

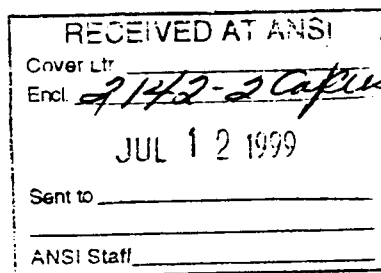
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## Dental equipment — Amalgam separators

*Matériel dentaire — Séparateurs d'amalgame*

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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).

## 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.

# 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*.

ISO 3585:1998, *Borosilicate glass 3.3 — Properties*.

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

ISO 9687:1993, *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

## 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 membrane filters and/or 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  $\mu\text{m}$ .

**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 hPa (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 hPa to 2 hPa, 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  $\mu\text{m}$ ;
- b) separating gauzes;
- c) membrane filter with a nominal pore size of 3  $\mu\text{m}$ ;
- d) separating gauzes;
- e) membrane filter with a nominal pore size of 1,2  $\mu\text{m}$ ;
- f) separating gauzes (drain side);
- g) supporting mesh.

The series of 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 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 should also be part of the installation of the amalgam separator.

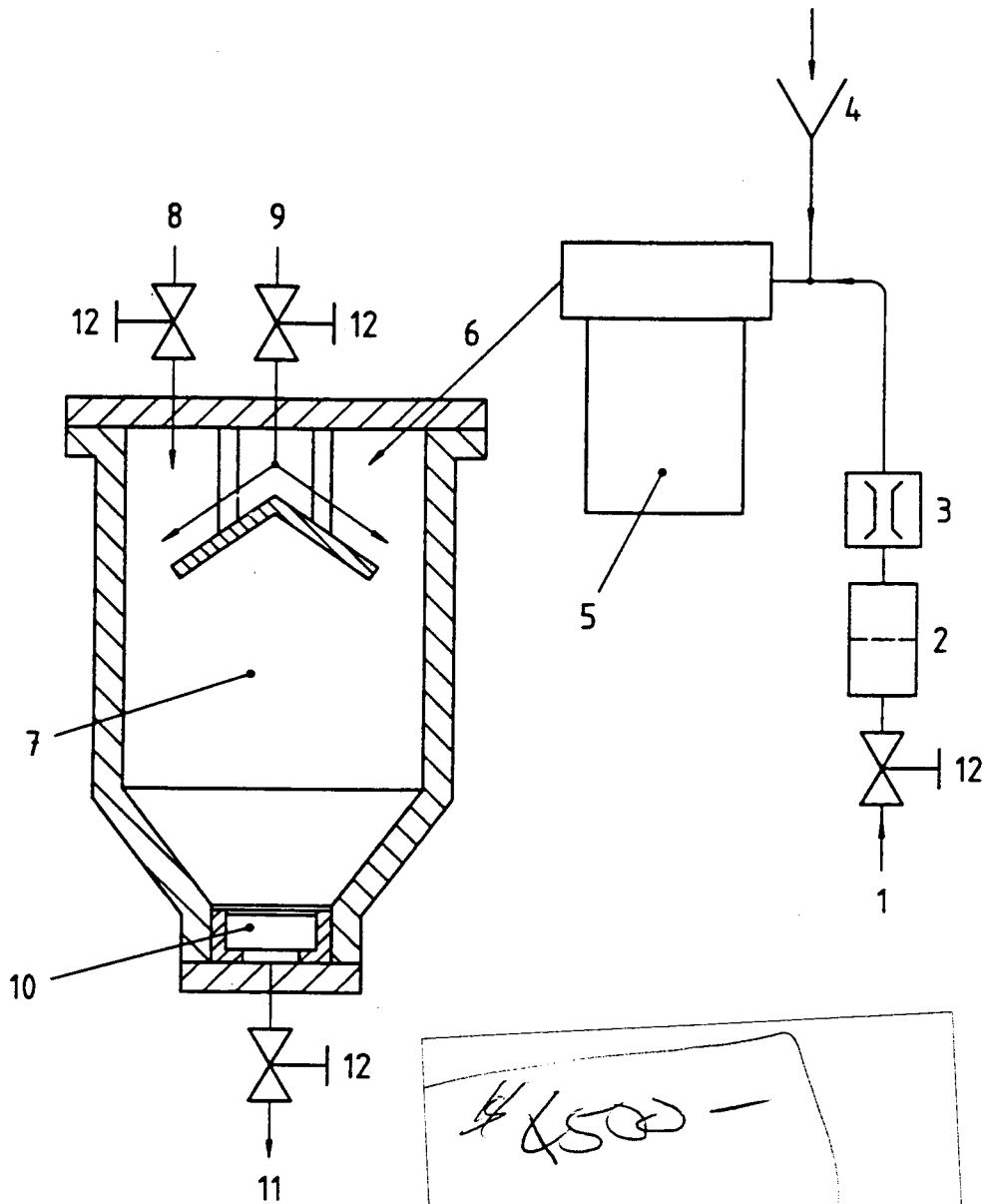
**7.2.2** Open the top of the effluent collecting vessel and put one of the transparent hoses into the effluent collecting vessel.

