INTERNATIONAL STANDARD

ISO 20749

Second edition
2023-06

Dentistry — Pre-capsulated dental amalgam

Médecine bucco-dentaire — Amalgame dentaire en capsules prédosées

Reference number
ISO 20749:2023(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

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 document 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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 20749:2017), which has been technically revised.

The main changes are as follows:

— a requirement for corrosion resistance has been added;

— the roughness measure 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 abrade lightly the ends of the cylindrical test pieces, if required, for removing flash has been deleted;

— the requirement for early compression fracture stress has been altered; measurement of the value is made at 2 h and not at 1 h;

— the thickness of the sheet specified for the mould to test for the consistency of dental amalgam from capsule to capsule has been reduced to 2,5 mm;

— a 20 min cooling time before weighing has been added for the determination of the yield of dental amalgam from a capsule;

— additional 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 explains the method adopted;

— for each test method used to determine conformity to a requirement, a new subclause, "Report", has been added;

— a new Clause 7, "Report", has been added which provides details of the evaluation that are to accompany a statement 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

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

Dentistry — Pre-capsulated dental amalgam

1 Scope

This document specifies the requirements and test methods for dental amalgam products supplied to the user in capsules, pre-dosed with dental amalgam alloy powder and dental mercury in quantities suitable for the creation of a single dental restoration.

This document specifies the requirements and test methods for the capsule and the requirements for packaging and marking.

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 is restricted to dental amalgam products marketed in pre-capsulated form, alone. Other products intended for use in the production of dental amalgam restorations (dental amalgam alloy as a free-flowing powder supplied in bulk masses, dental amalgam alloy powder supplied as compressed tablets and dental mercury sachets) are described in ISO 24234.

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 6344-3, *Coated abrasives — Determination and designation of grain size distribution — Part 3: Microgrit sizes P240 to P5000*

ISO 21920-2, *Geometrical product specifications (GPS) — Surface texture: Profile — Part 2: Terms, definitions and surface texture parameters*

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

ISO 15223-1:2021, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements*

ISO 23325:2020, *Dentistry — Corrosion resistance of dental amalgam*

Globally Harmonized System of Classification and Labelling of Chemicals (GHS). United Nations, New York and Geneva, 9th Revised Edition, 2021, eISBN 978-92-1-005213-9

Recommendations on the Transport of Dangerous Goods, Model Regulations. United Nations, New York and Geneva, 22st Edition (Vol.1), 2022, eISBN 978-92-1-005219-1

3 Terms and definitions

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

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
dental amalgam alloy
alloy in fine particles, composed mainly of silver, tin and copper, which when mixed with *dental mercury* (3.2) produces a dental amalgam for dental restoration

[SOURCE: ISO 24234:2021, 3.1]

3.2
dental mercury
mercury supplied for use in the preparation of dental amalgam

[SOURCE: ISO 24234:2021, 3.2]

3.3
pre-capsulated product
product supplied in a sealed capsule that contains measured amounts of *dental amalgam alloy* (3.1) powder and *dental mercury* (3.2) with masses that are appropriate for the production of a mass of dental amalgam that is considered to be suitable for a single small or medium size restoration in a single tooth

Note 1 to entry: The dental amalgam alloy powder and dental mercury are separated by a barrier that is broken immediately prior to mixing, allowing their contact. The capsule remains sealed until mixing has been completed.

[SOURCE: ISO 24234:2021, 3.3]

3.4
self-activating capsule
pre-capsulated product (3.3) capsule in which contact between the *dental amalgam alloy* (3.1) powder and the *dental mercury* (3.2) occurs automatically during mixing

3.5
mechanically-activated capsule
pre-capsulated product (3.3) capsule in which force is applied to the ends of the capsule to rupture the barrier between the *dental amalgam alloy* (3.1) powder and the *dental mercury* (3.2) for *activation* (3.6), before placing the capsule in the mechanical mixing machine

3.6
activation
action that renders the capsulated *dental amalgam alloy* (3.1) powder and *dental mercury* (3.2) mixable

3.7
dental amalgam pellet
coherent mass of dental amalgam that is produced by mixing and either drops from the opened and upended capsule, or is dislodged from the same when the rim of the open capsule is tapped lightly on a hard surface

3.8
mixing machine for dental amalgam
DEPRECATED: amalgamator
electrically-powered mixing machine that operates using an oscillating action for mixing *dental amalgam alloy* (3.1) powder and *dental mercury* (3.2) (in a capsule) to produce a dental amalgam

[SOURCE: ISO 24234:2021, 3.6, modified — the word "powder" has been added in the definition.]

4 Requirements

4.1 Package and capsule contamination

The interior of the packaging container and the outer surface of the capsules shall be free of both dental mercury and dental amalgam alloy powder contamination when tested in accordance with 6.1.

4.2 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 6.2.

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

4.3 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 %.

4.4 Loss of mass from the capsule during mixing

When conformity to this requirement is determined in accordance with 6.4, the mean loss in mass of dental mercury and dental amalgam alloy powder from a capsule (for the sample of 15 capsules), during mixing in accordance with the manufacturer's instructions, shall not exceed 0,5 mg.

