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Dental equipment — Amalgam separators

Matériel dentaire — Séparateurs d'amalgame

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 11143 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 6, *Dental equipment*.

Annex C forms a normative part of this International Standard. Annexes A, B and D are for information only.

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Introduction

Amalgam separators are items of dental equipment designed to retain amalgam particles carried by the waste water from the dental treatment centre, so as to reduce the number of amalgam particles and therefore the mass of amalgam entering the sewage system.

Separation of the amalgam particles may be effected by the use of a centrifuge, filtration, sedimentation or a combination of any of these methods.

It is recognized that the test sample used to assess the efficiency of an amalgam separator should have a particle size distribution which reflects the actual situation in dental treatment centres. The test sample used in this International Standard is based on investigations that have been carried out to determine the particle size distribution of amalgam particles in waste water from dental treatment centres (see annex D).

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Dental equipment — Amalgam separators

1 Scope

This International Standard specifies requirements for amalgam separators used in connection with dental equipment in the dental treatment centre. It specifies the efficiency of the amalgam separators in terms of the level of retention of amalgam based on a laboratory test and the test procedure for determining this efficiency. It also includes requirements for the safe functioning of the separator, marking, instructions for use, operation and maintenance.

All tests described in this International Standard are type tests.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 1559:1995, *Dental materials — Alloys for dental amalgam*.
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ISO 3585, *Borosilicate glass 3.3 — Properties*.

ISO 3696, *Water for analytical laboratory use — Specification and test methods*.

ISO 9687, *Dental equipment — Graphical symbols*.

ISO 10076:1991, *Metallic powders — Determination of particle size distribution by gravitational sedimentation in a liquid and attenuation measurement*.

IEC 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety*.

IEC 61010-1:1990, *Safety requirements for electrical equipment for measurement, control and laboratory use — Part 1: General requirements*.

3 Terms and definitions

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

3.1

amalgam separator

item of dental equipment designed to remove amalgam particles from the waste water from the dental treatment centre, so as to reduce the number of amalgam particles and therefore the mass (amount) of amalgam entering the sewage system

NOTE The amalgam separator may comprise any auxiliary units required for admission of water and the connecting lines inside the separator, but it does not include the supply and drainage pipes or tubes.

**3.2
collecting container**

that part of the amalgam separator for retention of separated amalgam waste for the purpose of disposal

**3.3
dental treatment centre**

combination of units, consisting as a minimum of the dental unit and the dental chair combination, which enable the dentist to perform patient therapy

**3.4
efficiency of amalgam separator**

mass percentage of the specified amalgam sample retained by the amalgam separator

**3.5
maximum filling level**

level defined by the maximum collecting capacity of the collecting container of the amalgam separator at which the efficiency is unaffected

**3.6
warning level**

level, below the maximum filling level, at which the collecting container should be emptied or replaced

**3.7
warning signal**

auditory or visual sign, signal and/or other kind of indicator, or a combination thereof, indicating an adverse condition likely to cause reduction of efficiency if unattended

**3.8
alarm signal**

auditory or visual sign, signal and/or other kind of indicator, or a combination thereof, indicating an adverse condition affecting the efficiency of the amalgam separator

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4 Classification

For the purposes of this International Standard, amalgam separator systems are classified according to the method of separation into the following types:

- Type 1: Centrifugal system
- Type 2: Sedimentation system
- Type 3: Filter system
- Type 4: Any combination of types 1, 2 and 3.

This classification is applicable to all amalgam separators, irrespective of whether the amalgam separator is included in every dental treatment centre or built as a central amalgam separator for one or several dental treatment centres.

5 Requirements

5.1 Efficiency

The efficiency of the amalgam separator shall be at least 95 % (mass fraction) when tested as specified in 9.3 to 9.6.

5.2 Warning system

The amalgam separator shall include a warning system to indicate the degree of filling at which the collecting container should be emptied or replaced. The warning signal shall be activated at the warning level and before the maximum filling level is reached.

Testing shall be carried out in accordance with 9.7.

For type 2 amalgam separators, the warning system requirement can be met if the manufacturer clearly defines procedures by which the proper function of the amalgam separator is ensured, giving controllable maintenance and disposal procedures as in 11.2. Compliance shall be tested by visual inspection.

5.3 Alarm system for collecting container

The amalgam separator shall include an alarm system to indicate that the collecting container has reached the maximum filling level, as specified by the manufacturer, at which the device can perform to the specified efficiency. The alarm signal shall be activated at the maximum filling level. The alarm signal shall remain activated until the collecting container and/or filter has been emptied or replaced.

Testing shall be carried out in accordance with 9.8.

