is completed.

If the manufacturer specifies a range for the contact time with any solution(s) for the cleaning process, the upper limit of the range shall be used.

Repeat the sequence of immersion in solution(s) and water, if specified, for the cleaning process for the specified contact times for 250 cycles.

EXAMPLE The manufacturer specifies a sequence of flushing the suction system lines with a cleaner solution for one minute, then flushing with a disinfectant solution for one minute, then flushing with a neutralizer for one minute, and then flushing with water for one minute. The immersion sequence for each of the 250 immersion cycles is as follows.

- The test specimens are placed in clean glass containers.
- The test specimens are immersed in the cleaner solution for one minute, then the test specimens are transferred to clean glass containers.
- The test specimens are immersed in the disinfectant solution for one minute, then the test specimens are transferred to clean glass containers.
- The test specimens are immersed in the neutralizer solution for one minute, then the test specimens are transferred to clean glass containers.
- The test specimens are immersed in the water for one minute, then the test specimens are removed.

7.5.6 Inspection

Immediately after the applicable immersion procedure specified in [7.5.5](#) is completed, rinse the test specimens with water.

Place the test specimens on an absorbent pad and dry the test specimens with unheated air. Carry out visual and tactile inspection of the test specimens and record changes with respect to the reference specimen (e.g. corrosion, pitting, discoloration, bubbles, stickiness).

The suction lines and components are deemed to pass if no inspection observations represent a concern for the suction lines and components to perform their function.

8 Information supplied by the manufacturer

8.1 General

Portable suction equipment shall be accompanied by documents containing relevant information as specified in ISO 23402-1. In addition, the following information shall be provided by the manufacturer:

All portable suction equipment shall be accompanied by documents containing at least the relevant information specified in [8.2](#) and [8.3](#).

Instructions for use and technical description of fully integrated equipment and standalone equipment, in accordance with [8.2](#), [8.3](#) and IEC 60601-1 shall apply where applicable.

Instructions for use and technical description of remote suction machine, in accordance with [8.2](#), [8.3](#) and IEC 60335-1 shall apply where applicable.

Compliance shall be checked in accordance with [7.4.2](#).

8.2 Instructions for use

If applicable, graphical symbols used in the instructions for use shall be in accordance with ISO 9687.

The instructions for use shall contain the following information:

- a) operation instructions, including operating limitations, e.g. nitrous oxide scavenging, air abrasion;
- b) explanation of all the labels and graphical symbols used on the portable suction equipment;
- c) maintenance instructions and schedule;
- d) information on amalgam separation from the fluids evacuated by the portable suction equipment and disposal of amalgam waste collected, if applicable;
- e) troubleshooting instructions;
- f) list of parts that are required in routine maintenance, if applicable;
- g) limitations to continuous operation for any of the portable suction equipment (e.g. suction machine, separators) and how this equipment can be successfully used considering any such limitations;
- h) mass and dimensions (length, width, height) of the equipment in its configurations for transporting, including any transport containers (if the equipment is intended to be transported in separate modules, the mass and dimensions of each transport module shall be provided by the manufacturer);
- i) instructions for unpacking, assembling and mounting the equipment after transport and before use, as applicable;
- j) instructions for dismounting, disassembling and packing the equipment for transport or storage, as applicable;