INTERNATIONAL STANDARD

ISO 11143

Second edition
2008-07-01

Dentistry — Amalgam separators

Art dentaire — Séparateurs d'amalgame

Reference number
ISO 11143:2008(E)

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Published in Switzerland

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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 2.

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

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

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

This second edition cancels and replaces the first edition (ISO 11143:1999) which has been technically revised by means of the following changes:

a) the description of the test method has been improved;

b) testing at a minimum flow rate for certain types of separator is now required;

c) updated labelling requirement has been introduced.

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, sedimentation, filtration, or a combination of any of these methods.

It is recognised 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).

The principle of the test is that the effluent water from the amalgam separator is collected in a vessel. The collected effluent water, containing amalgam particles not retained by the amalgam separator, is filtered through a series of preweighed filters. The filters, with the amalgam particles collected on them, are dried to a constant weight in a desiccator at room temperature and the total mass of collected particles is measured to determine the collection efficiency.

Dentistry — Amalgam separators

1 Scope

This International Standard specifies requirements and test methods 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 amalgam separator, for marking, and for instructions for use, operation and maintenance.

All tests described in this International Standard are type tests.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 1942, *Dentistry — Vocabulary*

ISO 3585, *Borosilicate glass 3.3 — Properties*

ISO 3696:1987, *Water for analytical laboratory use — Specification and test methods*

ISO 9687, *Dental equipment — Graphical symbols*

ISO 24234:2004, *Dentistry — Mercury and alloys for dental amalgam*

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

IEC 61010-1:2001, *Safety requirements for electrical equipment for measurement, control and laboratory use — Part 1: General requirements*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 and ISO 24234 and the following 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

3.2
collecting container
integrated part of the amalgam separator for retention of separated amalgam waste for the purpose of recovery

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 test sample retained by the amalgam separator

3.5
maximum fillable volume
level or volume defined by the maximum waste solids/sludge collecting capacity of the removable collecting container of the amalgam separator at which the efficiency is unaffected

NOTE For the purposes of conducting these tests the maximum fillable volume is 95 % of the maximum solids/sludge collecting capacity of the removable collecting container.

3.6
volume of an amalgam separator system
capacity of the collecting container and those cavities that are integral to the collecting container and/or to the operation of the collecting container, including, but is not limited to, air-water separator tanks or cavities that support or incorporate an outlet port for treated effluent, a flow restrictor, or water venturi

3.7
warning level
level, below the maximum fillable volume, at which the collecting container should be emptied or replaced

3.8
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

3.9
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

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).

The determination of the efficiency shall be carried out under empty and full conditions for all types of amalgam separators.

Test in accordance with 9.1 to 9.6.

5.2 Warning system for collecting container

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 fillable volume is reached.

Test in accordance with 9.7.

For Type 2 amalgam separators, the requirement for the warning system can be met if the manufacturer clearly defines procedures by which the proper function of the amalgam separator is ensured, giving controllable maintenance and recovery 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 amalgam separator can perform to the specified efficiency. The alarm signal shall be activated at the maximum fillable volume. The alarm signal shall remain activated until the collecting container and/or filter has been emptied or replaced.

Test in accordance with 9.8.

For Type 2 amalgam separators, the requirement for the alarm system can be met if the manufacturer clearly defines procedures by which the proper function of the amalgam separator is ensured, giving controllable maintenance and recovery procedures as in 11.2.

Compliance shall be tested by visual inspection.

5.4 Alarm system for malfunction of amalgam separator

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.

Test in accordance with 9.9.

5.5 Removal of removable filled collecting container

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

NOTE Filters are considered as removable collecting containers.

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

Test in accordance with 9.10.

5.6 Maximum fillable volume of the removable collecting container

The maximum fillable volume of the removable collecting container that shall be handled during emptying shall not exceed 4 l.

Test in accordance with 9.11.

5.7 Electrical safety

If an amalgam separator is electrically powered and

a) is connected as an integral part of the dental unit, it shall conform to IEC 60601-1;

b) is physically remote from the dental unit

   1) but electrically connected, it shall conform to IEC 60601-1;

   2) but not electrically connected, it shall conform to IEC 61010-1.