For type 2 amalgam separators, the alarm system requirement can be met if the manufacturer clearly defines procedures by which the proper function of the amalgam separator is ensured, giving controllable maintenance and disposal procedures as in 11.2. Compliance shall be tested by visual inspection.

5.4 Alarm system for malfunction

Malfunction of amalgam separators of types 1 and 4, but only if type 4 includes centrifugal systems, shall be indicated by activation of an alarm system. It shall not be possible to inactivate signals during use until the malfunction is corrected.

Testing shall be carried out in accordance with 9.9.

5.5 Removal of filled collecting container or filter

The collecting container and/or filter shall be capable of being removed easily and safely without discharging any of the contents into the public sewage system.

The collecting container, filters or separator shall be able to be sealed so that no leakage or spillage can occur during handling and transportation.

Testing shall be carried out in accordance with 9.10.

5.6 Maximum mass of filled collecting container

When fully loaded, the mass of the removable collecting container or the filters which have to be handled during emptying shall not exceed 15 kg.

Testing shall be carried out in accordance with 9.11.

5.7 Electrical safety

If an amalgam separator is electrically powered and is connected as an integral part of the dental unit, it shall conform to IEC 60601-1. If an amalgam separator is electrically powered and physically remote from the dental unit but electrically connected, it shall conform to IEC 60601-1. If an amalgam separator is electrically powered and physically remote but not electrically connected, it shall conform to IEC 61010-1.

Testing shall be carried out in accordance with 9.12.

6 Sampling

All type tests shall be made starting with testing of one representative sample of the amalgam separator (unused and empty).

7 Test apparatus

7.1 Set-up of test apparatus

The test apparatus, shown in Figure 1, consists of the following components:

7.1.1 Incoming water, passing through a water filter (7.1.2) and thereafter described as filtered tap water.

7.1.2 Water cartridge filter, of polypropylene, with a nominal filter pore size of 1 µm.

7.1.3 Flowrate meter, for laboratory use, capable of measuring the maximum flowrate stated by the manufacturer of the amalgam separator and with a tolerance of $\pm 2\%$ of the full-scale reading.

7.1.4 Sample delivery hopper, of glass or stainless steel with an interior polished surface, with an outlet at its lowest point having a diameter of the same size as the inlet diameter of the amalgam separator.

7.1.5 Amalgam separator under test.

7.1.6 Two transparent hoses, of plastics with a minimum wall thickness of 5 mm and an interior smooth surface for respectively connecting:

- a) the outlet of the sample delivery hopper to the inlet of the amalgam separator, with the same inside diameter as the outside diameter of the outlet of the delivery hopper;
- b) the outlet of the amalgam separator to the effluent collecting vessel, with the same inside diameter as the outside diameter of the outlet of the amalgam separator.

7.1.7 Effluent collecting vessel, of stainless steel with a polished interior surface, approved for a minimum pressure of 2×10^5 Pa (2 bar), with the following characteristics:

- a) minimum volume of 45 l;

NOTE The volume of the effluent collecting vessel depends on the volume of water allowed by the maximum water flowrate (see 9.3.2).

- b) inlet for filtered tap water with an on/off valve;
- c) inlet for compressed air with an on/off valve;
- d) pressure manometer in the range of 0 Pa to 2×10^5 Pa, tolerance class 4;

- e) safety device to reduce overpressure;
- f) spray bottle;
- g) bottom outlet to the filter assembly and then to the drain with an on/off valve after the filter assembly.

7.1.8 Series of membrane filters and separating gauzes, composed of cellulose nitrate or polycarbonate, each with an interior circle diameter of at least 50 mm.

The membrane filters shall be arranged into a series of filters and put in the support in the following descending order:

- a) membrane filter with a nominal pore size of 12 µm;
- b) separating gauzes;
- c) membrane filter with a nominal pore size of 3 µm;
- d) separating gauzes;
- e) membrane filter with a nominal pore size of 1,2 µm;
- f) separating gauzes (drain side);
- g) supporting mesh.

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The series of filters shall be mounted in the bottom outlet drain line of the effluent collecting vessel.

7.2 Installation of amalgam separator

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7.2.1 Install the amalgam separator in such a way that the flowrate of incoming water can be measured and regulated. Follow the installation instructions of the manufacturer. The set-up of test apparatus is shown in Figure 1 and described in 7.1.

NOTE If an air-water separator is needed as indicated by the manufacturer, then the air-water separator is part of the installation of the amalgam separator.