**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 nose, used only with open top
- 7 Effluent collecting vessel
- 8 Compressed air
- 9 Filtered tap water for rinsing
- 10 Series of filters
- 11 Drain
- 12 On/off valve

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

## 8 Amalgam sample

### 8.1 Fraction sizes

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

- a) Fraction 1: Particle size  $\leq 3,15$  mm and  $> 0,5$  mm.

Ground stock particles which 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) Fraction 2: Particle size  $\leq 0,5$  mm and  $> 0,1$  mm.

Ground stock particles which 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) Fraction 3: Particle size  $\leq 0,1$  mm.

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

### 8.2 Mass of amalgam sample

The total mass of the amalgam sample shall be 10,00 g, made from the three particle fractions described in 8.1 as follows:

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

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

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

NOTE This mean particle size distribution was calculated from particle size distributions of amalgam in dental waste water based on investigations of the American, Dutch and German Dental Associations (see annex D and annex E, [11], [12], [13]).

The mass of the three 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 fractions shall be changed in such a way that the ratios of mass fraction are preserved.

### 8.3 Sample preparation

For the preparation of the amalgam sample, capsules predosed with alloy and mercury and conforming to the chemical composition specified in ISO 1559 shall be used.

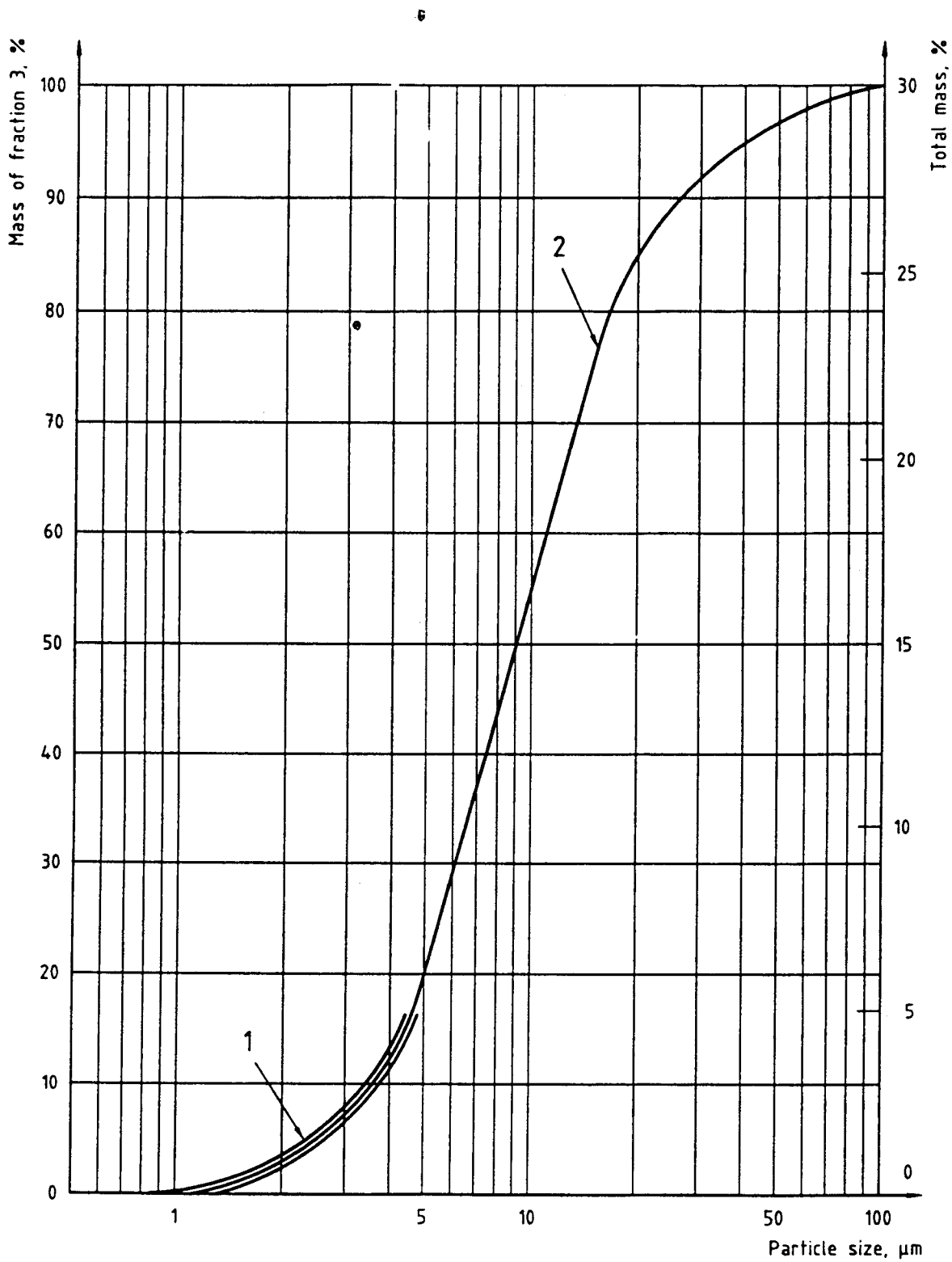
NOTE Annex A of this International Standard describes a procedure for preparation of the amalgam sample.

### 8.4 Particle size distribution

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

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