Test in accordance with 9.12.

6 Sampling

All type tests shall be made starting with the 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 cartridge 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 Flow rate meter, for laboratory use, appropriate for measuring the maximum water flow rate stated by the manufacturer of the amalgam separator and with a tolerance of ± 5 % 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 plastic 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, proved 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 flow rate (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 gauge, capable of measuring in the pressure range of 0 Pa to 2×10^5 Pa with an accuracy of 0,6 % of full-scale pressure;

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.

7.1.8 Series of membrane filters and separating gauzes, e.g. cellulose nitrate, polycarbonate.

NOTE Filter sizes with an interior diameter of 50 mm or larger may facilitate the filtration process.

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.

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

7.2 Installation of amalgam separator

7.2.1 Install the amalgam separator in such a way that the flow rate 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 integrated air-water separator or auxiliary unit is needed for the amalgam separator to function, as indicated by the manufacturer, then the additional element is part of the installation of the amalgam separator.

7.2.2 Open the top of the effluent collecting vessel (7.1.7) and put one of the transparent hoses (7.1.6) into the effluent collecting vessel.

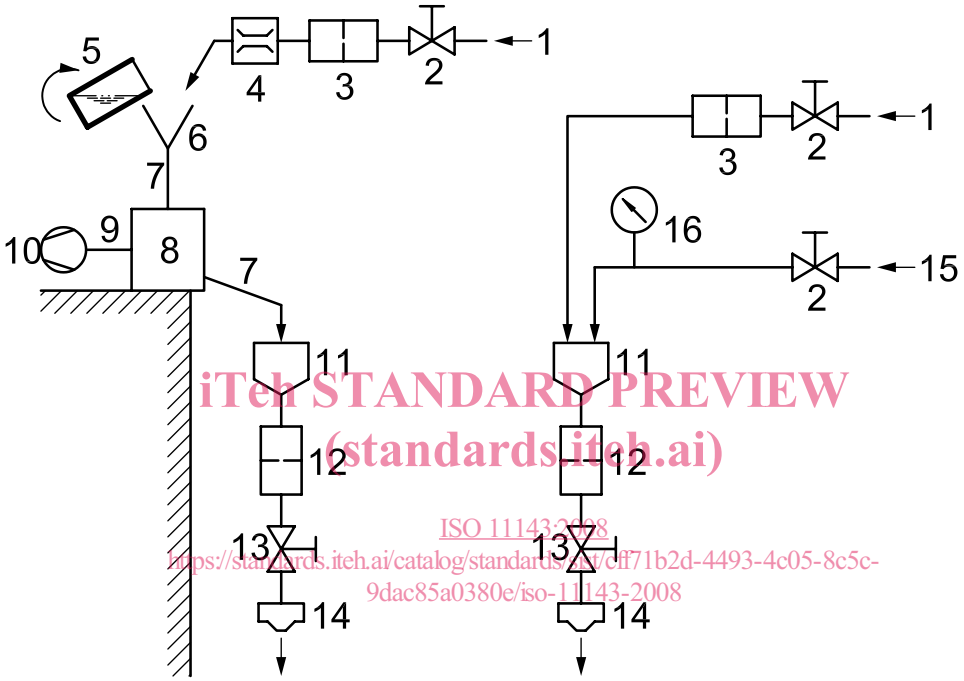
7.2.3 Connect a water cartridge filter (7.1.2) to the water supply of the test set-up. For the test, use tap water that is directed through the water filter (filtered tap water).

7.2.4 The transparent hose (7.1.6) connecting the sample delivery hopper (7.1.4) to the inlet of the amalgam separator should be positioned as vertically as possible in order to prevent trapping of amalgam particles.

Care shall be taken to avoid sedimentation of test sample particles outside of the effluent collecting vessel.

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 on/off valve
3 water cartridge filter
4 flow rate meter
5 test sample
6 delivery hopper
7 transparent connections
8 amalgam separator (under test)
9 vacuum connection (optional)
10 suction machine (optional)
11 effluent collecting vessel
12 series of membrane filters
13 on/off valve
14 drain
15 compressed air
16 pressure gauge

Figure 1 — Test apparatus for measuring the efficiency of amalgam separators