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Dentistry — Amalgam separators

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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 $\pm$ 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.

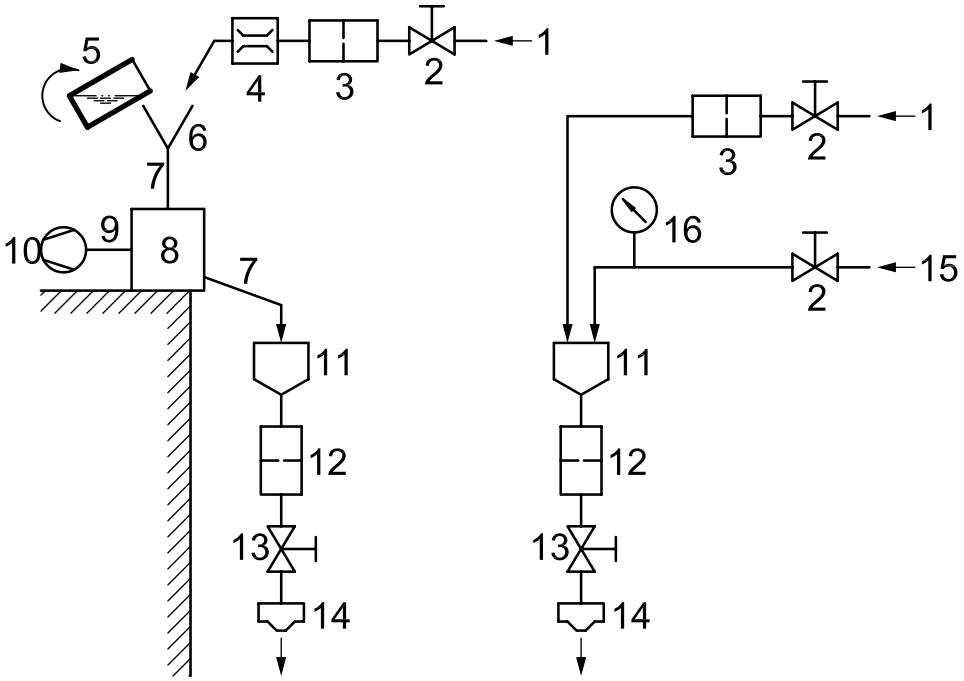
7.2.3 Connect a water cartridge filter (7.1.2) to the water supply of the test set-up. For the test, use tap water that is directed through the water filter (filtered tap water).

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

8 Test sample

8.1 Preparation of test sample

For the preparation of the test sample, capsules predosed with alloy and mercury conforming to the chemical composition specified in ISO 24234 shall be used.

NOTE Annex A describes a procedure for preparation of the test sample.

8.2 Particle fraction sizes

The test sample required for the efficiency test of the amalgam separator (9.3) shall be divided into three differently sized particle fractions.

a) Particle fraction 1: particle size $\leqslant$ 3,15 mm and $>$ 0,5 mm.

   Ground stock particles that pass through a sieve with 3,15 mm nominal aperture size and which are collected by a sieve with 0,5 mm nominal aperture size.

b) Particle fraction 2: particle size $\leqslant$ 0,5 mm and $>$ 0,1 mm.

   Ground stock particles that pass through a sieve with 0,5 mm nominal aperture size and which are collected by a sieve with 0,1 mm nominal aperture size.

c) Particle fraction 3: particle size $\leqslant$ 0,1 mm (100 µm).

   Ground stock particles that pass through a sieve with 0,1 mm nominal aperture size.

8.3 Mass of dry test sample

The total mass of the dry test sample shall be (10,000 $\pm$ 0,005) g, made from the three particle fraction sizes described in 8.2 as follows:

— 6,000 g (60 % mass fraction) particles of particle fraction 1;

— 1,000 g (10 % mass fraction) particles of particle fraction 2;

— 3,000 g (30 % mass fraction) particles of particle fraction 3.

NOTE This mean particle fraction size distribution was calculated from particle size distributions of amalgam in dental waste water based on investigations of the United States, Dutch and German dental associations (see Annex D).