For fraction 3 particles, the sedimentation X-ray absorption technique in accordance with annex C of this International Standard shall be used as the examination procedure.



**Key**

- 1 Tolerance of  $\pm 5\%$  for particles  $\geq 5\ \mu\text{m}$
- 2 Tolerance of  $\pm 2\%$  for particles  $< 5\ \mu\text{m}$

**Figure 2 — Cumulative mass distribution (average and 99 % forecasting area) of fraction 3 amalgam particles with diameter of less than 100  $\mu\text{m}$**

## 8.5 Preparation of test slurry

### 8.5.1 Apparatus and materials

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

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

8.5.1.3 Stirring rod.

8.5.1.4 Ultrasonic bath.

8.5.1.5 Sodium pyrophosphate,  $\text{Na}_4\text{P}_2\text{O}_7 \cdot 10 \text{H}_2\text{O}$ , Technical Grade, 1 g.

8.5.1.6 Filtered tap water, filtered with a water filter such as 7.1.2.

### 8.5.2 Procedure

8.5.2.1 Use the amalgam sample prepared in accordance with 8.2.

8.5.2.2 Weigh the dry amalgam sample to an accuracy of three decimal places and note the mass  $m_1$  in grams.

8.5.2.3 Put the amalgam sample into the glass beaker (8.5.1.2).

8.5.2.4 Prepare the dispersing agent solution by mixing  $(1 \pm 0,1)$  g of sodium pyrophosphate (8.5.1.5) with  $(10 \pm 0,1)$  ml of filtered tap water. Filter the solution through a  $1 \mu\text{m}$  pore size filter. Add the filtered dispersing agent to the glass beaker containing the amalgam test sample. Stir the slurry with a stirring rod (8.5.1.3) until all amalgam particles are completely wetted by the dispersing agent.

NOTE Sodium pyrophosphate prevents air bubbles from sticking to the dispersed amalgam.

8.5.2.5 Fill the glass beaker with additional filtered tap water up to a volume of  $(1 \pm 0,05)$  l and put it into an ultrasonic bath (8.5.1.4) for  $(15 \pm 1)$  min to disperse the remaining agglomerate. During this process, stir periodically by hand in order to avoid sedimentation of the amalgam.

