BS ISO 24234:2021

BSI Standards Publication

Dentistry — Dental amalgam

bsi.

National foreword

This British Standard is the UK implementation of ISO 24234:2021.

The UK participation in its preparation was entrusted to Technical Committee CH/106/1, Dental restorative and orthodontic materials.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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INTERNATIONAL STANDARD

ISO 24234

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2021-08-18

Dentistry — Dental amalgam

Médecine bucco-dentaire — Amalgame dentaire

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 1, *Filling and restorative materials*.

This third edition cancels and replaces the second edition (ISO 24234:2015), which has been technically revised.

The main changes compared to the previous edition are as follows.

— Pre-capsulated dental amalgam products have been removed from the scope of this document.

— A requirement for corrosion resistance has been added.

— In previous editions of this document, the presence of a limited number of foreign body particles in the dental amalgam alloy powder was permitted. Now, as a requirement, foreign body particles are not permitted to be present in the dental amalgam alloy powder.

— The roughness parameter used to specify the finish required on working surfaces of test-piece moulds has been changed from R_k to R_a.

— An instruction to lightly abrade the ends of the cylindrical test-pieces, if required for removing flash, has been deleted.

— The requirement for early compression strength has been altered. Measurement of the value is made at 2 h and not at 1 h.

— An additional four items of information have been added to each of the test reports.

— The edition number of the manufacturer's instructions and information, and the date of its introduction have been added as a requirement to the manufacturer's instructions.

— For each test method used to determine conformity to a requirement, a new subclause, "Principle", has been added in which a brief summary is present to explain the method adopted.

— For each test method used to determine conformity to a requirement, a new subclause, “Test report”, has been added.

— A new clause “7 Report" has been added which provides details of the evaluation that are to accompany a statement or claim of conformity to this document overall.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Continuing concern about the use of dental mercury and a move in some counties to limit its use to pre-capsulated products led to the development of ISO 20749. The scope of ISO 20749 is restricted to pre-capsulated products alone. Consequently, it is appropriate to remove pre-capsulated dental amalgam products from the scope of this document.

Dental amalgam alloy supplied as a free-flowing powder and as tablets remain in use in some countries. For their use, dental mercury is required and the supply of dental mercury sachets (also referred to as pillows) continues to be consistent with the objective to restrict the supply of dental mercury only in sealed capsules containing a mass suitable for a single restoration. All such products are within the scope of this revision.

NOTE In some jurisdictions only pre-capsulated products are allowed to be used. ISO TC 106, *Dentistry*, must consider global use and not restrict the standards it produces to the position prevailing in individual states or regional blocks. For as long as product types within the scope of this document are in legal use in other nations, this standard will continue to be required.

Specific qualitative and quantitative test methods for demonstrating freedom from unacceptable biological hazard are not included in this document. It is recommended that, for the assessment of possible biological hazards, reference should be made to ISO 10993-1 and ISO 7405.

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INTERNATIONAL STANDARD ISO 24234:2021

Dentistry — Dental amalgam

1 Scope

This document specifies the requirements and test methods for dental amalgam alloy powder and dental mercury that are suitable for the preparation of dental amalgam together with the requirements and test methods for that dental amalgam and the requirements for packaging and marking.

NOTE Two of the requirements apply only to dental mercury (as supplied). All of the other requirements apply to the dental amalgam alloy (as supplied) and dental amalgam.

This document is not applicable to dental amalgam alloy powder and dental mercury supplied in a pre-capsulated form.

This document is not applicable to other metallic materials in which an alloy powder reacts with an alloy that is liquid at ambient temperature to produce a solid metallic material intended for dental restoration.

This document applies to products used to make dental amalgam restorations, supplied to the user in the following forms: dental amalgam alloy as a fine free flowing powder, or as a fine powder compacted into tablets and dental mercury in dental mercury sachets (sometimes referred to as dental mercury pillows). The mass of dental mercury in these sachets is limited to the amount required to make a small to medium-sized restoration in a single tooth.

This document is not applicable to dental mercury that is supplied in a primary container in an undivided mass that exceeds the amount suitable for a small to medium-sized restoration.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 286-2, *Geometrical product specifications (GPS) — ISO code system for tolerances on linear sizes — Part 2: Tables of standard tolerance classes and limit deviations for holes and shafts*

ISO 1942, *Dentistry — Vocabulary*

ISO 3310-1, *Test sieves — Technical requirements and testing — Part 1: Test sieves of metal wire cloth*

ISO 3864-2, *Graphical symbols — Safety colours and safety signs — Part 2: Design principles for product safety labels*

ISO 4287, *Geometrical Product Specifications (GPS) — Surface texture: Profile method — Terms, definitions and surface texture parameters*

ISO 7488, *Dentistry — Mixing machines for dental amalgam*

ISO 13897, *Dentistry — Dental amalgam reusable mixing-capsules*

ISO 15223-1:2016, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 23325, *Dentistry — Corrosion resistance of dental amalgam*

UN Recommendations on the Transport of Dangerous Goods, Model Regulations. United Nations, New York and Geneva, 21st Edition, 2019, eISBN 978-92-1-004112-6

[SOURCE: ISO/TS 20746:2016, 3.5, modified — "dental amalgam alloy" has been replaced with "dental amalgam alloy powder" in the definition and the term "dental mercury pillow" has been added.]

3.6
mixing machine for dental amalgam
DEPRECATED: amalgamator
electrically powered mixing machine that operates using an oscillating action for mixing *dental amalgam alloy* (3.1) and *dental mercury* (3.2) (in a capsule) to produce a dental amalgam

[SOURCE: ISO/TS 17988: 2020, 3.12]

4 Requirements

4.1 Chemical composition and purity of the dental amalgam alloy

The manufacturer shall declare every element that is present in a concentration greater than, or equal to a mass fraction of 0,1 %. All alloying elements present in concentrations greater than a mass fraction of 0,5 % shall be given by name with mass fraction values rounded to the nearest whole percentage point. Alloying elements that are present in concentrations between a mass fraction of 0,1 % and 0,5 % shall be named without a percentage value.

Test in accordance with 6.1.

The chemical composition shall comply with Table 1.

The total mass fraction for other elements present in concentrations greater than a mass fraction of 0,01 % but below a mass fraction of 0,1 % that are not declared as alloying elements shall not exceed a mass fraction of 0,1 %.

Table 1 — Requirements for chemical composition of the dental amalgam alloy

Element	Mass fraction %
Silver	≥40
Tin	≤32
Copper	≤30
Indium	≤5
Palladium	≤1
Platinum	≤1
Zinc	≤2
Mercury	≤3

4.2 Purity of the dental mercury

Elements other than dental mercury shall not be present in a concentration greater than a mass fraction of 0,01 % in total. Test in accordance with 6.2.

4.3 Foreign material and large particles in the dental amalgam alloy powder

When conformity to this requirement is determined in accordance with 6.3, the proportion of the dental amalgam alloy powder that occurs as particles that have a size greater than 150 µm shall not exceed a mass fraction of 0,1 %.

When tested in accordance with 6.3, no particles of foreign matter shall be found on the sieve.

4.4 Accuracy and variability of pre-proportioned masses

4.4.1 For dental mercury sachets

The arithmetic mean of the mass of the dental mercury in the sachet shall be within ±2,0 % of the manufacturer's stated mass, when tested in accordance with 6.4.

The coefficient of variation of the mass of the dental mercury in the sachets shall not exceed 1,5 %, when tested in accordance with 6.4.

4.4.2 For dental amalgam alloy tablets

The arithmetic mean of the mass of the dental amalgam alloy tablet shall be within ±2,0 % of the manufacturer's stated mass, when tested in accordance with 6.4.

The coefficient of variation of the mass of the dental amalgam alloy tablets shall not exceed 1,5 %, when tested in accordance with 6.4.

4.5 Properties of the dental amalgam

4.5.1 General

Table 2 — Properties of the dental amalgam

Maximum creep %	Permitted dimensional change during hardening %	Minimum compressive fracture stress at 2 h MPa	Minimum compressive fracture stress at 24 h MPa
2,0	−0,10 to +0,15	100	350

4.5.2 Creep

When conformity to this requirement is determined in accordance with 6.5, the results for either three out of three, or four out of five test-pieces shall meet the requirement in Table 2.

4.5.3 Dimensional changes during hardening

When conformity to this requirement is determined in accordance with 6.5, the results for at least four out of five test-pieces shall meet the requirement in Table 2.