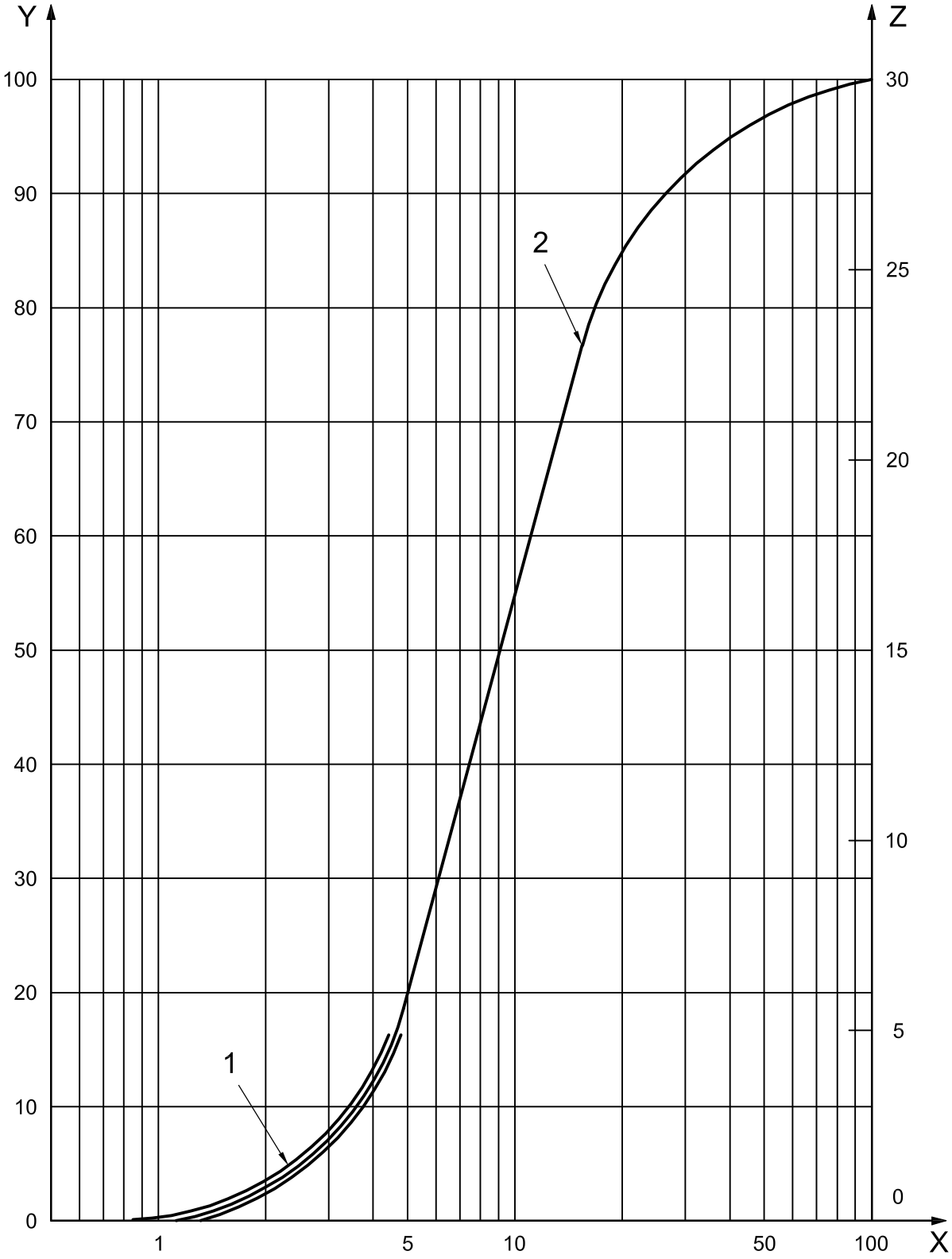
The mass of the three particle fractions shall be measured to an accuracy of three decimal places. If the production of the mass of particles of fraction 1 is only possible with mass deviations greater than 0,01 g, then the mass amounts of the other two particle fractions shall be changed in such a way that the ratios of mass fraction are preserved.

8.4 Particle fraction size distribution

8.4.1 For particle fractions 1 and 2, the particle size distributions shall be within the limits described in 8.2.

8.4.2 For particle fraction 3, the cumulative mass distribution of amalgam particles shall be in accordance with Figure 2.

For particle fraction 3, the sedimentation X-ray absorption technique in accordance with Annex C shall be used as the examination procedure. Other investigation techniques such as Coulter counter technique are acceptable, provided they give comparable results.



Key

X particle size, in micrometres

Y mass of particle fraction 3, in percent

Z cumulative mass, in percent

1 tolerance of ± 2 % for particles < 5 μm

2 tolerance of ± 5 % for particles ⩾ 5 μm

Figure 2 — Cumulative mass distribution (average and 99 % forecasting area) of test particles of particle fraction 3 with particle size ⩽ 100 µm (0,1 mm)

8.4.3 The manufacturer of the test sample shall provide data on the particle size distribution [see 10 g)].

8.5 Preparation of test slurry

8.5.1 Reagents

8.5.1.1 Dispersing agent, such as

a) sodium pyrophosphate ($Na_4P_2O_7$), technical grade or

b) Waxit[1)] or

c) alcohol ethoxylate (R-O-[CH_2-CH_2-O]$_n$-H), technical grade.

8.5.1.2 **Filtered tap water**, filtered with a water cartridge filter (7.1.2).

8.5.1.3 **Dry test sample**, prepared in accordance with 8.1.

8.5.2 Apparatus

8.5.2.1 **Scales**, with a measuring range of 0,01 g to 10 g and a measuring accuracy of $\pm$ 0,000 1 g.

8.5.2.2 **Glass beaker of borosilicate**, minimum capacity 1,2 l, with an internal diameter of at least 70 mm, conforming to ISO 3585.

8.5.2.3 **Stirring rod**, glass or plastic.

8.5.2.4 **Ultrasonic bath**, with a power density of at least 240 W/l and of a size appropriate for the size of the glass beaker.