## 9 Test procedure

### 9.1 General

All tests described in this International Standard are type tests. 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  $(23 \pm 2)$  °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.

### 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 litre.

9.3.1.3 Spray bottle.

9.3.1.4 Ceramic tile.

9.3.1.5 Oven or drying cabinet, capable of being maintained at  $(90 \pm 2)$  °C.

9.3.1.6 Desiccator.

9.3.1.7 Scales, with an appropriate measuring range and an accuracy of  $\pm 0,000$  1 g.

### 9.3.2 Test method

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

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

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

9.3.2.3 Open the water inlet and conduct the test at the maximum water flowrate as specified by the manufacturer, reduced by 0,5 l/min to compensate for the water of the test slurry.

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

9.3.2.4 Stir the test slurry (8.4).

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

NOTE 1 The water of the test slurry (approximately 1 l over 2 min) is part of the maximum water flowrate.

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

Rinse the glass beaker with  $(0,1 \pm 0,01)$  l filtered 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 which flows into the delivery hopper until all visible residue is removed from the delivery hopper walls. Remove the sample delivery hopper.

9.3.2.5 Increase the water flowrate to the maximum water flowrate as specified by the manufacturer. Stop the water flow 8 min after the end of the addition of the test sample in order to include in the measurements any possible flush-out of sample already sedimented in the amalgam separator. For amalgam separators of type 2, if the total volume is less than 10 l, it is essential that the volume of water flow for this procedure be at least twice the amalgam waste-water volume of the amalgam separator.

9.3.2.6 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 hPa to 2 hPa to the effluent collecting vessel in order to force the fluid through the series of 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 hPa to 2 hPa to the effluent collecting vessel to ensure that all remains are forced against the series of filters. Again rinse the interior walls of the effluent collecting vessel with filtered tap water to ensure that no residue sticks to the interior walls of the effluent collecting vessel. Apply the air pressure again and finally rinse the interior walls.

Repeat the described procedure two times.

9.3.2.7 Carefully remove the series of filters, put them on a ceramic tile, store them in the drying oven and dry them at  $(90 \pm 2)$  °C for at least 3 h to constant mass. Cool the ceramic tile and the series of filters with their contents to room temperature in a desiccator. Weigh the series of filters to an accuracy of three decimal places. Return the series of filters to the desiccator. After 24 h reweigh the series of filters. If the result is consistent, note the mass  $m_3$  in grams.

**WARNING — The drying process can produce mercury vapour.**

9.3.2.8 The determination of the efficiency of the amalgam separator shall be carried out at 0 % (empty) and 100 % (maximum filling level). These levels are specified by the manufacturer.

9.3.2.9 To simulate a filling level of 100 %, the collecting container of the amalgam separator should be filled to 70 % of the maximum filling volume with glass beads of 1 mm diameter. The remaining volume should be filled to 100 % with amalgam scrap with a maximum particle size of 0,3 mm.

NOTE For practical reasons, use approximately the maximum filling level minus 15 g.

For amalgam separators of types 3 and 4, but only if a filter is included, the collecting container of the amalgam separator shall be filled completely with the sample material.

## 9.4 Number of tests

### 9.4.1 Empty amalgam separator

9.4.1.1 The efficiency test shall be carried out three times on the empty amalgam separator. 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.

9.4.1.2 The efficiency shall be calculated according to 9.5. The average of the three test results shall be calculated as the separation degree  $\eta_1$ .

### 9.4.2 Full amalgam separator

9.4.2.1 The efficiency test shall be carried out three times on the full amalgam separator, with the amalgam separator filled to its maximum filling level.

9.4.2.2 The efficiency shall be calculated according to 9.5. The average of the three test results shall be calculated as the separation degree  $\eta_2$ .

## 9.5 Calculation of efficiency

The value for the efficiency  $\eta$ , in percent, shall be calculated from the following equation:

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

where

$m_1$  is the mass, in grams, of the amalgam sample according to 8.2, recorded to three decimal places;

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

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

## 9.6 Determination of efficiency

The lower value of the efficiency calculated from the two test series ( $\eta_1$  or  $\eta_2$ ) is the efficiency of the amalgam separator. This value shall be compared with the requirement given in 5.1.