4.5.4 Compressive fracture stress at 2 h

When conformity to this requirement is determined in accordance with 6.5, the results for at least four out of five test-pieces or eight out of 10 test-pieces shall meet the requirement in Table 2.

4.5.5 Compressive fracture stress at 24 h

When conformity to this requirement is determined in accordance with 6.5, the results for at least four out of five test-pieces or eight out of 10 test-pieces shall meet the requirement in Table 2.

4.6 Appearance of the mixed dental amalgam before setting

When conformity to this requirement is determined in accordance with 6.6, the dental amalgam alloy and dental mercury being mixed according to the manufacturer's instructions, the dental amalgam shall form a coherent plastic mass with a shiny surface before packing and remain a coherent body after packing is completed.

4.7 Corrosion resistance of the dental amalgam

When conformity to this requirement is determined in accordance with 6.7, the mean value (in newtons) of 10 valid results for corrosion test-pieces shall not be less than 80 % of the mean value (in newtons) of 10 valid results for control test-pieces.

5 Sampling

Procure material in packages that have been produced for retail and that are from a single lot.

To evaluate a dental amalgam alloy, procure a mass of dental amalgam alloy sufficient to conduct all the testing needed to evaluate the alloy itself and to make the required number of test-pieces, including the maximum number of test-pieces allowed to replace any that are rejected. To make the dental amalgam test-pieces, procure a sufficient number of dental mercury sachets from a single lot that has been produced for retail. These sachets shall comply with the requirements for dental mercury of this document.

A minimum of 200 g is advisable. There is waste amalgam with the production of each test-piece and an allowance for this is needed.

To evaluate a dental mercury sachet product for conformity to the requirements for dental mercury (see 4.2 and 4.4.1) 30 sachets are required.

6 Test methods

6.1 Chemical composition and purity of the dental amalgam alloy

6.1.1 Principle

Chemical analysis of the dental amalgam alloy using an instrumented technique for metallic materials.

6.1.2 Test sample

10 g of dental amalgam alloy powder or dental amalgam alloy tablets, as appropriate.

6.1.3 Apparatus

Recognized, instrumented analytical instrument, with sensitivity adequate to determine the composition of the dental amalgam alloy for each of the elements declared by the manufacturer in compliance with 4.1.

NOTE Inductively coupled plasma atomic emission spectroscopy (ICP-AES) is an example of a suitable analytical procedure.

6.1.4 Procedure

Determine the composition of the dental amalgam alloy for the elements declared by the manufacturer in compliance with 4.1. Other elements may be detected during the analysis, being undeclared or impurities. Determine the concentration of each of these as a mass fraction percentage.

6.1.5 Expression of results

Record all alloying elements detected in concentrations greater than a mass fraction of 0,01 % and their mass fraction percentages.

For other elements that are detected in concentrations greater than a mass fraction of 0,01 % and below a mass fraction of 0,1 % but are not alloying elements (declared as such by the manufacturer in

compliance with 4.1), sum these values and record the sum as the mass fraction percentage of other elements. For an element, that is not a declared alloying element detected in a concentration greater than a mass fraction of 0,1 %, record this value and the name of the element.

6.1.6 Report

6.1.6.1 Test report

A test report shall be prepared. At least the following information shall be included:

a) the name of the dental amalgalm alloy product and its lot number;

b) the name and address of the manufacturer;

c) the International Standard used (i.e. ISO 24234:2021);

d) analytical method used;

e) any irregularities in the test procedure;

f) the mass fraction percentages for those elements that are alloying elements according to Table 1 and declared as such by the manufacturer, as recorded in 6.1.5;

g) if any other element is declared by the manufacturer as an alloying element, report this and its mass fraction percentage as recorded in 6.1.5;

h) each undeclared element found in a concentration greater than a mass fraction of 0,1 % by name and the mass fraction percentage as recorded in 6.1.5;

i) the sum of the mass fraction percentages of undeclared elements present in concentrations greater than a mass fraction of 0,01 % as recorded in 6.1.5;

j) the name and address of the organization responsible for the testing (e.g. test house, university, department of manufacturer);

k) the date of testing.

6.1.6.2 Conformity

Report whether the product does or does not conform with the requirement for composition and purity of the dental amalgam alloy in accordance with 4.1

6.2 Purity of the dental mercury

6.2.1 Principle

Chemical analysis of the dental mercury by using an instrumented technique for metallic materials.

6.2.2 Sample

One dental mercury sachet.

6.2.3 Apparatus

6.2.3.1 Recognized, instrumented analytical instrument, with sensitivity adequate to determine elements present as impurities in dental mercury, in compliance with 4.2.

NOTE ICP-AES is an example of a suitable analytical procedure.

6.2.3.2 Surgical scalpel.

6.2.3.3 Watch glass.

6.2.4 Procedure

Cut open the dental mercury sachet and empty its contents onto the watch glass.

Determine the purity of the dental mercury in compliance with 4.2 by using the analytical instrument to determine the concentration of any element (other than mercury) that is present in a concentration greater than a mass fraction of 0,000 5 %. Record these elements and their concentrations as mass fraction percentages.

6.2.5 Expression of results

Other than the value for dental mercury, sum the values recorded for elements that are present.

6.2.6 Report

6.2.6.1 Test report

A test report shall be prepared. At least the following information shall be included:

a) the name of dental mercury product and its lot number;

b) the name and address of the manufacturer;

c) the International Standard used (i.e. ISO 24234:2021);

d) the analytical method used;

e) any irregularities in the test procedure;

f) mass fraction percentages for those elements that are present in the dental mercury in concentrations greater than a mass fraction of 0,000 5 % (see 6.2.5);

g) the sum of these concentrations as a mass fraction percentage;

h) the name and address of the organization responsible for testing (e.g. test house, university, department of the manufacturer);

i) the date of testing.

6.2.6.2 Conformity

Report whether the product does or does not conform to the requirement for purity of dental mercury in accordance with 4.2.

6.3 Foreign material and large particles in the dental amalgam alloy powder

6.3.1 Principle

Foreign particles, separated from the dental amalgam alloy powder by sieving, are identified by visual inspection. The large dental amalgam alloy particles (defined as >150 μm in size) separated from the sample (a known mass of dental amalgam alloy powder) are weighed.

6.3.2 Test sample

A (10,0 ± 0,1) g sample of dental amalgam alloy powder.

6.3.3 Apparatus

6.3.3.1 Chemical balance, having a resolution and accuracy to 1 mg.

6.3.3.2 Sieve, having a mesh size 150 µm that conforms to ISO 3310-1 with collection pan and cover.

6.3.3.3 Tweezers, with pointed ends.

6.3.3.4 Weighing boat, or similar.

6.3.3.5 Stereomicroscope, set at ×10 magnification.

6.3.3.6 Mixing machine for dental amalgam, complying with ISO 7448 (for use with dental amalgam alloy tablets).

6.3.3.7 Reusable dental amalgam mixing capsule, complying with ISO 13897 (for use with dental amalgam alloy tablets).

6.3.4 Test procedure

For free-flowing dental amalgam alloy powder, weigh out a (10 ± 0,1) g sample to an accuracy of 1 mg and record this as m_P .

For dental amalgam alloy tablets, place a tablet in the reusable dental amalgam mixing capsule. Break the tablet in the capsule into the constituent powder particles by using the mixing machine at the setting and for half of the mixing time recommended (to produce an acceptable dental amalgam) by the manufacturer of the tablet. If the manufacturer's recommendations include any other action to beak-up the tablet (e.g. use a pestle), incorporate this at the appropriate time. Repeat this using a sufficient number of tablets to obtain (10 ± 0,1) g of powder. Weigh this sample to an accuracy of 1 mg and record as m_P .

Place the sample on the sieve. Hold the sieve assembly (consisting of collecting pan, sieve and cover) in one hand and tap it gently against the other hand at a rate of approximately twice a second for 120 s. Use the stereomicroscope to inspect the sieve for any foreign material. Record the number of foreign material particles.

Remove these foreign particles. Then, transfer the dental amalgam alloy particles remaining on the sieve to the balance. Weigh the dental amalgam alloy particles to an accuracy of 1 mg and record as m_r .