Also, the loss from any one capsule shall not exceed 1 mg.

4.5 Yield of dental amalgam from the capsule

When conformity to this requirement is determined in accordance with 6.5, the mean mass of the pellet of dental amalgam obtained from a capsule (for the sample of 15 capsules) shall not be less than 95,0 %

of the sum of the manufacturer's stated masses for dental mercury and dental amalgam alloy powder in the capsule.

Also, no capsule shall yield a pellet of dental amalgam that is less than 90,0 % of the sum of the manufacturer's stated masses for dental mercury and dental amalgam alloy powder in the capsule.

There can be some small free pieces of dental amalgam as well as the pellet. These are available for use and are regarded as part of the yield, i.e. their mass should be added to that of the pellet.

4.6 Consistency of the dental amalgam from capsule to capsule

When conformity to this requirement is determined in accordance with 6.6, the mean value for the hardness of dental amalgam produced from the content of any one capsule shall not be less than 85 % of the overall mean value of the hardness of the dental amalgam obtained from a sample of 10 capsules.

The content of one capsule is used to make one test piece only.

The mean value for the hardness of a test piece is calculated from all measurements made on that test piece. The overall mean value for hardness is calculated from all measurements made on all 10 test pieces.

4.7 Properties of the dental amalgam

4.7.1 General

The following properties are required, regarding creep, dimensional change during hardening and compressive fracture stress.

Table 2 — Properties of the dental amalgam

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

4.7.2 Creep

When conformity to this requirement is determined in accordance with 6.7, the results for either three out of three or four out of five test pieces shall meet the requirement in Table 2.

4.7.3 Dimensional changes during hardening

When conformity to this requirement is determined in accordance with 6.7, the results for at least four out of five test pieces shall meet the requirement in Table 2.

4.7.4 Compressive fracture stress at 2 h

When conformity to this requirement is determined in accordance with 6.7, 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.

4.7.5 Compressive fracture stress at 24 h

When conformity to this requirement is determined in accordance with 6.7, 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.

4.8 Appearance of mixed dental amalgam before setting

When conformity to this requirement is determined in accordance with 6.8, 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.

4.9 Corrosion resistance of the dental amalgam

When conformity to this requirement is determined in accordance with 6.9, 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.

4.10 Length tolerance for the capsule

When conformity to this requirement is determined in accordance with 6.10, the overall length of the activated capsule shall be within ±1 mm of the length specified by the manufacturer. All 10 capsules in the sample tested shall meet the requirement.

5 Sampling

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

Procure a sufficient number of capsules to conduct all the testing needed to evaluate the alloy, the capsules and to make the required number of dental amalgam test pieces, including the maximum number of test pieces allowed to replace any that are rejected.

NOTE The number of capsules required depends on the masses of dental amalgam alloy powder and dental mercury in each.

6 Test methods

6.1 Package and capsule contamination

6.1.1 Principle

Any loss of either component from a capsule between production and receipt by the user is of concern. Such a loss can be detected by visual examination of capsule and container surfaces at low power magnification.

6.1.2 Test sample

All the containers holding capsules from the sample procured for testing the product for conformity to all other requirements, as well as 25 capsules selected at random from the same sample.

6.1.3 Apparatus

Stereomicroscope, ×10 magnification.

6.1.4 Procedure

Using the stereomicroscope, inspect the interior surfaces of all the containers holding capsules and the external surfaces of the 25 capsules. Examine these for traces of dental amalgam alloy powder and visible beads of dental mercury.

6.1.5 Treatment of the results

Record the observations.

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

b) name and address of the manufacturer;

c) the International Standard used (i.e. ISO 20749:2023);

d) the test method used;

e) any irregularities in the test procedure;

f) if contamination is seen on the surface of a container, report this and the number of containers that were contaminated;

g) if it is the capsule surface that is contaminated, report this and the number of capsules that were contaminated;

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

i) date of testing.

6.1.6.2 Conformity

Report whether the product does or does not conform to the requirement for package and capsule freedom from contamination, in accordance with 4.1.

6.2 Chemical composition and purity of the dental amalgam alloy

6.2.1 Principle

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

6.2.2 Test sample

Extract the dental amalgam alloy powder from one capsule selected at random. This sample should not be contaminated with the dental mercury during extraction from the capsule.

6.2.3 Apparatus

Recognized, instrumented analytical instrument, with a sensitivity adequate to determine the composition of the dental amalgam alloy for each of the elements declared by the manufacturer in compliance with 4.2.

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

6.2.4 Procedure

Determine the composition of the dental amalgam alloy for the elements declared by the manufacturer in compliance with 4.2. Other elements can be detected during the analysis, being undeclared or impurities. Determine the concentration of each of these as a mass fraction (percentage).

6.2.5 Treatment of the results

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

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 4.2), 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 and detected in a concentration greater than a mass fraction of 0,1 %, record this value and the name of the element.