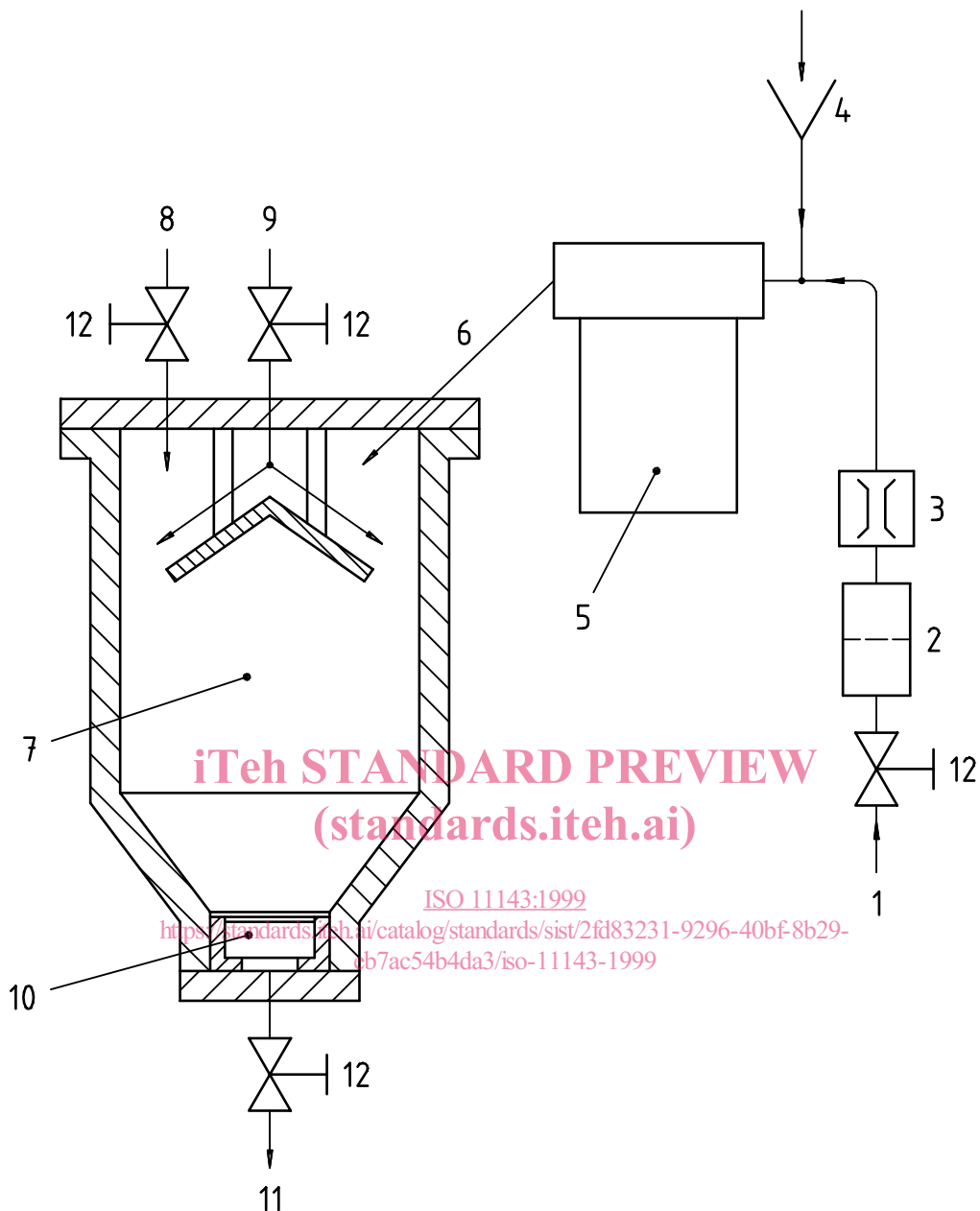
7.2.2 Open the top of the effluent collecting vessel and put one of the transparent hoses into the effluent collecting vessel.

7.2.3 Connect a water filter (7.1.2) to the water supply of the test set-up. For the test, use tap water that is directed through the water filter (filtered tap water).

7.2.4 The transparent hose connecting the sample delivery hopper to the inlet of the amalgam separator should be positioned as vertically as possible in order to prevent trapping.

7.2.5 The transparent hose connecting the outlet of the amalgam separator to the effluent collecting vessel shall be positioned with a straight constant slope. The angle of the slope of the transparent hose shall be more than 30° from the horizontal.

7.2.6 The set-up of test apparatus shall permit the entire amount of the test slurry (8.5) to enter the amalgam separator.



Key

- 1 Incoming water
- 2 Water filter
- 3 Flowrate meter
- 4 Sample delivery hopper
- 5 Amalgam separator
- 6 Transparent hose
- 7 Effluent collecting vessel
- 8 Compressed air
- 9 Filtered tap water for rinsing
- 10 Series of filters
- 11 Drain
- 12 On/off valve

Figure 1 — Schematic set-up of test apparatus for measuring the efficiency of amalgam separators