6.3.5 Expression of the results

Calculate *w,* the proportion of the dental amalgam alloy powder present as particles that have a size greater than 150 µm (expressed as a percentage of the mass of the sample), as follows:

$$w = \frac{m_r}{m_p} \times 100(\%)$$

where

m_r is the mass of dental amalgam alloy particles remaining on the sieve;

m_p is the mass of the powder sample.

6.3.6 Report

6.3.6.1 Test report

A test report shall be prepared. At least the following information shall be included:

a) the name of the dental amalgam alloy product and its batch number;

b) the name and address of the manufacturer;

c) the International Standard used (i.e. ISO 24234:2021);

d) the test method used;

e) any irregularities in the test procedure;

f) whether foreign material was found on the sieve and the number of these particles;

g) the proportion of the dental amalgam alloy that is present as particles greater than 150 µm in size, expressed as a percentage of the mass of the test sample (see 6.3.5);

h) the name and address of the organization responsible for the testing (e.g. test house, university, department of manufacturer);

i) the date of testing.

6.3.6.2 Conformity

Report whether the product does or does not conform to the requirement for foreign matter and for large particles in accordance with 4.3.

6.4 Determination of the accuracy and variability of pre-proportioned masses

6.4.1 Principle

The value of both parameters is obtained by weighing.

6.4.2 Test sample

25 dental mercury sachets, or 25 dental amalgam alloy tablets, as is appropriate.

6.4.3 Apparatus

6.4.3.1 **Surgical scalpel** (for dental mercury sachets).

6.4.3.2 **Watch glass.**

6.4.3.3 **Chemical balance,** having a resolution and accuracy to 1 mg.

6.4.4 Test procedure

6.4.4.1 Dental mercury sachets

Select 25 dental mercury sachets at random.

Determine the mass of the dental mercury in each of these as follows.

Remove all dental mercury from one of these sachets. Cut it open using the scalpel and empty the dental mercury onto the watch glass. Weigh this dental mercury and the empty sachet separately, to the nearest 1 mg. Record these masses.

Weigh the other 24 sachets with the dental mercury *in situ* individually to the nearest 1 mg. Subtract the mass of the empty sachet (found previously) to obtain the mass of dental mercury in each of these. Record these masses.

6.4.4.2 Dental amalgam alloy tablets

Select 25 dental amalgam alloy tablets at random. Weigh these individually to the nearest 1 mg. Record the masses.

6.4.5 Treatment of data

Determine the arithmetic mean and standard deviation for the set of 25.

Calculate the coefficient of variation, C_v :

$$C_v = \frac{s}{\overline{x}} \times 100(\%)$$

where

s is the standard deviation;

$\overline{x}$ is the arithmetic mean.

6.4.6 Report

6.4.6.1 Test report

A test report shall be prepared. At least the following information shall be included:

a) the name of the dental mercury or dental amalgam alloy tablet product (as appropriate) and its lot number;

b) the name and address of the manufacturer;

c) the International Standard used (i.e. ISO 24234:2021);

d) the test method used;

e) any irregularities in the test procedure;

f) all values for the masses of dental mercury in the sachets or dental amalgam alloy tablets, each to 1 mg (see 6.4.4.1 or 6.4.4.2, as appropriate);

g) the arithmetic mean, the standard deviation and the coefficient of variation;

h) any unusual features observed;

i) the name and address of the organization responsible for the testing (e.g. test house, university, department of manufacturer);

j) the date of testing.

6.4.6.2 Conformity

Report whether the product does or does not conform to the requirement for the accuracy and consistency of the pre-proportioned mass, in accordance with 4.4.

6.5 Properties of the dental amalgam

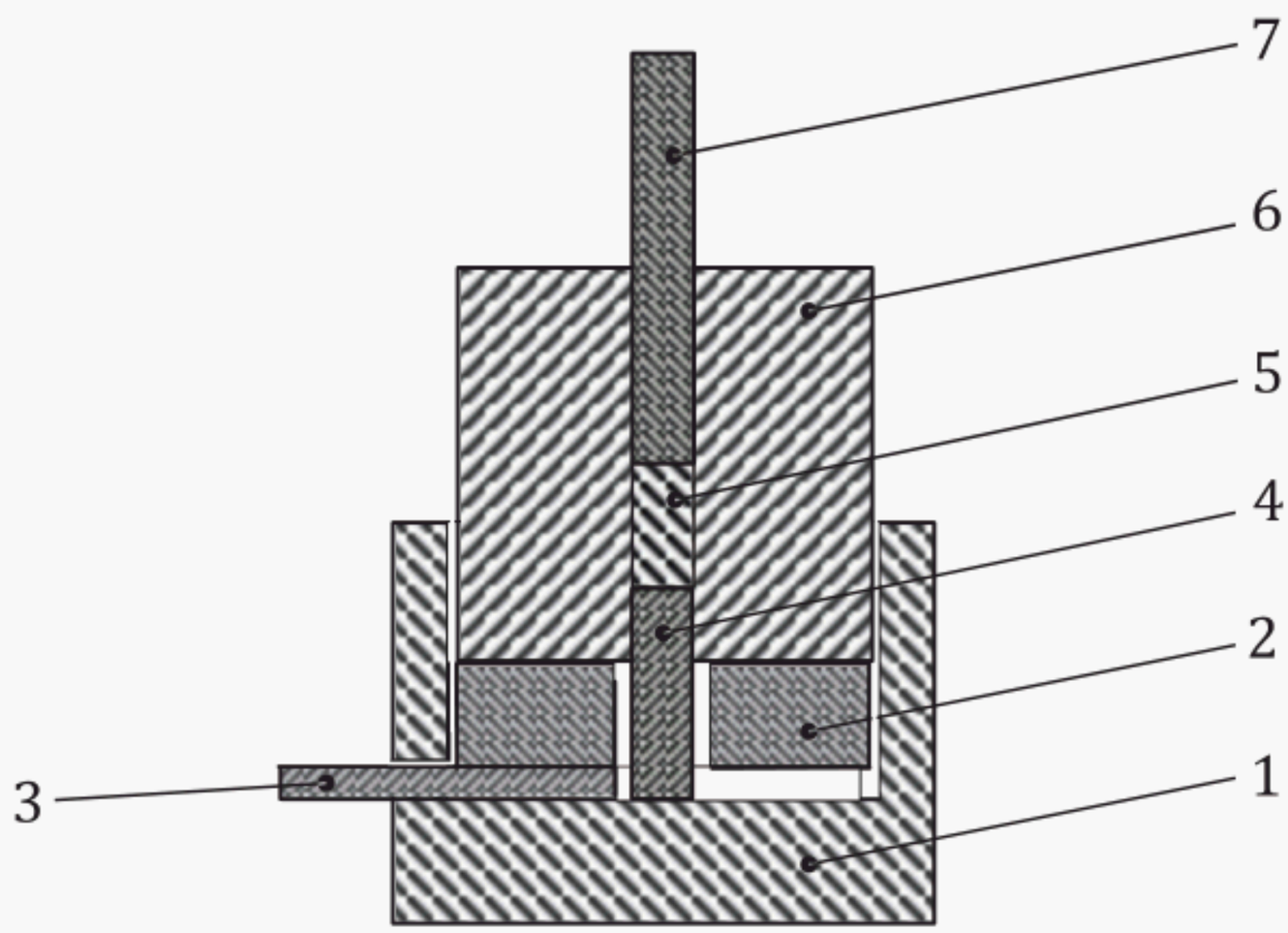
6.5.1 Principle

All three properties for the requirement described in 4.5 are determined using cylindrical test-pieces. To produce consistency in packing throughout the body of the test-piece and consistency from one to the next, a standardized procedure is used to produce these test-pieces.

6.5.2 Mould for the preparation of test-pieces for determining creep, dimensional change during hardening and compressive fracture stress

6.5.2.1 General

The mould and its component parts are shown in Figures 1 to 5.