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

b) name and address of the manufacturer;

c) the International Standard used (i.e. ISO 20749:2023);

d) the analytical method used;

e) any irregularities in the test procedure;

f) mass fraction (percentages) for those elements that are alloying elements according to Table 1 and declared as such by the manufacturer (see 6.2.5);

g) if any other element is declared by the manufacturer as an alloying element, report this and its mass fraction as a percentage (see 6.2.5);

h) each undeclared element found in a concentration greater than a mass fraction of 0,1 % by name and the mass fraction as a percentage (see 6.2.5);

i) sum of the mass fractions (percentages) of undeclared elements present in concentrations greater than mass fractions of 0,01 % (see 6.2.5);

j) any unusual features observed;

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

l) date of testing.

6.2.6.2 Conformity

Report whether the product does or does not conform to the requirement for composition and purity of the dental amalgam alloy in accordance with 4.2.

6.3 Large particles in the dental amalgam alloy powder

6.3.1 Principle

Large 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

Select and open a sufficient number of capsules to obtain a (10,0 ± 0,1) g sample of dental amalgam alloy powder. This sample should not be contaminated with the dental mercury during extraction from the capsules.

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.

6.3.4 Procedure

Weigh the (10 ± 0,1) g test sample to an accuracy of 1 mg and record this mass as m_P.

Place the sample on the sieve. Hold the sieve assembly (consisting of a collecting pan, sieve and cover) in one hand and tap it gently against the other hand at a rate of approximately two times per second for 120 s. Use the stereomicroscope to inspect the sieve for any large dental amalgam alloy particles. If any are present, pick these up with the tweezers and place them on the weighing boat. Weigh this to obtain the mass of the dental amalgam alloy particles to an accuracy of 1 mg. Record this mass as m_r.

6.3.5 Treatment 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, expressed in grams;

m_p is the mass of the powder sample, expressed in grams.

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

b) name and address of the manufacturer;

c) the International Standard used (i.e. ISO 20749:2023);

d) the test method used;

e) any irregularities in the test procedure;

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

g) any unusual features observed;

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

i) date of testing.

6.3.6.2 Conformity

Report whether the product does or does not conform to the requirement for the limit to the mass fraction percentage of large particles in accordance with 4.3.

6.4 Loss of mass from the capsule during mixing

6.4.1 Principle

The loss of content from the capsule during mixing is determined by weighing it initially and again after mixing. Testing a number of capsules is required because the amount lost can vary from capsule to capsule.

6.4.2 Test sample

Select 15 capsules at random.

6.4.3 Apparatus

6.4.3.1 Mechanical mixing machine for dental amalgam, that is recommended by the manufacturer of the dental amalgam product and which conforms to ISO 7488.

6.4.3.2 Weighing boat, or similar (15 are required).

6.4.3.3 Chemical balance having an accuracy and resolution of 0,1 mg.

6.4.3.4 Surgical gloves, latex or similar, powder-free.

6.4.3.5 Stereomicroscope, ×10 magnification.

6.4.4 Test procedure

At all times, wear the surgical gloves when handling the capsules to avoid contaminating the surface.

Take the first capsule and blow oil-free compressed air over the surface to remove any adhering powder and dust.

Although, according to 4.1, the surface should be free from contamination, it is a good laboratory practice to do this.

Use the stereomicroscope to inspect the surface of the capsule for any remaining contaminant and for any attached moulding flash. If either is present, remove it. Then inspect the surface of the capsule for blemishes. If any blemishes are present, note these.

Place the capsule in the weighing boat and record their combined masses (m_s). This and all subsequent weighings shall be accurate to 0,1 mg.

Taking care not to score the plastic, place the weighed capsule in the mechanical mixing machine.

NOTE Sharp edges on the metal fork (or similar device) that holds the capsule in the mechanical mixing machine can cut small amounts of plastic from the capsule when the necessary force is applied to seat the capsule. Such a loss can affect the result.

Mix using the setting on the mechanical mixing machine and mixing time recommended by the manufacturer for the combined mass of dental amalgam alloy powder and dental mercury (in the capsule) that is being mixed [see 8.4 b)].

Once again taking care not to score its surface, remove the capsule from the mechanical mixing machine. Use the stereomicroscope to inspect the surface for any marks that can be produced when the capsule was placed in or removed from the mechanical mixing machine. If any are seen, note these.

Place the capsule in the weighing boat and leave at ambient temperature for 20 min. (The mixing process generates heat which affects the weighing at the accuracy required, if the temperature of the capsule is above ambient temperature.) It is necessary to let the temperature of the capsule equilibrate with the ambient temperature before it is reweighed.

Reweigh the capsule and weighing boat (m_m).

Repeat this procedure for the 14 other capsules and record all results.

6.4.5 Treatment of the results

Tabulate the results.

The loss of dental mercury and amalgam alloy powder during mixing (m_l), expressed in grams is:

$$m_l = (m_s - m_m)$$

where

m_s is the mass of the sealed capsule (and weighing boat) before mixing, expressed in grams;

m_m is the mass of the sealed capsule (and weighing boat) after mixing, expressed in grams.

If the loss in mass m_l is 0,5 mg or more, examine the record to ascertain whether scoring or other markings had been introduced onto the capsule surface when it was put into or taken from the mechanical mixing machine. Reject the result if such scoring is present. Record this rejection. Take a replacement capsule and test it using the procedure in 6.4.4. Record this result.