8.5.3 Procedure

8.5.3.1 Weigh the dry test sample (8.5.1.3) to an accuracy of three decimal places and note the mass m_1 in grams.

8.5.3.2 Put the dry test sample into the glass beaker (8.5.2.2).

8.5.3.3 Prepare or use the dispersing agent solution as follows:

a) prepare the solution by mixing (1 $\pm$ 0,1) g of sodium pyrophosphate [8.5.1.1 a)] with (20 $\pm$ 0,1) ml of filtered tap water or

NOTE If hard water is used the calcium of the water reacts with the sodium pyrophosphate. If flocculation is observed, either water in accordance with ISO 3696:1987, grade 3, or options b) or c) in 8.5.1.1 should be used.

b) use 2 ml Waxit [8.5.1.1 b)] or

c) use 10 ml alcohol ethoxylate [8.5.1.1 c)].

Filter the dispersing agent solution through a 1 µm pore size filter.

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1) Waxit is the trade name of a product supplied by Degussa, Rodenbacher Chaussee, 63457 Hanau, Germany. This information is given for the convenience of the users of this International Standard and does not constitute an endorsement by ISO of the product named. Equivalent products may be used if they can be shown to lead to the same results.

Add the dispersing agent solution to the glass beaker containing the dry test sample. Stir the slurry with a stirring rod (8.5.2.3) until all test particles are completely wetted by the dispersing agent.

NOTE Dispersing agents are used prevent air bubbles from sticking to the dispersed test particles.

8.5.3.4 Fill the glass beaker with additional filtered tap water up to a volume of (1 ± 0,05) l and put it into an ultrasonic bath (8.5.2.4) for (15 ± 1) min to disperse the remaining agglomerate. During this process, stir periodically by using the stirring rod in order to avoid sedimentation of the test particles.

9 Test method

9.1 General

The type tests shall be carried out on one representative sample of the item being tested.

9.2 Preconditioning

Before testing is started, the equipment shall be kept in the testing location unoperated for at least 24 h. All testing shall be carried out at a room temperature of (23 ± 2) °C. If the amalgam separator requires electricity for operation, before the actual series of tests, operate the equipment at rated voltage in accordance with the instructions for use.

Flush the amalgam separator with 1 µm filtered water with an amount three times its volume. If contaminated particles are visible in the effluent water repeat the procedure one more time.

The amalgam separator shall be filled with water unoperated for 24 h before and at the beginning of the tests.

9.3 Efficiency test

9.3.1 Apparatus

9.3.1.1 **Test apparatus**, as specified in Clause 7.

9.3.1.2 **Glass beaker of borosilicate**, minimum capacity of 1,2 l.

9.3.1.3 **Spray bottle**.

9.3.1.4 **Ceramic tile**.

9.3.1.5 **Drying cabinet (or drying oven)**, capable of being maintained at (90 ± 2) °C and at (30 ± 2) °C.

9.3.1.6 **Desiccator**.

9.3.1.7 **Scales**, with an appropriate measuring range and an accuracy of ± 0,000 1 g.

9.3.2 Test procedure

9.3.2.1 General

Test the amalgam separator in the test apparatus set up in accordance with 7.1.

9.3.2.2 Preparation

Before the measurement, dry the series of membrane filters (7.1.8) in a drying cabinet (9.3.1.5) at (30 ± 2) °C for at least 3 h until constant mass is reached. Cool the series of membrane filters to room temperature in a desiccator. Weigh the series of membrane filters to an accuracy of three decimal places. Return the series of membrane filters to the desiccator. After 24 h reweigh the series of membrane filters. If the result is consistent, record the mass m_2 in grams.

Prepare the series of membrane filters (7.1.8) and fix them in the outlet of the effluent collecting vessel.

9.3.2.3 Water flow rate during test slurry addition

9.3.2.3.1 General

Conduct the test at the maximum water flow rate and, if required, at the minimum water flow rate as specified in 9.3.2.3.2 and 9.3.2.3.3.

9.3.2.3.2 Maximum water flow rate

For all amalgam separators conduct the test at the maximum water flow rate.

The maximum water flow rate for testing is established according to the manufacturer's instructions for use, reduced by 0,5 l/min to compensate for the water of the test slurry.

If the resulting water flow rate is lower than 0,5 l/min, then set the water flow rate to 0,5 l/min. The total maximum flow rate shall be 0,5 l/min (test slurry) plus at least 0,5 l/min (filtered tap water) for a total of at least 1,0 l/min during the 2 min time period that the test slurry is put into the separator.

Auxiliary equipment may be used to accommodate excessive water flow rates for amalgam separators equipped with flow-reducing devices that restrict water flow rate below 1 l/min.

NOTE The inlet water should be directed through the amalgam separator starting immediately before the test slurry is added to the sample delivery hopper.

9.3.2.3.3 Minimum water flow rate

For Type 1 amalgam separators and Type 4 amalgam separators that include centrifugal systems, conduct the test at the minimum water flow rate. For Type 2 and Type 3 amalgam separators a test at the minimum water flow rate is not necessary.