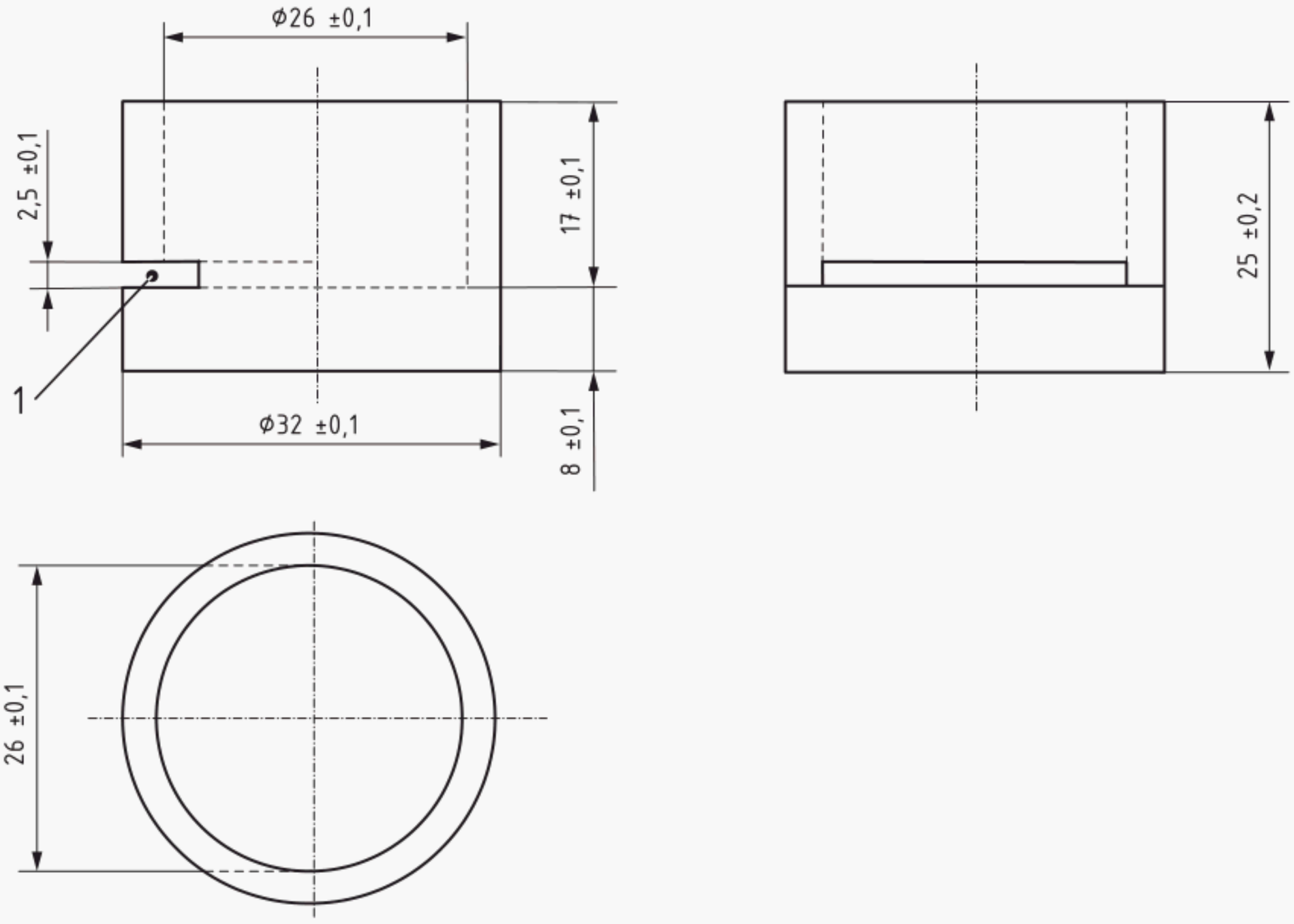
Key

1 holder
2 spacer No. 1
3 spacer No. 2
4 plunger No. 2
5 test-piece
6 die
7 plunger No. 1

NOTE The dimensions for each of the components are given in the figures that follow.

Figure 1 — Vertical section through the mould for making cylindrical dental amalgam test-pieces, showing the assembled mould with a test-piece in place

Dimensions in millimetres



Key

1 slot

Figure 2 — Holder

Dimensions in millimetres

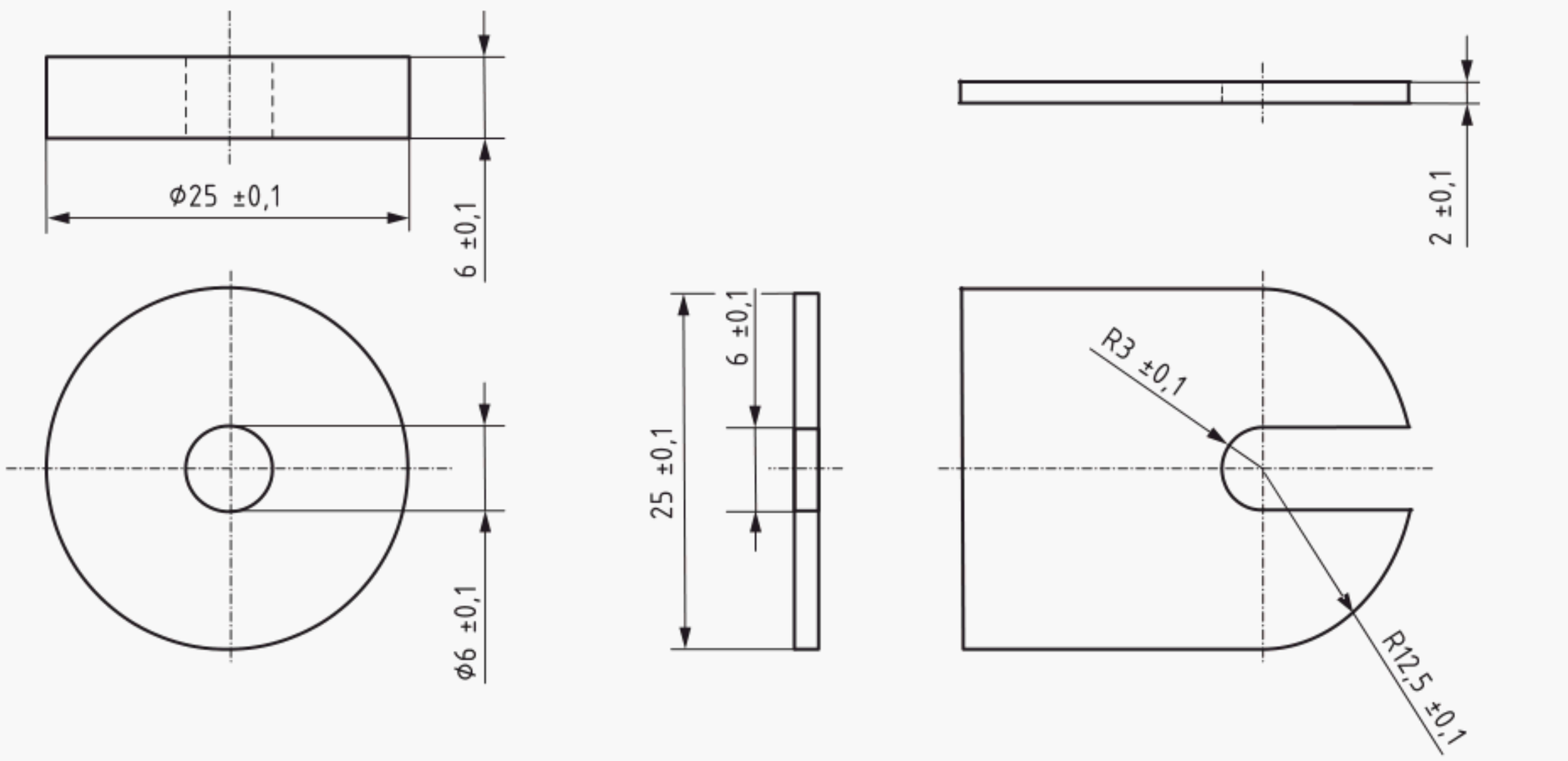


Figure 3 — Spacer No. 1 (left) and spacer No. 2 (right)