Calculate the mean value of m_l for the losses from all 15 capsules and record this.

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

b) name and address of the manufacturer;

c) the International Standard used (i.e. ISO 20749:2023);

d) the test method used;

e) any irregularities in the test procedure;

f) the loss of mass from each of the 15 accepted capsules (each to 0,1 mg) (see 6.4.5);

g) the mean value for the loss of mass from the 15 accepted capsules (to 0,1 mg) (see 6.4.5);

h) any rejected result and give the reason for rejection (see 6.4.5);

i) any unusual features observed;

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

k) date of testing.

6.4.6.2 Conformity

Report whether the product does or does not conform to the requirement for the loss of mass from the capsule during mixing, in accordance with 4.4.

6.5 Yield of amalgam from the capsule

6.5.1 Principle

The yield of usable dental amalgam is determined by weighing the dental amalgam pellet. The amount can vary from capsule to capsule. For this reason, testing a number of capsules is required.

NOTE The dental professional is interested in the dental amalgam that is released by the capsule after mixing, i.e. the pellet. This will have a mass less than the stated summed masses of dental mercury and dental amalgam alloy powder in the capsule if there is a loss during mixing or retention in the capsule on emptying it.

6.5.2 Test sample

Select 15 capsules at random.

6.5.3 Apparatus

6.5.3.1 Mechanical mixing machine for dental amalgam, that is recommended by the manufacturer of the dental amalgam product and which conforms to ISO 7488.

6.5.3.2 Weighing boat or similar (15 are required).

6.5.3.3 Chemical balance having an accuracy and resolution of 0,1 mg.

6.5.3.4 Tweezers, stainless steel.

6.5.4 Test procedure

All weighings shall be accurate to 0,1 mg and recorded.

Weigh one weighing boat (m_w).

Use the mechanical mixing machine setting and mixing time that are recommended by the manufacturer for the combined mass of dental amalgam alloy and dental mercury (in the capsule) that is being mixed [see 8.4 b)]. Place the first capsule in the mechanical mixing machine and mix its contents.

Immediately after mixing, open the capsule and empty the amalgam pellet onto the weighing boat. If necessary, use the tweezers to dislodge any small piece of dental amalgam lightly adhering to the capsule. Inspect the pellet for any material from the sachet or membrane. Remove this using the tweezers. (It can be necessary to break-up the pellet to do this.) Similarly, remove the pestle, if one is present. Leave for 20 min to let the temperature of the dental amalgam equilibrate with the ambient temperature. Weigh the weighing boat and the dental amalgam collected on it (m_a).

NOTE A plastic membrane or plastic sachet is used to separate the dental mercury from the dental amalgam alloy powder in the capsule. It is ruptured on activation.

Repeat this procedure for the 14 other capsules.

6.5.5 Treatment of the results

Tabulate the results.

The yield of dental amalgam from the capsule (m_y), expressed in grams, is:

$$m_y = (m_a - m_w)$$

where

m_a is the mass of the weighing boat and collected amalgam, expressed in grams;

m_w is the mass of the weighing boat, expressed in grams.

Use m_y and the sum of the masses of dental amalgam alloy powder and dental mercury in a capsule, declared by the manufacturer in accordance with 8.1 e) and 8.1 f) to calculate the yield of amalgam as a percentage.

6.5.6 Report

6.5.6.1 Test report

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

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

b) name and address of the manufacturer;

c) the International Standard used (i.e. ISO 20749:2023);

d) the test method used;

e) any irregularities in the test procedure;

f) the results for the yield of amalgam from each of the 15 capsules tested (each to 0,1 mg) (see 6.5.5);

g) each of these masses converted to a percentage of the sum of the masses of dental amalgam alloy powder and dental mercury (in a capsule) as declared by the manufacturer in accordance with 8.1 e) and 8.1 f) (see 6.5.5);

h) if seen, any excessive inclusion of remnants of the membrane or sachet (i.e. the separating barrier) in the dental amalgam pellet;

i) any unusual features observed;

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

k) date of testing.

6.5.6.2 Conformity

Report whether the product does or does not conform to the requirement for the yield of dental amalgam from the capsule in accordance with 4.5.

6.6 Consistency of the dental amalgam from capsule to capsule

6.6.1 Principle

Small variations in the masses of dental amalgam alloy powder and dental mercury occur when these are dispensed into the capsule during production. When acceptable production tolerances are applied, the variation in this ratio can lead to a significant variation in properties, particularly when the extremes (of the tolerances) coincide. The consequence of the variation in the ratio within the production tolerances accepted by the manufacturer is determined by measuring the hardness (using a pyramidal diamond microhardness test) on a set of dental amalgam test pieces. This property is chosen because it is suitable for testing dental amalgam from a single capsule.

6.6.2 Test sample

Select 10 capsules at random to produce 10 test pieces.

6.6.3 Apparatus

6.6.3.1 Items of equipment

6.6.3.1.1 Mould. An example of a suitable mould is shown in Figure 1.

6.6.3.1.2 Glass plate, with a scratch-free polished surface, approximately 75 mm × 75 mm.

6.6.3.1.3 Glass microscope slide.

6.6.3.1.4 Hand-instrument for amalgam packing, with an end surface (smooth or serrated) that is appropriate for the product being tested and that is slightly less than 4 mm in diameter.