The minimum water flow rate for testing is established according to the manufacturer's instructions for use. If the minimum water flow rate as specified by the manufacturer is lower than 0,5 l/min, then set the "minimum" water flow rate to 0,5 l/min.

The total minimum flow rate shall be 0,5 l/min (test slurry) plus at most 0,5 l/min (filtered tap water) for a total of at least 1,0 l/min during the 2 min time period that the test slurry is put into the separator.

9.3.2.4 Collecting the water

Open the water inlet. Ensure that all water passing through the amalgam separator is collected in the effluent collecting vessel (7.1.7).

9.3.2.5 Addition of test slurry

Stir the test slurry (see 8.5).

Carefully pour the test slurry evenly without stopping, over a period of (120 ± 10) s while stirring constantly, into the sample delivery hopper (7.1.4), adding it to the water flowing into the amalgam separator.

NOTE 1 The water of the test slurry (volume approximately 1 l, added over the prescribed 2 min) is part of the total water flow rate.

NOTE 2 It is important to pour the test slurry as evenly as possible into the sample delivery hopper, resulting in constant flow of test slurry over the entire 120 s.

Rinse the glass beaker with $(0,1 \pm 0,01)$ l filtered tap water from the spray bottle [7.1.7 f)] until the glass beaker is visibly free from residue.

Flush the sample delivery hopper with the filtered tap water that flows into the sample delivery hopper until all visible residue is removed from the walls of the sample delivery hopper. Remove the sample delivery hopper.

9.3.2.6 Water flow rate during the flushing period (after the test slurry addition)

9.3.2.6.1 Maximum water flow rate during the flushing period

Increase the water flow rate to the maximum water flow rate as specified by the manufacturer. If the manufacturer's specified maximum flow rate is less than 1 l/min, set the water flow rate at 1 l/min.

For Type 1 separators stop the water flow 3 min after the end of the addition of the test slurry.

For all other types stop the water flow after five times the maximum fillable volume of the removable collecting container has passed through the collecting container after the end of the addition of the test slurry, in order to include in the measurements any possible flush-out of the amalgam already sedimented in the collecting container.

9.3.2.6.2 Minimum water flow rate during the flushing period

When testing is done at the minimum water flow rate conduct the flushing procedure of 9.3.2.6.1 at the minimum water flow rate.

9.3.2.7 Rinsing procedure

Close the valve for the incoming water and remove the transparent hose from the effluent collecting vessel. Put the top on the effluent collecting vessel and secure it. Open the drain. Apply an air pressure of $1,5 \times 10^5$ Pa to 2×10^5 Pa to the effluent collecting vessel in order to force the fluid through the series of membrane filters. Wait until all water has flowed out of the effluent collecting vessel. Close the air pressure valve. Open the inlet to the rinse water. Rinse the interior walls of the effluent collecting vessel using approximately 1 l filtered tap water. Close the inlet to the rinse water. Again apply an air pressure of $1,5 \times 10^5$ Pa to 2×10^5 Pa to the effluent collecting vessel to ensure that all remains are forced against the series of membrane filters. Repeat the rinsing of the interior walls of the effluent collecting vessel and filtering procedure two more times.

9.3.2.8 Drying

Carefully remove the series of membrane filters, put them on a ceramic tile (9.3.1.4), store them in the drying cabinet and dry them at (90 ± 2) °C for at least 3 h until constant mass is reached. Cool the ceramic tile and the series of membrane filters with their contents to room temperature in a desiccator (9.3.1.6).

Weigh the series of membrane filters to an accuracy of three decimal places. Return the series of membrane filters to the desiccator. After 24 h reweigh the series of membrane filters. If the result is consistent, note the mass m_3 in grams.

WARNING — The drying process can produce mercury vapour.

9.3.2.9 Simulating full testing

To simulate a fillable volume of 95 %, the collecting container of the amalgam separator should be filled to 70 % of the maximum fillable volume with glass beads of 1 mm diameter. The remaining volume should be filled to 95 % with amalgam scrap with a maximum particle size of 0,3 mm.

9.4 Number of tests

9.4.1 General

Test all types of amalgam separators using both the empty and the full test condition at the maximum water flow rate as specified by the manufacturer.

Test Type 1 amalgam separators and Type 4 amalgam separators that include centrifugal systems using both the empty and the full test condition at the minimum water flow rate as specified by the manufacturer.

9.4.2 Condition of amalgam separator

9.4.2.1 Empty amalgam separator

9.4.2.1.1 All amalgam separators shall be empty at the beginning of the first test. The following two tests are performed subsequently, on the same empty amalgam separator.

9.4.2.1.2 For all amalgam separators the efficiency test shall be carried out three times on the empty amalgam separator operated at the maximum water flow rate.

9.4.2.1.3 For Type 1 and Type 4 amalgam separators the efficiency test shall be carried out three times on the empty amalgam separator operated at the minimum water flow rate.

9.4.2.2 Full amalgam separator

9.4.2.2.1 All tests are performed on the same amalgam separator. The condition of a full amalgam separator is specified in 9.3.2.9. The following two tests are performed subsequently, on the same full amalgam separator.