## 9.7 Test of warning system

If applicable, conduct testing of the warning system 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 filling container

If applicable, conduct testing of the alarm system after testing of the warning system (9.7), using the same amalgam separator.

For the test, use an amalgam separator filled over the warning level and approaching the maximum filling level. 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

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 mass of filled collecting container

Weigh the removed collecting container or filters, fully loaded with amalgam, to an accuracy of  $\pm 2$  %.

## 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) type classification;
- d) reference to this International Standard;
- e) particle size distribution used, including a particle size distribution curve (e.g. name and/or trademark of the manufacturer or distributor of the amalgam sample, a certificate, a report of the X-ray sedimentation test);
- f) lot number of amalgam sample;
- g) maximum water flowrate used during the test;
- h) type of membrane filters used during the test;
- i) number of tests performed;
- j) separation degree of empty and full amalgam separator;
- k) value of the efficiency;
- l) result obtained (pass/fail);
- m) all operations not specified in this International Standard;
- n) details of any occurrence which may have affected the test result;
- o) name of investigator;
- p) date of investigation;
- q) signature of investigator.

## **11 Instructions for installation, use, maintenance and service**

**11.1** Instructions for installation, use, maintenance and service shall be provided by the manufacturer for 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;
- d) specifications and instructions for installing and connecting the amalgam separator;
- e) rated electrical characteristics (voltage, frequency, fuse values), if applicable;
- f) maximum water flowrate, if applicable;
- g) description of the procedure for emptying the collecting device;
- h) description of the appropriate procedure for disposal of the separated substances;
- i) description of the removable parts for removal of the filled collecting container;
- j) description of the appropriate interval for changing of the collecting container, if applicable;
- k) description of the contractor, if applicable;

- l) description of the alarm signal and warning signal, if applicable;
- m) a statement that if the separator is installed distant from the dental treatment centre, the warning signal and the alarm signal shall be installed at or near the dental treatment centre;
- n) 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 disposal routines.

**11.3** The manufacturer shall clearly indicate how to empty the collecting device before the maximum filling level 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**

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

- a) manufacturer's name or trademark;
- b) serial number;
- c) model or type reference;
- d) maximum water flowrate, if applicable;
- e) rated electrical characteristics (voltage, frequency, fuse values), if applicable;
- f) whether a controlled change of containers is required.

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

### **12.3 Marking of liquid inlet and outlet**

The liquid inlet and outlet shall be appropriately marked.

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

### **12.4 Marking of collecting container**

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

- a) manufacturer's name or trademark;
- b) model and type of the corresponding amalgam separator.

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

## Annex A (informative)

### Preparation of amalgam sample

#### A.1 Apparatus and materials

**A.1.1 Encapsulated alloy and mercury for dental amalgam**, conforming to ISO 1559.

**A.1.2 Dental amalgamator**, conforming to ISO 7488.

**A.1.3 Nest of three round sieves**, of the following nominal aperture sizes: 3,15 mm, 500  $\mu\text{m}$  and 100  $\mu\text{m}$ , conforming to ISO 3310-1, sized in descending order with a collecting cup (pan) at the bottom.

**A.1.4 Collecting cup**, stainless steel, round.

**A.1.5 Spatula**, stainless steel.

**A.1.6 Quartering device**, conforming to Figure 4 of ISO 3954:1977.

**A.1.7 Collecting receptacle**.

**A.1.8 Scales** with a measuring accuracy of  $\pm 0,0001$  g.

**A.1.9 Thermometer**.

#### A.2 Amalgam preparation

**A.2.1** Prepare approximately 100 g amalgam (A.1.1) to give nine samples.

**A.2.2** Use encapsulated alloy and mercury (A.1.1), and amalgamate as many capsules as needed. An amalgamator (A.1.2) shall be used. The amalgamator's frequency (or machine setting) and the amalgamation time shall conform to the manufacturer's instructions.

**A.2.3** Prepare the amalgam according to the amalgam preparation description of ISO 1559:1995, 6.1 as cylindrical samples. Remove the free mercury from the mould. Then remove the amalgam.