6.6.3.1.5 Microhardness test instrument with a pyramidal diamond indenter, Vickers or Knoop.

6.6.3.1.6 Air oven, or incubator maintained at (37 ± 2) °C.

6.6.3.1.7 Mechanical mixing machine for dental amalgam, that is recommended by the manufacturer of the dental amalgam product and which conforms to ISO 7488.

6.6.3.1.8 Coated abrasive that conforms to microgrit size P1200, in accordance with ISO 6344-3.

6.6.3.2 Materials and tolerances of the mould

Make the mould of poly(methyl methacrylate) or polycarbonate sheet that is 2,5 mm thick. Drill 10 holes that are 4,0 mm in diameter, spaced no closer than 10 mm to each other. An example of a suitable mould is shown in Figure 1.

It is permissible to produce the mould using 3,0 mm thick sheet provided the yield from the capsule is sufficient to overfill the cylindrical hole into which the dental amalgam is packed, according to 6.6.5.

NOTE This simple and low-cost mould can be considered to be consumable.

For convenience, to readily distinguish the two surfaces during test piece production and hardness measurement, an identification mark on one of the mould faces is recommended.

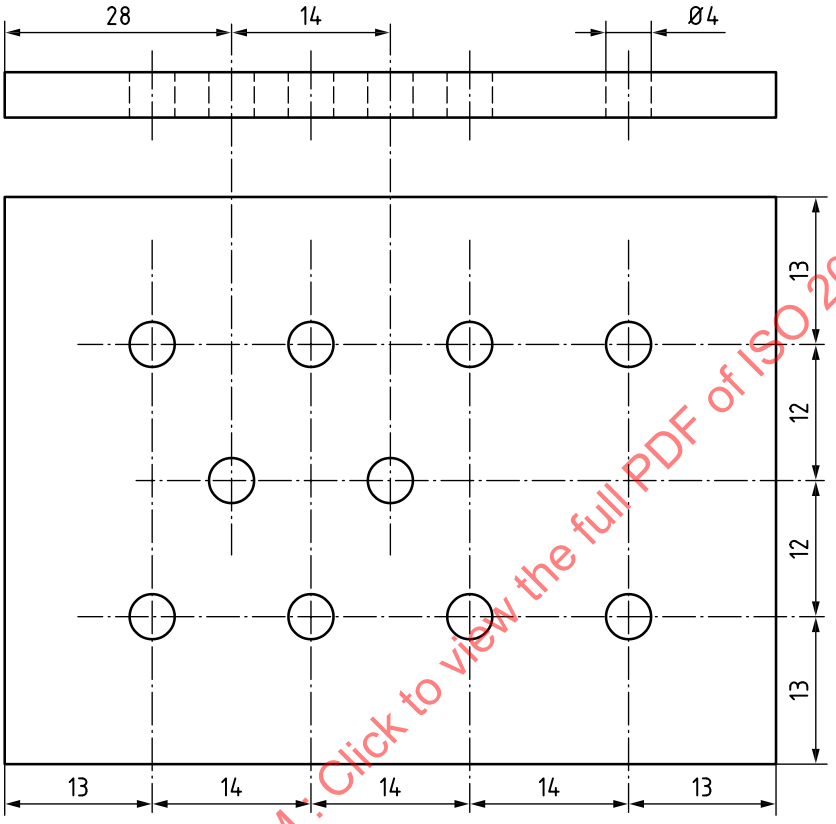
6.6.4 Test piece production

Produce the test pieces at (23 ± 2) °C.

Produce a total of 10 test pieces using the procedure set out in 6.6.5.

NOTE A test piece is the amalgam that is packed in one of the holes in this mould.

Dimensions in millimetres



NOTE 1 The tolerance for all dimensions is ±0,1 mm.

NOTE 2 All 10 holes are 4,0 mm in diameter.

Figure 1 — Mould that is suitable for the production of test pieces for microhardness measurements

6.6.5 Procedure

Place the mould on the glass plate.

Use the setting on the mechanical mixing machine and mixing time that are recommended by the manufacturer for the combined mass of dental amalgam alloy powder and dental mercury (in the capsule) that is being mixed [see 8.4 b)]. Place a capsule in the mechanical mixing machine and mix.

Using the hand instrument (for amalgam packing), pack the dental amalgam from this capsule into one of the holes in the mould. Use a consistent packing force and efficient packing technique. Overfill it slightly. Carve back using the edge of the microscope slide to produce a flat surface (on the dental amalgam) that is level with that of the mould surface. This is the first test piece. Record the time at which it was made.

Repeat this procedure, packing amalgam from the other nine capsules into each of the other nine holes to produce a total of 10 test pieces. (Dental amalgam from one capsule only is to be used to fill a hole to make a test piece.) For each test piece, record the time at which it is made. For all test pieces the same

surface of the mould should be placed in contact with the glass plate during production. The surface of the amalgam test piece formed in contact with the glass plate is the “test surface”, being the surface on which microhardness indentations will be made.