9.4.2.2.2 For all amalgam separators the efficiency test shall be carried out three times on the full amalgam separator operated at the maximum flow rate.

9.4.2.2.3 For Type 1 and Type 4 amalgam separators the efficiency test shall be carried out three times on the full amalgam separator operated at the minimum flow rate.

9.5 Calculation of efficiency

9.5.1 The efficiency for the empty amalgam separator at the two water flow rates (if required) shall be calculated according to 9.5.3. The average of the three test results for both water flow rates (if required) shall be calculated as the separation degrees η_1 and η_2.

9.5.2 The efficiency for the full amalgam separator at the two water flow rates (if required) shall be calculated according to 9.5.3. The average of the three test results for both water flow rates (if required) shall be calculated as the separation degrees η_3 and η_4.

9.5.3 The value for the efficiency, η, in percent, shall be calculated using the following equation:

$$\eta = \frac{100\,[m_1 - (m_3 - m_2)]}{m_1}$$

where

m_1 is the mass, in grams, of the test sample according to 8.3, recorded to three decimal places (see 8.5.3.1);

m_2 is the mass, in grams, of the series of membrane filters (7.1.8) before the efficiency test, recorded to three decimal places (see 9.3.2.2);

m_3 is the mass, in grams, of the series of membrane filters (7.1.8) after the efficiency test, recorded to three decimal place (see 9.3.2.8).

9.6 Determination of efficiency

The lowest value of the efficiency from all required test conditions:

a) for Type 2 and Type 3 amalgam separators: η_1 or η_3,

b) for Type 1 and Type 4 amalgam separators: η_1, η_2, η_3 or η_4

is the value for the efficiency of the amalgam separator.

This value for the efficiency of the amalgam separator shall be compared with the requirement given in 5.1.

9.7 Test of warning system for removable collecting container

If applicable, conduct testing of the warning system for the removable collecting container after the efficiency test (9.3), using the same amalgam separator.

For the test, use an amalgam separator filled almost up to the warning level. Slowly fill the amalgam separator with filling material as specified in 9.3.2.9. Continue filling until a warning signal is given.

9.8 Test of alarm system for removable collecting container

If applicable, conduct testing of the alarm system for the removable collecting container after testing of the warning system (9.7).

For the test, use the same amalgam separator as in 9.7 filled over the warning level and approaching the maximum fillable volume. Slowly fill the amalgam separator with filling material as specified in 9.3.2.9. Continue filling until an alarm signal is given.

Remove the collecting container or filter or both, following the instructions for use (see Clause 11), and check whether the signal ceases properly.

9.9 Test of alarm system for malfunction of amalgam separator

The following two tests shall be performed.

a) Block the centrifugal drive in order to stop or hinder the rotation, and note if an alarm signal is given.

b) Switch off the drive supply and note if an alarm signal is given.

9.10 Removal of filled collecting container

When the collecting container is full, remove the collecting container according to the manufacturer's instructions. Observe if there is visible spill or splashing of liquid and/or collected material outside the collecting container or in areas around the amalgam separator.

9.11 Maximum fillable volume of the removable collecting container

Measure the maximum fillable volume of the removable collecting container to an accuracy of ± 2 %.

9.12 Electrical safety

Check the electrical safety in accordance with IEC 60601-1 or, if applicable, IEC 61010-1.

10 Test report

The test report for the efficiency test (9.3) of the amalgam separator shall include the following information:

a) designation of the amalgam separator;

b) name and/or trademark of the manufacturer of the amalgam separator;

c) model reference and serial number of the amalgam separator tested;

d) pictures and/or photo of the amalgam separator tested;

e) type classification in accordance with Clause 4;

f) reference to this International Standard, i.e. ISO 11143:2008;

g) particle size distribution used, including a particle size distribution curve (e.g. name and/or trademark of the manufacturer or distributor of the test sample, a certificate, a report of the X-ray sedimentation test);

h) lot number of test sample;

i) only for Type 1 and Type 4 amalgam separators: minimum water flow rate used during the test;

j) maximum water flow rate used during the test;

k) type of membrane filters used during the test;

l) number of tests performed;

m) efficiency values of each individual test expressed to three decimal places (e.g. 98,217 %);

n) efficiency of amalgam separator expressed to three decimal places;

o) result obtained (pass/fail);

p) all operations not specified in this International Standard;

q) details of any occurrence which may have affected the test result;

r) name of investigator;

s) date of investigation;

t) signature of investigator;

u) maximum fillable volume of the removable collecting container;

v) volume of the entire amalgam separator system as defined in 3.6, in litres;

w) the physical dimensions of the amalgam separator.