**A.2.4** Divide the amalgam with a spatula (A.1.5) on a glass surface into portions with average diameters of 2 mm to 3 mm.

**A.2.5** Allow a hardening period of at least 30 days at a temperature of  $(23 \pm 2)$  °C and a relative humidity of  $(50 \pm 10)$  % according to ISO 554.

NOTE Shorter hardening periods create grinding problems.

#### A.3 Grinding

Grind the hardened amalgam as described in annex B.

## A.4 Sieving

Empty the mill cups into the nest of sieves (A.1.3). Scrape out any residue from the mill cups into the nest of sieves.

Check with a thermometer (A.1.9) that the grinding process did not overheat the amalgam, which can lead to smearing. The temperature shall be below 25 °C.

Sieve the amalgam using the nest of sieves (A.1.3):

- a) 3 150 µm sieve;
- b) 500 µm sieve;
- c) 100 µm sieve;
- d) Collecting cup.

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

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

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

The amalgam particles which 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.1.6) into sample heaps of final amounts of approximately 6 g each.

Repeat the grinding process with the amalgam prepared according to A.1 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 amalgam prepared according to A.2 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 amalgam prepared according to A.2 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.5 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 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 10 grinding processes might be necessary.

Check the particle size distribution again according to annex C.

## A.6 Preparation of amalgam sample

Weigh each sample of amalgam fraction 1 on the scales. Prepare  $(6 \pm 0,1)$  g of fraction 1.

Add  $(1 \pm 0,005)$  g of fraction 2 in order to compensate a possible mass deviation of fraction 1 (up to  $\pm 0,1$  g) to give a total mass of  $(7 \pm 0,005)$  g.

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

## Annex B (informative)

### Procedure for grinding the amalgam

#### B.1 Apparatus

**B.1.1 Microplanetary ball-bearing mill**, with a wheel allowing rotation at  $(1\,300 \pm 100)$  r/min and a distance of  $(90 \pm 10)$  mm between each mill cup and the midpoint of the sun wheel.

**B.1.2 Ball bearings**, of stainless steel, with a diameter of  $(15 \pm 1)$  mm.

**B.1.3 Two mill cups, each with a top** and a volume of  $(45 \pm 2)$  cm<sup>3</sup> and an internal diameter of  $(39 \pm 1)$  mm.

**B.1.4 Laboratory spoon**, of stainless steel.

**B.1.5 Clock**, with a measuring accuracy of  $\pm 1$  s.

**B.1.6 Thermometer**.

#### B.2 Procedure

Check with the thermometer that the temperature of the mill cups is below 25 °C.

**NOTE** Overheating due to repeated grinding can create problems.

Put five to seven ball bearings in each mill cup.

Using a laboratory spoon, fill the mill cup to  $(50 \pm 10)$  % of its volume with amalgam prepared in accordance with annex A.

Cover the cups and put the mill cups into the microplanetary ball-bearing mill (B.1.1). Lock the mill cups into place. Grind the amalgam for a period of  $(60 \pm 2)$  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 cups. Open the cups and take the ball bearings out. Sieve the amalgam according to annex A.

## Annex C (normative)

### Examination of fraction 3 particles using sedimentation with X-ray absorption

#### C.1 Apparatus

C.1.1 X-ray equipment for X-ray absorption measurements in accordance with ISO 10076.

C.1.2 Sedimentation cell.

C.1.3 Stirring rod or magnetic bar.

C.1.4 Suspension liquid, 65 % glycerine, Technical Grade, and 35 % deionized water of grade 3 in accordance with ISO 3696.

C.1.5 Acacia gum,  $(1,8 \pm 0,2)$  g.

C.1.6 Spatula, of stainless steel.

C.1.7 Glass plate,  $(60 \pm 5)$  mm  $\times$   $(60 \pm 5)$  mm  $\times$   $(5 \pm 1)$  mm.

C.1.8 Ceramic bowl.

C.1.9 Rubber rod, cylindrical, 1 cm diameter, 5 cm long.

C.1.10 Ultrasonic bath.

#### C.2 Preparation procedure

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

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

With the spatula take a weighed quantity of  $(1,5 \pm 0,3)$  g from the amalgam sample.