Immediately after the tenth test piece has been made, place the mould in the air oven or incubator that is maintained at (37 ± 2) °C and store for (23 ± 1) h.

If a mould of the type shown in Figure 1 is used, all test pieces are contained in this single mould and are made over a period of time. Because this mould is put in the oven when the last test piece has been made and held there for (23 ± 1) h, ensure that the period of time over which the 10 test pieces are made results in ageing of both the first and the tenth test piece that complies to the ageing time. Thus, there should be the minimum of delay between packing each test piece.

At the end of the storage period, remove the mould from the oven. The formation of a test surface with an orange-peel appearance at a microscopic level is a consequence of the setting reaction and this makes the definition of the hardness indentation less clear. To form a surface suitable for microhardness measurement, gently rub the test surface (i.e. of the mould and the 10 test pieces it contains) on coated abrasive that complies with microgrit size P1200, in accordance with ISO 6344-3. Use a copious flow of cold water as a coolant and lubricant, together with a light pressure. The required surface is flat with very fine parallel scratches. Inspect the surface between passes until this is created. (Such a surface can be achieved, usually, with just four or five passes.)

Blow compressed air on the test surface to dry it. For the time remaining before hardness measurement, place the mould on the bench with the test surface upwards and allow 20 min for the test piece to equilibrate with the ambient test temperature [(23 ± 2) °C].

6.6.6 Microhardness measurement

At (24 ± 1) h, measure the microhardness on the test surface for each of the 10 test pieces.

Make these measurements at a room temperature of (23 ± 2) °C.

Use a load that will produce an indentation that, when measured to the accuracy of the instrument, will differentiate between dental amalgam test pieces for which the hardness differs by 50 MPa. Use the same load for all test pieces. Use a dwell time that is consistent.

For example, for the Vickers Hardness of dental amalgam at 24 h, an applied load between 5 N (0,5 kgf) and 10 N (1 kgf) is suitable and recommended. Such loads produce indentations with diagonal lengths between 80 µm and 120 µm, depending on the product and applied load. A 50 MPa difference in Vickers Hardness value results in a difference in the indentation diagonal length of between 1 µm and 3 µm. Thus, an instrument with a measurement accuracy of 0,1 µm is recommended.

Make 10 hardness indentations on the test surface (of each test piece). These should be sited no closer than five indentation diameters to each other and to the edge of the test piece. Depending on the instrument being used, it can be necessary to measure the diagonal lengths of the pyramidal indentation manually and from the loading force calculate the hardness value. An automated instrument will give the hardness value directly. The hardness value shall be given in SI units, GPa or MPa, and to an accuracy of 50 MPa.

NOTE Traditionally, hardness has been reported with metric units, kg/mm^2. In ISO standards the SI system has been adopted and is to be used. To convert the hardness value from the traditional metric value to one that has MPa units, that value is multiplied by 9,81.

6.6.7 Treatment of the results

Tabulate the hardness values for all 10 measurements on each test piece. Calculate the test piece mean value for each of the 10 test pieces. Calculate the overall mean value for all 100 measurements. Calculate the value that is 85 % of the overall mean value. Compare the test piece mean value of each of the 10 test pieces with this.

6.6.8 Report

6.6.8.1 Test report

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

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

b) name and address of the manufacturer;

c) the International Standard used (i.e. ISO 20749:2023);

d) the microhardness test method used – Vickers or Knoop;

e) any irregularities in the test procedure;

f) for each test piece, the values for all 10 hardness measurements and their mean value ("the test piece mean value") (see 6.6.6);

g) the overall mean hardness value, calculated using all 100 hardness measurements ("the overall mean value") (see 6.6.6);

h) the hardness value that is 85 % of the overall mean value (see 6.6.6);

i) any unusual features observed;

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

k) date of testing.

6.6.8.2 Conformity

Report whether the product does or does not conform to the requirement for the consistency of the dental amalgam from capsule to capsule, in accordance with 4.6.

6.7 Properties of the dental amalgam

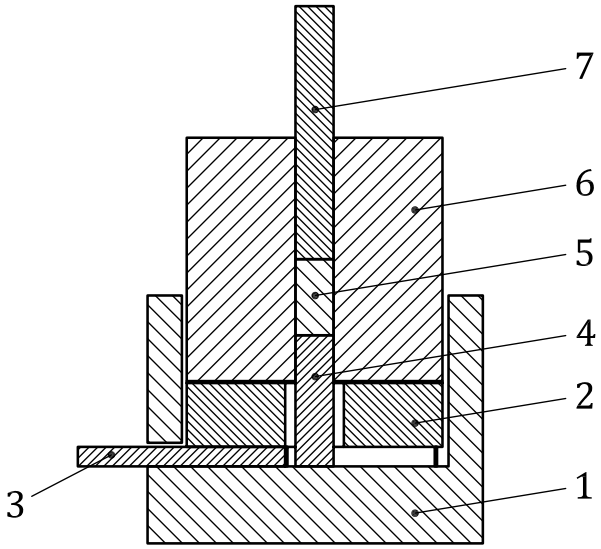
6.7.1 Principle

All three properties for requirement 4.7 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.