11 Manufacturer's instructions for installation, use, maintenance and service

11.1 Instructions for installation, use, maintenance and service for the amalgam separator shall be provided by the manufacturer of the amalgam separator. The instructions shall include at least the following information:

a) designation of the amalgam separator;

b) name and/or trademark and address of manufacturer or distributor;

c) type classification in accordance with Clause 4;

d) specifications and instructions for installing and connecting the amalgam separator;

e) rated electrical characteristics (e.g. voltage, frequency, fuse values), if applicable;

f) only for Type 1 and Type 4 amalgam separators: minimum water flow rate;

g) maximum water flow rate;

h) description of the procedure for emptying the collecting container;

i) description of the appropriate procedure for recovery of the separated substances;

j) maximum fillable volume of the removable collecting container;

k) description of the removable parts for removal of the removable fillable collecting container;

l) description of the appropriate interval for changing of the collecting container, if applicable;

m) description of the contractor, if applicable;

n) description of the alarm signal and warning signal, if applicable;

o) a statement that if the amalgam separator is installed distant from the dental treatment centre, the warning signal and the alarm signal shall be installed so that it is capable of being monitored from the dental treatment centre;

p) the flow rate (litres per minute) and, if necessary, the level of vacuum strength (hectopascals) which still allows the operation of the amalgam separator;

q) instructions for trouble-shooting, if applicable.

Verification of compliance with these information requirements shall be carried out visually.

11.2 If for Type 2 amalgam separators the warning system and/or the alarm system is omitted, the manufacturer shall clearly define procedures by which the proper function of the amalgam separator is ensured, giving controllable maintenance and recovery routines.

11.3 The manufacturer shall clearly indicate how to empty the removable collecting container before the maximum fillable volume is reached, without spilling the contents.

12 Marking

12.1 General

Graphical symbols used for marking shall be in accordance with ISO 9687.

12.2 Marking of the amalgam separator

Amalgam separators shall be marked with at least the following information:

a) manufacturer's name and/or trademark;

b) serial number;

c) model reference;

d) minimum water flow rate, if applicable;

e) maximum water flow rate;

f) rated electrical characteristics (e.g. voltage, frequency, fuse values), if applicable;

g) whether a controlled change of collection containers is required.

Verification of compliance with these marking requirements shall be carried out visually.

12.3 Marking of liquid inlet and outlet of the amalgam separator

The liquid inlet and outlet of the amalgam separator shall be appropriately marked.

Verification of compliance with these marking requirements shall be carried out visually.

12.4 Marking of removable collecting container

The removable collecting container shall be marked with at least the following information:

a) manufacturer's name and/or trademark;

b) model reference of the corresponding amalgam separator.

Verification of compliance with these marking requirements shall be carried out visually.

Annex A
(informative)

Preparation of amalgam test sample

A.1 Reagents

A.1.1 Encapsulated mercury and alloys for dental amalgam, conforming to ISO 24234.

A.2 Apparatus

A.2.1 Dental amalgamator, conforming to ISO 7488.

A.2.2 Nest of three round sieves, of the following nominal aperture sizes: 3,15 mm, 500 µm and 100 µm, conforming to ISO 3310-1, sized in descending order with a collecting cup (pan) at the bottom.

A.2.3 Collecting cup, of stainless steel, round.

A.2.4 Spatula, of stainless steel.

A.2.5 Quartering device, conforming to ISO 3954:1977, Figure 4.

A.2.6 Collecting receptacle.

A.2.7 Scales, with a measuring accuracy of ± 0,000 1 g.

A.2.8 Thermometer.

A.3 Preparation of hardened amalgam

A.3.1 Prepare approximately 100 g amalgam to give nine samples.

Use the following procedure.

A.3.2 Use encapsulated alloy and mercury for dental amalgam (A.1.1), and amalgamate as many capsules as needed. A dental amalgamator (A.2.1) shall be used. The frequency of the dental amalgamator (or machine setting) and the amalgamation time shall conform to the manufacturer's instructions.

A.3.3 Prepare the amalgam according to the amalgam preparation description of ISO 24234:2004, 6.6 as cylindrical samples. Remove the free mercury from the mould. Then remove the amalgam.

A.3.4 Divide the amalgam with a spatula (A.2.4) on a glass surface into portions with average diameters of 2 mm to 3 mm.

A.3.5 Allow a hardening period of at least 30 days at a temperature of (23 ± 2) °C and a relative humidity of (50 ± 10) % according to ISO 554.

NOTE Shorter hardening periods create grinding problems.

A.4 Grinding

Grind the hardened amalgam as described in Annex B.

A.5 Sieving

Empty the mill cups into the nest of sieves (A.2.2). Scrape out any residue from the mill cups into the nest of sieves.

Check with a thermometer (A.2.8) that the grinding process does not overheat the amalgam, which can lead to smearing. The temperature shall be below 25 °C.

Sieve the hardened amalgam using the nest of sieves (A.2.2):

a) 3 150 µm sieve;

b) 500 µm sieve;

c) 100 µm sieve;

d) collecting cup.

Grind again the amalgam particles that do not pass through the 3 150 µm sieve.

The amalgam particles that pass through the 3 150 µm sieve but which do not pass through the 500 µm sieve comprise fraction 1 particles.

The amalgam particles that pass through the 500 µm sieve but which do not pass through the 100 µm sieve comprise fraction 2 particles.

The amalgam particles that pass through the 100 µm sieve are intended for fraction 3 particles.