Put the weighed amalgam sample into a ceramic bowl (C.1.8).

#### C.3 Measurement procedure

Prepare  $(35 \pm 2)$  ml of suspension liquid (C.1.4), consisting of 65 %/35 % (mass fraction) water/glycerine solution.

Before starting the test, record the baseline of the X-ray absorption of 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  $(1,8 \pm 0,2)$  g acacia gum onto the weighed quantity (1,5 g) of amalgam sample in the ceramic bowl.

Knead the mixture for 1 min with the cylindrical rubber rod.

Add the  $(35 \pm 2)$  ml suspension liquid. Knead again. Sonicate the sample using the ultrasonic bath (C.1.10) until sample dispersion is complete. Then place the sample in the X-ray equipment (C.1.1).

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

#### **C.4 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.

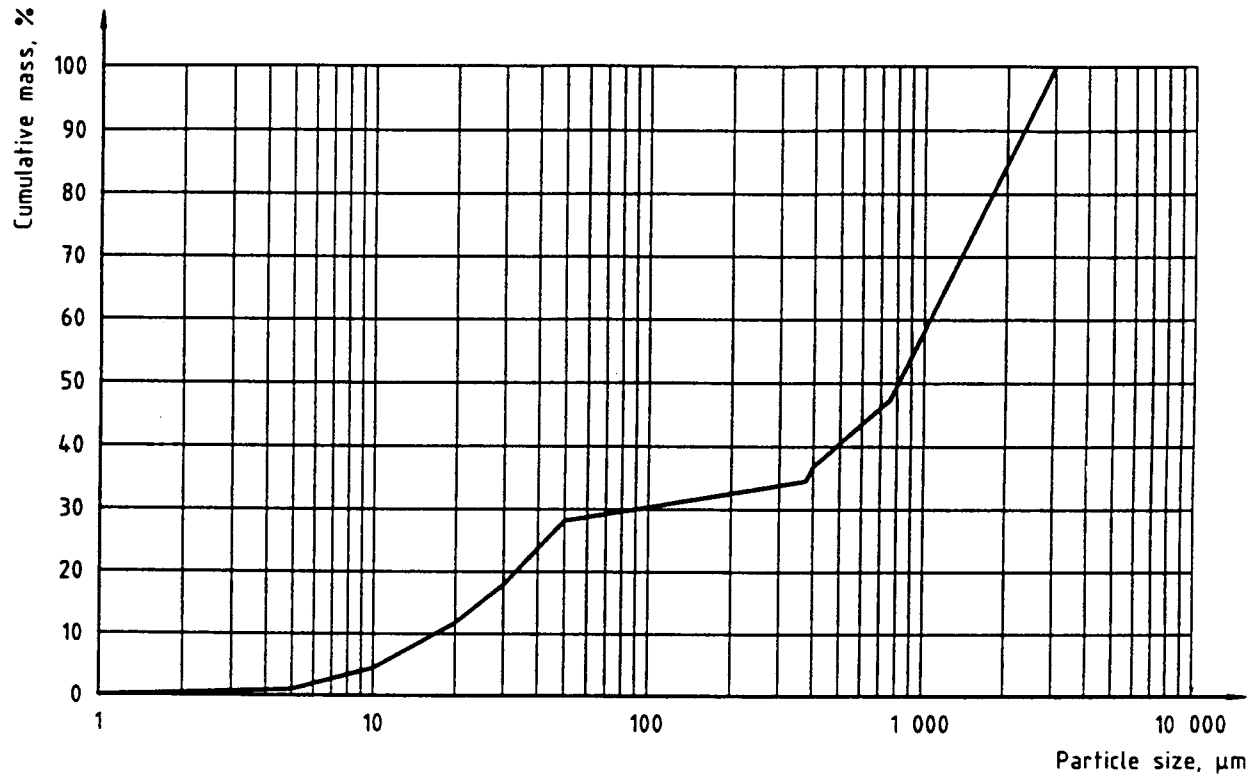
Compare the measured sedigram with the curve shown in Figure 2. If the measured sedigram is coarser than the curve shown in Figure 2, repeat the grinding process for fraction 3 particles until the measured sedigram is in accordance with Figure 2.