Dimensions in millimetres

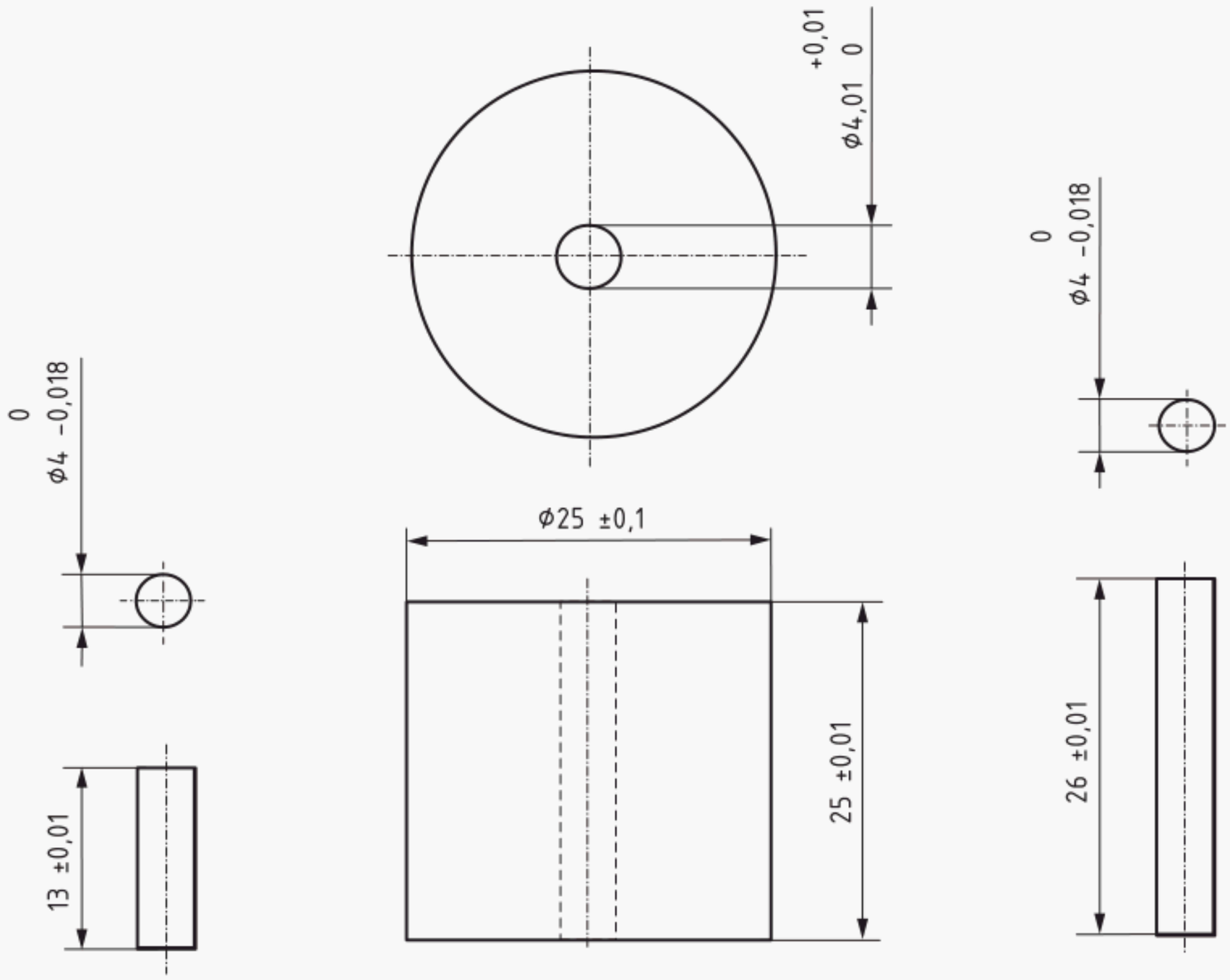


Figure 4 — Plunger No. 2 (left), the die (centre) and plunger No. 1 (right)

Dimensions in millimetres

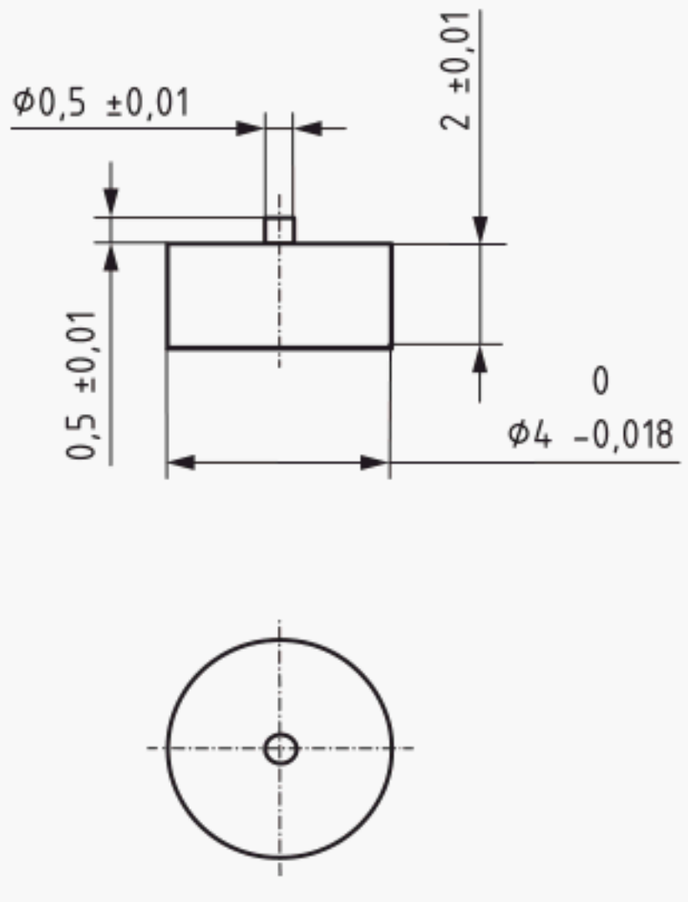


Figure 5 — Cap used for the production of test-pieces used for the measurement of dimensional change during hardening

To assist the operator in judging whether the correct quantity of dental amalgam has been inserted into the die, for the test-piece to be within the permitted range for length [i.e. (8 ± 1) mm], circumferential datum lines may be scribed at 9 mm, 11 mm and 13 mm from one end of plunger No. 1. This end (from which the distances to the scribed lines are measured) shall be in contact with the dental amalgam. Though such datum lines are not mandatory, their use is recommended.

The diameters of the plungers shall be subject to a shaft (or in this case a plunger) clearance (with a tolerance) of h7 according to ISO 286-2. For a plunger that is nominally 4,000 mm in diameter, its diameter shall be between 0 µm and 18 µm less than 4,000 mm. Thus, the diameter of the plunger is to be between 3,982 mm and 4,000 mm.

The diameter of the hole in the die is subject to a clearance (with a tolerance) of F7 according to ISO 286-2. For a hole that is nominally 4,000 mm in diameter, its diameter shall be between 10 µm and 20 µm more than 4,000 mm. Thus, the diameter of the hole shall be between 4,010 mm and 4,020 mm.

6.5.2.2 Materials and working surface finishing for construction of the apparatus

Make the holder, the spacers and the cap of cold-rolled or stainless steel. Make the die and the plungers of hardened tool steel or hardened stainless steel. Hone the working surfaces of the die and the plungers to an arithmetic mean roughness (R_a) not greater than 6,3 µm when tested in accordance with ISO 4287.

6.5.2.3 Assembly of the apparatus

For the production of creep and compressive strength test-pieces, assemble the holder, spacers No. 1 and No. 2, the die and plunger No. 2 as shown in Figure 1. At this point in time, do not insert plunger No. 1.

NOTE Plunger No. 1 is inserted after the dental amalgam mix is placed in the die.

Particular measuring instruments used in the test for dimensional change during hardening (e.g. interferometers) may require an impression on the end surface of the test-piece. It is produced by the cap that is shown in Figure 5. For the production of test-pieces for the measurement of dimensional change during hardening, include the cap in the assembly if this is appropriate for the measuring instrument that is to be used. In that case, position the cap on top of the plunger No. 2.

6.5.3 Sample

Sufficient dental amalgam alloy powder or tablets to produce the required number of test-pieces for each property determination. An appropriate number of dental mercury sachets.

6.5.4 Test-piece production

6.5.4.1 Temperature

Prepare test-pieces at (23 ± 2) °C.

6.5.4.2 Apparatus

6.5.4.2.1 Dental amalgam mixing machine, complying with ISO 7448 and recommended by the manufacturer of the dental amalgam alloy product.

6.5.4.2.2 Reusable dental amalgam mixing-capsule, complying with ISO 13897.

6.5.4.2.3 Timer, with an accuracy and resolution to 1 s.

6.5.4.2.4 Tweezers, with pointed ends.

6.5.4.2.5 Hand-instrument for dental amalgam packing.

6.5.4.2.6 Light source, with an illuminance ≥1 000 lux.

6.5.4.2.7 Mould, shown in Figures 1 to 5.

6.5.4.2.8 Apparatus to apply (176 ± 13) N to the mould plunger No. 1.

6.5.4.2.9 **Air oven,** set at a temperature of (37 ± 1) °C.