Combine the total quantity of fraction 1 particles. Divide the amalgam powder with a quartering device (A.2.5) into sample heaps of final amounts of approximately 6 g each.

Repeat the grinding process with the hardened amalgam prepared according to A.3 until the amount of fraction 1 particles is sufficient for 10 heaps.

Remove the 3 150 µm sieve. Grind again the amalgam particles which do not pass through the 500 µm sieve.

Combine the total quantity of fraction 2 particles. Divide the amalgam powder with a quartering device into sample heaps of final amounts of approximately 1 g each.

Repeat the grinding process with the hardened amalgam prepared according to A.3 until the amount of fraction 2 particles is sufficient for 10 heaps.

Remove the 500 µm sieve. Grind again the amalgam particles which do not pass through the 100 µm sieve. Repeat the grinding process with the hardened amalgam prepared according to A.3 until all amalgam is ground.

Combine the total quantity of fraction 3 particles, resulting in an amount of fraction 3 particles of approximately 30 g.

A.6 Additional grinding of amalgam particles below 100 µm

Repeat the grinding procedure at least twice for amalgam particles below 100 µm.

Check the particle size distribution, e.g. in accordance with Annex C. If the distribution is too coarse and not within the limits of Figure 2, repeat the grinding process.

NOTE The particle size distribution can be shifted by repeated grinding. Up to ten grinding processes might be necessary.

Check the particle size distribution again, e.g. according to Annex C.

A.7 Preparation of amalgam test sample

Weigh each sample of amalgam particle fraction 1 on the scales. Prepare (6 ± 0,1) g of fraction 1.

Add (1 ± 0,1) g of particle fraction 2 in order to compensate a possible mass deviation of particle fraction 1 to give a total mass of (7 ± 0,005) g.

Add (3 ± 0,005) g of particle fraction 3 in order to compensate again a possible mass deviation of particle fractions 1 and 2 (up to ± 5 mg) to give a total mass of (10 ± 0,005) g.

Annex B
(informative)

Procedure for grinding the hardened amalgam

B.1 Reagents

B.1.1 Hardened amalgam, prepared in accordance with A.3.

B.2 Apparatus

B.2.1 Microplanetary ball-bearing mill, with a wheel allowing rotation at (1 300 ± 100) r/min and a distance of (90 ± 10) mm between each mill cup and the midpoint of the sun wheel.

B.2.2 Ball bearings, of stainless steel, with a diameter of (15 ± 1) mm.

B.2.3 Two mill cups, each with a top and a volume of (45 ± 2) cm^3 and an internal diameter of (39 ± 1) mm.

B.2.4 Laboratory spoon, of stainless steel.

B.2.5 Clock, with a measuring accuracy of ± 1 s.

B.2.6 Thermometer.

B.3 Procedure

Check, using the thermometer (B.2.6), that the temperature of the mill cups (B.2.3) is below 25 °C.

NOTE Overheating due to repeated grinding can create problems.

Put five to seven ball bearings (B.2.2) into each mill cup.

Using the laboratory spoon (B.2.4), fill the mill cup to (50 ± 10) % of its volume with hardened amalgam (B.1.1).

Cover the mill cups and put the mill cups into the microplanetary ball-bearing mill (B.2.1). Lock the mill cups into place. Grind the hardened amalgam for a period of (60 ± 2) s.

WARNING — The grinding process can produce mercury vapour. For health reasons the grinding process should be conducted in a well-ventilated area.

Remove the mill cups. Open the mill cups and take the ball bearings out. Sieve the amalgam according to A.5.

Annex C
(informative)

Examination of particle fraction 3 using sedimentation with X-ray absorption

C.1 Reagents

C.1.1 Suspension liquid, consisting of 65 % (mass fraction) glycerine, technical grade, and 35 % (mass fraction) water of grade 3 in accordance with ISO 3696:1987.

NOTE According to ISO 10076:1991, Table C.1, the recommended suspension liquid for molybdenum powder (comparable to the amalgam sample) is water/glycerine.

C.1.2 Acacia gum, (1,8 ± 0,2) g.

C.1.3 Amalgam particle fraction 3.

C.2 Apparatus

C.2.1 X-ray equipment, for X-ray absorption measurements in accordance with ISO 10076.

C.2.2 Sedimentation cell.

C.2.3 Spatula, of stainless steel.

C.2.4 Glass plate, (60 ± 5) mm × (60 ± 5) mm × (5 ± 1) mm.

C.2.5 Ceramic bowl.

C.2.6 Rubber rod, cylindrical, 1 cm diameter, 5 cm long.

C.2.7 Ultrasonic bath, with a power density of at least 240 W/l and of a size appropriate for the size of the ceramic bowl (C.2.5).

C.3 Preparation procedure

Select at random one of the test samples of particle fraction 3 and subject it to sedimentation with X-ray absorption in accordance with ISO 10076.

Use the spatula (C.2.3) and take a weighed quantity of (1,5 ± 0,3) g from the amalgam sample.

Put the weighed amalgam sample into the ceramic bowl (C.2.5).

C.4 Measurement procedure

Prepare (35 ± 2) ml of suspension liquid (C.1.1).