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

6.7.2.1 General

The mould and its component parts are shown in Figures 2 to 6.



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.

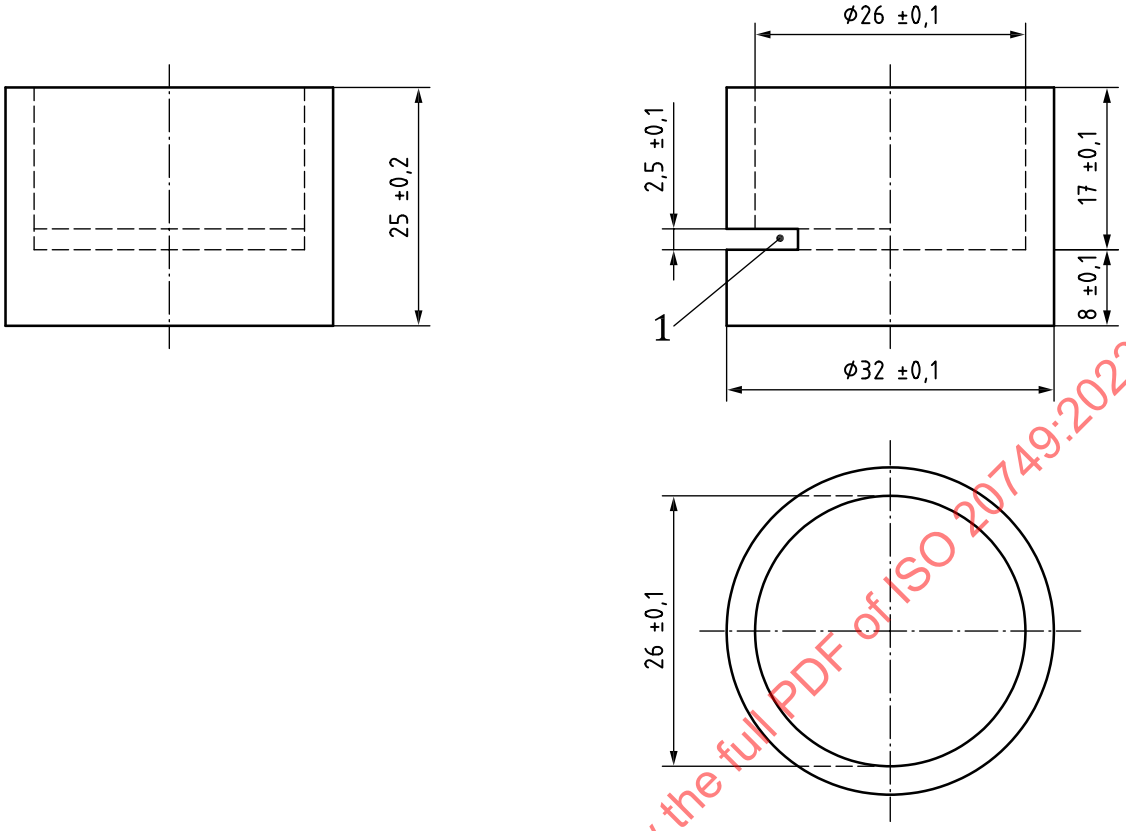
Figure 2 — Vertical section through the mould for making cylindrical dental amalgam test pieces, showing the assembled mould with a test piece in place

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 can 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 and cap 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 or cap 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 or cap shall be between 3,982 mm and 4,000 mm.

The diameter of the hole in the die shall be subject to a clearance (with a tolerance) of F7 in accordance with 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.