6.5.4.3 Mixing

Use the ratio by mass of the dental amalgam alloy to the mass of dental mercury that is recommended by the manufacturer. Use a reusable mixing capsule (with a pestle, if needed) to contain the mix. Use any other mixing accessory that is required, as recommended by the manufacturer. If more than one mix is required to make the test-piece, produce these mixes simultaneously using equipment of the same type for each mix. However, if the last mix can be produced within the working time of the first mix, mixing these masses sequentially on a single piece of equipment is permitted.

Mix a mass of dental amalgam sufficient to make a 4 mm diameter cylindrical test-piece (8 ± 1) mm in length.

NOTE The mass of a 4 mm diameter dental amalgam cylinder 8 mm in length is approximately 1,2 g.

Use the setting and the mixing time that are recommended by the manufacturer for the mass of dental amalgam alloy that is being mixed [see 8.4 b)].

6.5.4.4 Packing

Using tweezers, place the coherent mass of mixed dental amalgam on top of the die cavity and insert immediately with several thrusts of a hand-instrument for dental amalgam packing. Do not express mercury during this insertion. Then insert plunger No. 1 and proceed, following the schedule in Table 3.

After ejection, the test-piece shall not be trimmed.

Inspect the surfaces of the test-piece for any defects. Use visual inspection without magnification. Carry out this inspection at an illuminance of at least 1 000 lux and at a distance not exceeding 250 mm. A person making the inspection shall have nominally normal visual acuity. Corrective (non-magnifying) non-tinted lenses may be worn. If the test-piece is defective, replace it.

Transfer the test-piece to air maintained at (37 ± 1) °C.

Table 3 — Schedule for the preparation of the cylindrical test-pieces

Procedure	Time s
End of mixing at	0
Insert the mixed mass into the die cavity, then plunger No. 1 and apply a force of (176 ± 13) N to produce a pressure of (14 ± 1) MPa at	30
Release the force and remove spacer No. 2 at	45
Reapply the force at	50
Re-release the force at	90
Carefully remove excess dental mercury and eject the test-piece at	120

NOTE 1 If the cap (see Figure 5) is not present in the assembled apparatus and plunger No. 1 has circumferential datum lines scribed on its cylindrical surface, the test-piece will have a length that is (8 ± 1) mm if the 13 mm datum line alone can be seen.

NOTE 2 If the cap (see Figure 5) is present in the assembled apparatus and both 11 mm and 13 mm datum lines can be seen but the 9 mm line cannot, the test-piece will have a length that is (8 ± 1) mm.

6.5.5 Procedure for the determination of creep

6.5.5.1 Apparatus

6.5.5.1.1 Instrument for determining creep, to apply and sustain a compressive stress of (36,0 ± 0,2) MPa continuously for a period not less than 4 h. The instrument is to maintain the test-piece at a temperature of (37,0 ± 0,5) °C during the test period. The accuracy of the creep measurement shall be 0,01 mm.

NOTE The application of (456,0 ± 2,5) N force to a 4 mm diameter test-piece produces (36,0 ± 0,2) MPa stress.

6.5.5.1.2 Micrometer screw gauge, or similar measuring instrument, with an accuracy of 0,01 mm;

6.5.5.1.3 Air oven, or incubator to maintain a temperature of (37 ± 1) °C.

6.5.5.2 Test-pieces

Make five test-pieces. After ejection from the mould and inspection (see 6.5.4.4), immediately transfer the test-piece to air maintained at (37 ± 1) °C. One hour after the test-piece has been removed from the mould take it from the oven or incubator and measure its length to determine whether this is acceptable (8 ± 1) mm. If it is acceptable, return it to the oven or incubator. If it is not acceptable, reject and replace this test-piece.

Checking acceptability at this time is recommended to avoid a lengthy delay, should it be found to have an unacceptable length when this is measured at 7 d.

Store for (7,0 ± 0,2) d.

A minimum of three test-pieces are tested and for each the creep stress is applied for 4 h. Because the tolerance in time for the application of the creep force is ±0,2 d (i.e. 4,8 h) after 7 d of storage, it will be necessary to stagger the production of test-pieces if fewer than three sets of creep test apparatus are available.

6.5.5.3 Test procedure

At the end of the storage period, remove the test-piece from the oven or incubator and measure the length to the nearest 0,01 mm. Record this as the original length.

Directly after measuring the original length [i.e. at (7,0 ± 0,2) d] apply a compressive force normally and uniformly over the cylinder ends (of the first test-piece) to produce a stress of (36,0 ± 0,2) MPa. This stress is applied continuously for 4 h at a test temperature of (37,0 ± 0,5) °C. Measure the change in length of the test-piece to an accuracy of 0,01 mm between (1,00 ± 0,05) h and (4,0 ± 0,1) h after the force is first applied. Record the new length of the test-piece.

Measure and test two more test-pieces.

If necessary, in accordance with 6.5.5.4, test both the remaining test-pieces.

6.5.5.4 Expression of the results

For each test-piece, calculate the creep strain, ε_c , as a percentage of the original length to the nearest 0,1 %, as follows:

$$\varepsilon_c = \frac{\Delta l}{l_o} \times 100(\%)$$

where

Δl is the change in length between 1 h and 4 h, to an accuracy of 0,01 mm;

l_o is the original length, to an accuracy of 0,01 mm.

If all three results conform to requirement in Table 2, it is not necessary to test the other two test-pieces.

If two or all three test-pieces fail to conform to the requirement in Table 2, the product fails to conform to the requirement for creep. As a consequence, it is not necessary to test the remaining two test-pieces.

If one of the three test-pieces fails to meet the requirement in Table 2, test two more test-pieces.

Test no more than five test-pieces. Record all results.

6.5.5.5 Report

6.5.5.5.1 Test report

A test report shall be prepared. At least the following information shall be included:

a) the name of the dental amalgam alloy product and its lot number;

b) the name and address of the manufacturer;

c) the International Standard used (i.e. ISO 24234:2021);

d) the test method used;

e) any irregularity during test-piece production or testing;

f) results for all test-pieces that were subjected to creep loading (see 6.5.5.4);

g) any unusual features observed;

h) the name and address of the organization responsible for the testing (e.g. test house, university, department of manufacturer);

i) the date of testing.

6.5.5.5.2 Conformity

Report whether the product does or does not conform to the requirement for creep, in accordance with 4.5.2.

6.5.6 Procedure for the determination of dimensional change during hardening

6.5.6.1 Apparatus

6.5.6.1.1 Instrument for measuring the dimensional change during hardening, that does not subject the test-piece to a restraint greater than 20 mN during the test and with which the change in test-piece length can be measured to an accuracy of 0,5 µm.

6.5.6.1.2 Micrometer screw gauge, or similar measuring instrument, with an accuracy of 0,01 mm.

6.5.6.1.3 Air oven or incubator to maintain a temperature of (37 ± 1) °C. This is required only if the test-piece is removed from the apparatus after the initial measurement at 5 min and reinserted at 24 h to make the second measurement.

6.5.6.2 Test-pieces

Make five test-pieces.

6.5.6.3 Test procedure

Place the test-piece in the instrument immediately after its production. Measure the dimensional change that occurs between (5,0 ± 0,1) min and (24,0 ± 0,1) h from the end of mixing, to an accuracy of 0,5 µm. Record this.

Maintain the test-piece at a temperature of (37 ± 1) °C during the 24 h test period.

At (24,0 ± 0,1) h, remove the test-piece from the instrument and measure the test-piece length to an accuracy of 0,01 mm. If the length of the test-piece is not within the specified length, (8 ± 1) mm, reject the result and replace the test-piece. Using this replacement test-piece, repeat the preceding test procedure in 6.5.6.3.

Rejection of a test-piece because its length is inadequate does not constitute a test failure and further replacements are permitted to obtain five test-pieces with acceptable lengths.

Test all five test-pieces.

During the 24 h test period, the test-piece may remain in the measuring instrument and the change in length monitored continuously, or it may be removed from the measuring instrument after the first measurement, held at 37 °C without an applied force then returned to the measuring instrument for the second measurement.