Before starting the test, record the baseline of the X-ray absorption for the suspension liquid and adjust the X-ray equipment so that the baseline of the suspension liquid corresponds to 0 % absorption.

In order to allow deagglomeration, drop (1,8 ± 0,2) g acacia gum (C.1.2) on to the weighed quantity (1,5 g) of the test sample in the ceramic bowl.

Knead the mixture for 1 min with the cylindrical rubber rod (C.2.6).

Add the (35 ± 2) ml suspension liquid. Knead again. Sonicate the sample using the ultrasonic bath (C.2.7) until the dispersion of the amalgam sample is complete. Then place the amalgam sample in the X-ray equipment (C.2.1).

Subject the sample to sedimentation with X-ray absorption in accordance with ISO 10076.

C.5 Expression of results

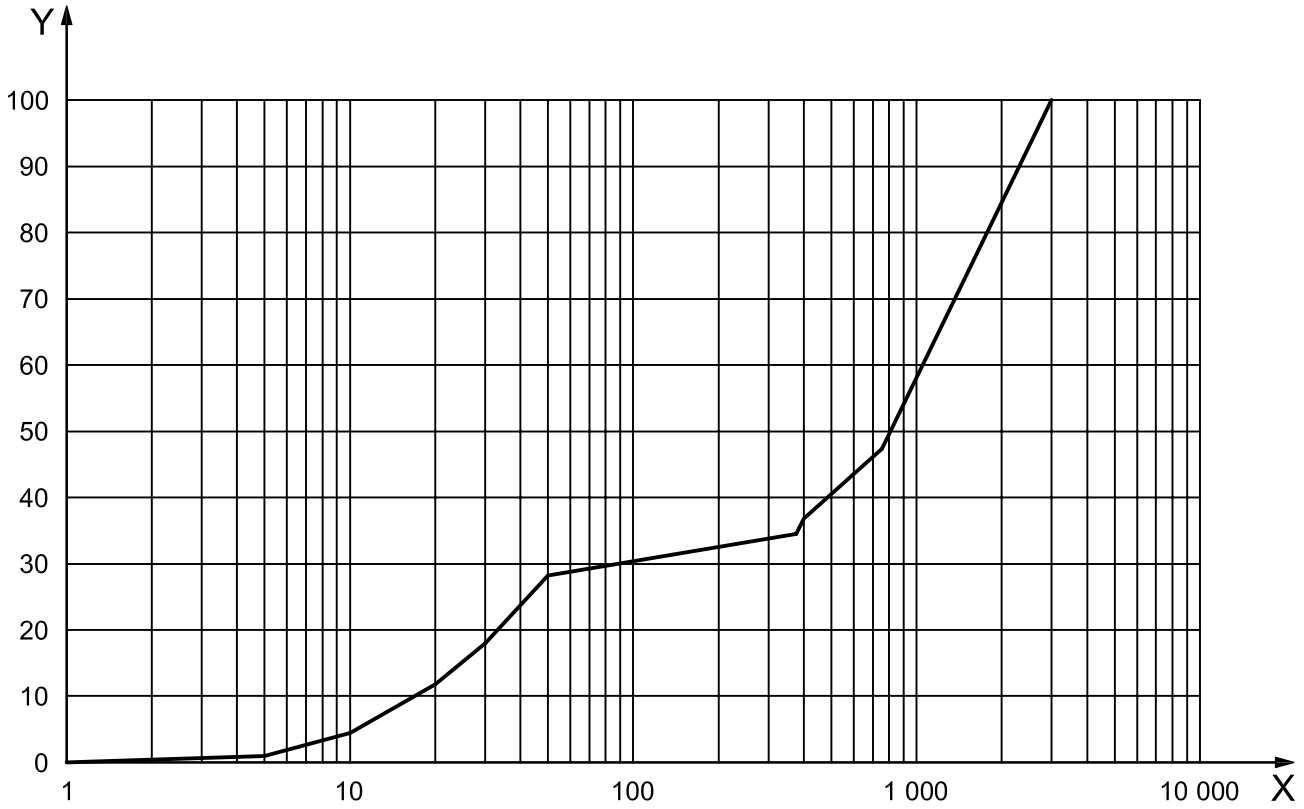
Present the results as a graph (sedigram) plotting cumulative undersize by mass on a linear scale from 0 % to 100 % as a function of Stokes' diameter on a logarithmic scale.

Compare the measured sedigram with the curve shown in Figure 2. If the measured sedigram is coarser than the curve shown in Figure 2, repeat the grinding process for particle fraction 3 until the measured sedigram is in accordance with Figure 2.

Prepare a test report in accordance with ISO 10076:1991, Clause 8.

Annex D
(informative)

Particle fraction size distribution of amalgam in dental waste water



NOTE This particle size distribution was used to determine the mass of particle fractions 1 and 2 of the amalgam sample (see 8.4).

Key

X particle size, in micrometres

Y cumulative mass, in percent

Figure D.1 — Particle size distribution of amalgam in dental waste water based on investigations of the United States, Dutch and German dental associations

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