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



## Annex D (informative)

### Particle size distribution of amalgam in dental waste water



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

**Figure D.1 — Particle size distribution of amalgam in dental waste water based on investigations of the American, Dutch and German Dental Associations.**

## Bibliography

### International Standards

- [1] ISO 554:1976, *Standard atmospheres for conditioning and/or testing — Specifications.*
- [2] ISO 3310-1:1990, *Test sieves — Requirements and tests — Part 1: Metal wire cloth sieves.*
- [3] ISO 3954:1977, *Powders for powder metallurgical purposes — Sampling.*
- [4] ISO 7488:1991, *Dental amalgamators.*

### Other publications

- [5] HÖJLUND, A.: *Behandlung von Amalgam aus der Zahnbehandlung*, Bericht der Arbeitsgruppe im Staatlichen Schwedischen Umweltschutzamt, 1979.
- [6] HÖJLUND, A.; DURING; JAKOBSON, B.; TYREFORS, L.: *Standardtest für Abscheideanordnungen für quecksilberhaltigen Abfall aus dem Abwasser zahnärztlicher Behandlungseinheiten*, Staatliches Schwedisches Umweltschutzamt, 1979.
- [7] European Council Directive, 8 March 1984, *Limit values and quality objectives for mercury discharges by sectors other than the chlor-alkali electrolysis industry (84/156/EEC, Official Journal of the European Communities No. L74/49, 1984).*
- [8] TÖPPER, H.: *Rückhaltung von Amalgamabfällen aus Zahnarztpraxen. Schriftenreihe der Hessischen Landesanstalt für Umwelt, 44, 1986.*
- [9] GOUD, R; LETZEL, H.: *Amalgam in het Afvalwater van tandheelkundige Behandelingsinstallaties. Rijkswaterstaat/Ministere van Verkeer en Waterstaat, 88,020, 1988.*
- [10] ROTGANS, J.: *Requirements for testing amalgam separating devices in dental offices — Development of specimen for testing amalgam separating devices*, Report No. UBA-FB 102 06 503/05 of Universität Witten/Herdecke, 1988.
- [11] Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit.: *Bau- und Prüfgrundsätze für Amalgamabscheider - Amalgam Standardprobe und Quarz Standardprobe*, Institut für Bautechnik Berlin, 1989.
- [12] WERK GROEP VI.: *Afvalwaterproblematiek in de tandheelkundige Verzorging*. CUWYO Hoofddirectie van de Waterstaat s' Gravenhage, 1990.
- [13] Danish Dental Association.: *Principles for evaluation/testing of amalgam separators*, 1990.
- [14] MUSCHELKNAUTZ, E; DAHL, H.-D.; KUNTNER, P.: *Expert report on grain analyses of chips of dental amalgam from various practices in Germany and The Netherlands*, Report of the Institute for Mechanical Process Engineering - University of Stuttgart, 1992.
- [15] Dutch Dental Association.: *The determination of the size of amalgam particles in dental treatment waste*. Report of the Haskoning Royal Dutch Consulting Engineers and Architects 11499.B0705.A0/R004/FDB/MMF, 1993.
- [16] Bundeszahnärztekammer.: *Examination of sediment from amalgam settlers*, Report of the IGB Ingenieurbüro für Grundbau und Umwelttechnik Hamburg H24112/92, 1993.
- [17] Dutch Dental Association.: *The amalgam particle size distribution of dental treatment waste*, Report of the Haskoning Royal Dutch Consulting Engineers and Architects, 1994.

- [18] POTZE, H. A. and FEILZER, A. J. *Determination of particle size distribution in amalgam test samples*, Research Report, October 1, 1996.
- [19] FAN, P. L.; ARENHOLT-BINDSLEV, D.; SCHMALZ, G.; HALBACH, S. and BERENDSEN, H.: Environmental issues in dentistry — Mercury, *Int. Dental Journal*, **47**, 1997, pp. 105-109.
- [20] LETZEL, H.; DE BOER, F. A. and VAN'T HOF, M. A.: An estimation of the size distribution of amalgam particles in dental treatment waste, *J. Dent. Res.*, **76**(3), 1997, pp. 780-788.