If the test-piece is retained in the measuring instrument for the full test period, it is necessary to complete the test before making the next test-piece.

6.5.6.4 Expression of the results

Calculate the dimensional change during hardening, ε_d , as a percentage of the test-piece length to the nearest 0,01 %, as follows, and record these results:

$$\varepsilon_d = \frac{\Delta l_{\mathrm{d}}}{l_{\mathrm{d}}} \times 100(\%)$$

where

Δl_{d} is the dimensional change between 5 min and 24 h;

l_{d} is the length at 24 h.

6.5.6.5 Report

6.5.6.5.1 Test report

A test report shall be prepared. At least the following information shall be included:

a) the name of the dental amalgam alloy product and its lot number;

b) the name and address of the manufacturer;

c) the International Standard used (i.e. ISO 24234:2021);

d) the test method used;

e) results for all test-pieces (see 6.5.6.4);

f) any irregularity during test-piece production or testing;

g) any unusual features observed;

h) the name and address of the organization responsible for the testing (e.g. test house, university, department of manufacturer);

i) the date of testing.

6.5.6.5.2 Conformity

Report whether the product does or does not conform to the requirement for dimensional change during hardening in accordance with 4.5.3.

6.5.7 Procedure for the determination of compressive fracture stress

6.5.7.1 Apparatus

6.5.7.1.1 Universal mechanical testing machine, configured for compressive testing, with at least 10 kN frame and load cell capacity, and with a resolution and accuracy better that is better than 10 N.

6.5.7.1.2 Micrometer screw gauge, or similar measuring instrument, with an accuracy of 0,01 mm.

6.5.7.1.3 Air oven or incubator, to maintain a temperature of (37 ± 1) °C.

6.5.7.2 Test-pieces

Make 20 test-pieces.

6.5.7.3 Test procedure

6.5.7.3.1 General

Immediately after ejection from the mould, transfer the test-piece to an air environment maintained at (37 ± 1) °C. Store it in this environment until 30 min before it is to have force applied. At this time, remove the test-piece from the oven or incubator and place it on a clean surface in air at (23 ± 2) °C to allow it to cool and equilibrate with the test temperature.

During this equilibration period, measure the diameter of the test-piece to an accuracy of 0,01 mm and record the value. Measure the length to determine whether the length of the test-piece is within the specified length of (8 ± 1) mm. If it is not, reject the test-piece and make a replacement.

Determine the compressive strength using the mechanical testing machine. During the test, maintain the test-piece at a temperature of (23 ± 2) °C. Apply an increasing compressive force normally and uniformly over the circular ends of the test-piece at a constant crosshead speed of (0,5 ± 0,1) mm/min.

For each test-piece, record the force that produces failure and calculate the compressive fracture stress to the nearest 5 MPa.

6.5.7.3.2 Compressive fracture stress at 2 h

Determine the compressive fracture stress of five test-pieces at (120 ± 5) min after mixing.

If only three test-pieces conform to the requirement in Table 2 for compressive fracture stress at 2 h, determine the compressive fracture stress of five more test-pieces.

Test no more than 10 test-pieces at 2 h.

6.5.7.3.3 Compressive fracture stress at 24 h

Determine the compressive fracture stress of five test-pieces at (24 ± 1) h after mixing.

If only three test-pieces conform to the requirement in Table 2 for the compressive fracture stress at 24 h, determine the compressive fracture stress of five more test-pieces.

Test no more than 10 test-pieces at 24 h.

6.5.7.4 Expression of the results

Record the compressive fracture stress for all test-pieces that were loaded to failure.

6.5.7.5 Report

6.5.7.5.1 Test report

A test report shall be prepared. At least the following information shall be included:

a) the name of the dental amalgam alloy product and its lot number;

b) the name and address of the manufacturer;

c) the International Standard used (i.e. ISO 24234:2021);

d) the test method used;

e) results for all test-pieces that were loaded to failure (see 6.5.7.4);

f) any irregularity during test-piece production or testing;

g) any unusual features observed;

h) the name and address of the organization responsible for the testing (e.g. test house, university, department of manufacturer);

i) the date of testing.

6.5.7.5.2 Conformity

Report whether the product does or does not conform to the requirement for compressive fracture stress at 2 h, in accordance with 4.5.4.

Report whether the product does or does not conform to the requirement for compressive fracture stress at 24 h, in accordance with 4.5.5.

6.6 Appearance of the mixed dental amalgam before setting

6.6.1 Principle

Visual inspection is used to determine the appearance of the surface of the mixed dental amalgam, whether a coherent mass exists initially and whether a coherent mass has been maintained during packing.

6.6.2 Apparatus

6.6.2.1 Reusable dental amalgam mixing capsule, that complies with ISO 13897.

6.6.2.2 Dental amalgam mixing machine, that complies with ISO 7448 and recommended by the manufacturer of the dental amalgam alloy product.

6.6.2.3 Glass plate, with an area of at least 50 mm × 50 mm, a thickness of at least 5 mm and having polished surfaces.

d) the test method used;

e) any irregularity in the production of the test-piece;

f) any unusual features observed;

g) the appearance of the surface on the dental amalgam at the end of mixing (see 6.6.3);

h) the whether or not the body of the dental amalgam pellet is coherent at the end of mixing (see 6.6.3);

i) whether or not the body of the amalgam test-piece is coherent at 120 s after the end of mixing (see 6.6.3);

j) the name and address of the organization responsible for the testing. (e.g. test house, university, department of manufacturer);

k) the date of testing.

6.6.5.2 Conformity

Report whether the product does or does not conform to the requirement for the appearance of the mixed dental amalgam before setting, in accordance with 4.6.

6.7 Corrosion resistance of the dental amalgam

6.7.1 Principle

Corrosion produces clinical failure of some dental amalgam restorations. There are a number of corrosion mechanisms, the most important of these for dental amalgam being crevice corrosion. Fortunately, corrosion proceeds at a very slow rate. However, this means that laboratory testing for the resistance to corrosion requires the use of an accelerated test. The accelerated test procedure used in this document simulates crevice corrosion with the effect limited to one surface of a disc shaped test-piece. The resistance to corrosion of the dental amalgam product is determined by the reduction in force to fracture the disc. The protocol for the test and treatment of the results given in ISO 23325 shall be followed.

6.7.2 Sampling

At least 3 g of dental amalgam alloy is required per test-piece. Ten test-pieces are subjected to corrosion and 10 test-pieces are required as controls. If there is an invalid result for a test-piece in either set, retesting is permitted using a replacement test-piece. The number of replacement test-pieces is limited to five in each set. Thus, a minimum of 20 test-pieces are required with a possible additional 10 more. i.e. In total at least 90 g of dental amalgam alloy powder is required. A sufficient number of dental mercury sachets are required, also.

NOTE The mass of mercury in the sachet dictates the number required to mix with the dental amalgam alloy (powder or tablets at the recommended ratio) to obtain a mass of dental amalgam sufficient to fill the mould. It stands to reason that the mass of mercury used, being available in quantum amounts, dictates the mass of dental amalgam alloy powder required for a mix and this can be in excess of 3 g.

6.7.3 Test procedure

All details on the test-piece mould, production of test-pieces, and testing are present in ISO 23325. Use ISO 23325:2020, Clauses 6, 7, 8 and 9 for test-piece production and testing.

6.7.4 Treatment of results

Record all test results. Include any result that has not been accepted with the reason for this rejection.

Calculate and record the mean values for the accepted results for the control test-pieces and for the corrosion test-pieces. Calculate and record the difference between these means, this being the reduction in fracture force resulting from corrosion.

Use the unpaired student *t*-test to determine the level of significance (*p*-value) for the difference between the two sets of values.

Calculate and record the variance for the accepted results of the control test-pieces. Calculate and record the variance for the accepted results of the corrosion test-pieces. Calculate and record the variance ratio (*F*-test statistic). Determine whether the variance ratio is significant. It should not be significant.

Calculate and record the mean value (in newtons) of 10 valid results for corrosion test-pieces as a percentage of the mean value (in newtons) of 10 valid results for control test-pieces.

6.7.5 Report

6.7.5.1 Test report

A test report shall be prepared. At least the following information shall be included:

a) the name of the dental amalgam alloy product and its lot number;

b) the name and address of the manufacturer;

c) the International Standard used (i.e. ISO 24234:2021);

d) the test method used;

e) any irregularities in the test procedure;

f) all test results; including any result that had not been accepted with the reason for this rejection (see 6.7.4);

g) the mean value for the accepted results for the control test-pieces (see 6.7.4);

h) the mean value for the accepted results for the corrosion test-pieces (see 6.7.4);

i) the variance for the control test-pieces (see 6.7.4);

j) the variance for the corrosion test-pieces (see 6.7.4);

k) the variance ratio (*F*-test statistic) and if this is significant (see 6.7.4);

l) the level of significance (*p*-value), obtained using the Student *t*-test, for the difference between the two sets of values (see 6.7.4);

m) the mean value (in newtons) of the 10 valid results for corrosion test-pieces as the percentage of the mean value (in newtons) of the 10 valid results for control test-pieces (see 6.7.4);

n) the name and address of the organization responsible for the testing (e.g. test house, university, department of manufacturer);

o) the date of testing.

6.7.5.2 Conformity

Report whether the product conforms to the requirement for corrosion resistance given in 4.7.

7 Report

If the product conforms to all the requirements in Clause 4 and Clause 8, the product is deemed to have demonstrated conformity to this document, i.e. ISO 24234 . A statement to this effect can be made by the manufacturer of the product in any report on its evaluation. Such a report should also contain the following items of information:

a) the name of the product;

b) the name and address of the manufacturer;

c) the lot number tested;

d) the use by date of this product (if one is given);

e) the International Standard used (i.e. ISO 24234:2021);

f) the name of the organization evaluating the product and the site at which this took place;

g) the date of the evaluation;

h) a statement that the product conforms to this document.

8 Marking and labelling

8.1 Information

8.1.1 General

The information given in 8.1.2 and 8.1.3 shall be present on the surface of the package or included as part of the accompanying printed literature.

8.1.2 Dental amalgam alloy products

a) the type of material and its application;

b) the product's brand- or trade-name;

c) the name and address of the manufacturer or authorized representative in the country of sale;

d) the lot number;

e) the mass of dental amalgam alloy in a package;

f) whether the powder is free-flowing or compacted into tablets;

g) if appropriate, the mass of one tablet to an accuracy of 5 mg;

h) a general description of the dental amalgam alloy particle shape(s);

i) a list of those elements present in the dental amalgam alloy in concentrations greater than a mass fraction of 0,1 %; if an element is present in greater than a mass fraction of 0,5 %, its mass fraction percentage shall also be listed to the nearest percentage point;

j) for a free-flowing powder, the nominal recommended dental amalgam alloy: dental mercury ratio (by mass);

k) for dental amalgam alloy tablets the nominal recommended mass of dental mercury for one tablet and the nominal recommended ratio for dental amalgam alloy: dental mercury ratio (by mass).

8.1.3 Dental mercury

a) the type of material (dental mercury) and its application;

b) the product's brand- or trade-name;

c) the name and address of the manufacturer or authorized representative in the country of sale;

d) the lot number;

e) the mass of dental mercury in one sachet;

f) the mass of dental mercury in one container;

g) a recommendation to store at a temperature no higher than 28 °C;

h) those pictographs, hazard statements and signal words that are applicable to elemental mercury and that are mandatory on package inserts (or on accompanying literature) for the country in which the product is marketed. This shall be in accordance with the "Globally Harmonized System of Classification and Labeling of Chemicals" (GHS) (United Nations).

8.2 Labelling for a package containing dental mercury

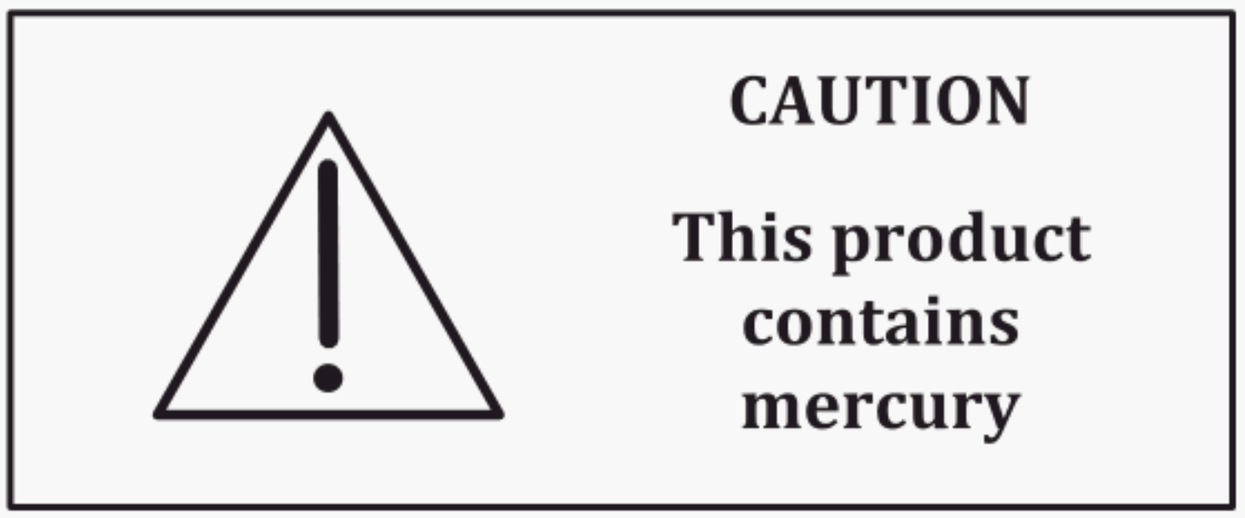


Figure 6 — Cautionary label — ISO 7000-0434A modified

Mark with the label given in Figure 6. The general warning symbol and informative text shall comply with the requirements of ISO 3864-2 and the meaning of the symbol (number 5.4.4) in ISO 15223-1:2016 presented as follows:

a) an exclamation mark within a triangle shall be printed in black on a white background;

b) the text "CAUTION This product contains mercury" shall be printed in black;

c) The outline of the box containing this cautionary symbol and text shall be printed in black.

This labelling requirement is intended to advise the user to consult the accompanying documents for important safety-related information. In this instance, it is the precautionary notes contained in the manufacturer's instructions (see 8.5).

8.3 Labelling of the outer surface of package or container used for shipping dental mercury

For shipment, the container or outside packaging in which the package is placed shall be marked in accordance with the *UN Model Regulations on the Transport of Dangerous Goods.* Pictographs and additional safety information shall be applied that are appropriate for a manufactured product that contains mercury (UN Substance 3506).

NOTE 1 Whereas 8.2 is information intended for the user, 8.3 is intended for shippers.

NOTE 2 In addition to this, labelling in accordance with the requirement(s) for shipping mercury-added products in the country or countries in which it is shipped or trans-shipped can be mandatory.

8.4 Manufacturer's instructions

Printed instructions shall accompany each package and shall include at least the following information:

a) specified brand and model number or name of at least one mixing-machine for dental amalgam complying with ISO 7488 that is recommended;

b) the machine setting(s) and the time required for the mixing of a capsule of dental amalgam using this mixing-machine, as specified in 8.4 a);

c) specified brand or name of at least one reusable mixing-capsule for dental amalgam complying with ISO 13897 that is recommended for mixing the product and any accessory (e.g. pestle) that is required;

d) a description of the initial characteristics of a correctly-mixed dental amalgam, such as the initial appearance (reflectivity), texture and coherence;

e) the edition number of the manufacturer's instructions and information provided (i.e. 8.1) with the date this edition was introduced.

8.5 Precautionary notes

The manufacturer's printed instructions shall contain the following precautionary notes.

a) Effect of mercury on metals: "Mercury reacts with and embrittles particular metals and their alloys. Avoid unnecessary contact between mercury and those metals (and their alloys)".

b) Moisture contamination: "If moisture is introduced into the dental amalgam before it has set, properties such as strength and corrosion resistance can be affected adversely. If the dental amalgam alloy contains zinc, such contamination can result in an excessive expansion (delayed expansion). Use a dry field, whenever it is possible".

c) Waste disposal of dental mercury sachets: "Used dental mercury sachets shall be disposed of following appropriate management practice".

Bibliography

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[3] ISO/TS 17988, *Dentistry — Corrosion test methods for dental amalgam*

[4] ISO/TS 20746, *Dentistry — Determination of the strength of dental amalgam by the Hertzian indentation strength (HIT) method*

[5] ISO 20749, *Dentistry — Pre-capsulated dental amalgam*

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