Dimensions in millimetres

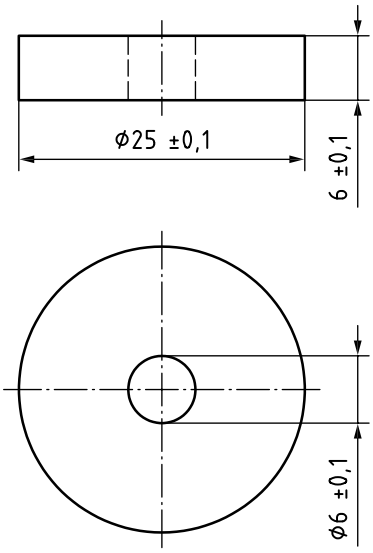


Key

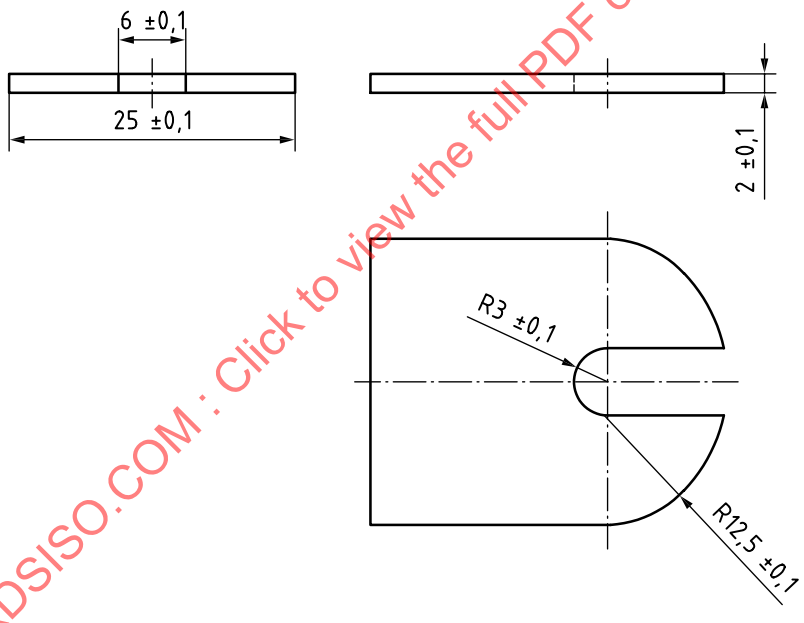
1 slot

Figure 3 — Holder

Dimensions in millimetres



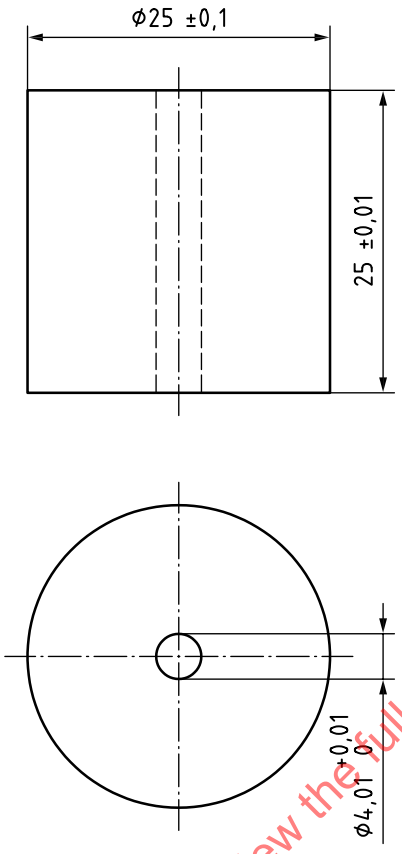
a) Spacer no. 1



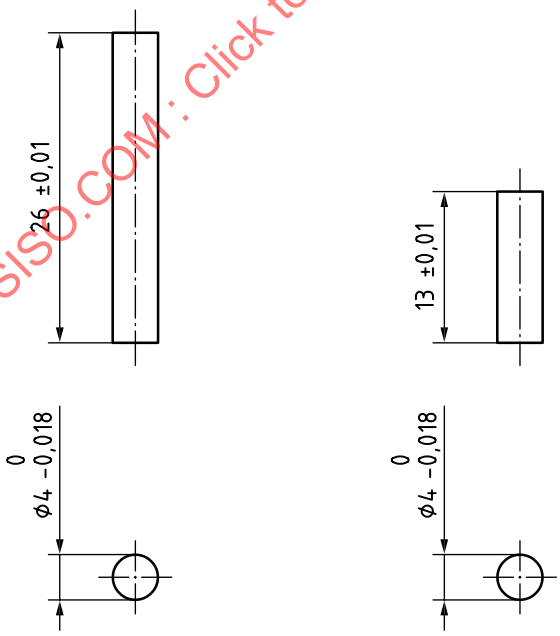
b) Spacer no. 2

Figure 4 — Spacers

Dimensions in millimetres



a) Die



b) Plunger no. 1 (left) and plunger no. 2 (right)

Figure 5 — Die and plungers

Dimensions in millimetres

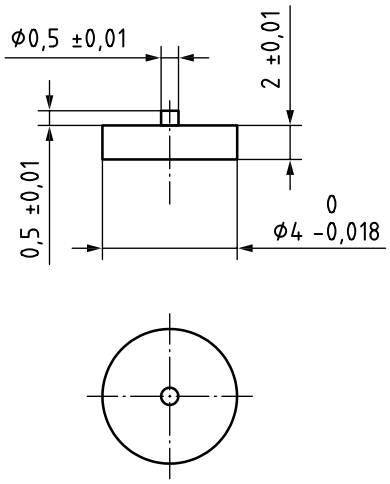


Figure 6 — Cap required for the production of test pieces used for the measurement of dimensional change during hardening

6.7.2.2 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 21920-2.

6.7.2.3 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 2. 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) can require an impression on the end surface of the test piece. It is produced by the cap that is shown in Figure 6. 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 which case, position the cap on top of the plunger no. 2.

6.7.3 Test sample

Sufficient number of capsules to produce the required number of test pieces and maximum number of replacement test pieces for each property determination.

6.7.4 Test piece production

6.7.4.1 Temperature

Prepare test pieces at (23 ± 2) °C.

6.7.4.2 Apparatus

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

6.7.4.2.2 **Timer**, with an accuracy and resolution to 1 s.

6.7.4.2.3 **Tweezers**, with pointed ends.

6.7.4.2.4 **Hand-instrument for dental amalgam packing**.

6.7.4.2.5 **Light source**, with an illuminance ≥1 000 lux.

6.7.4.2.6 **Mould**, shown in Figures 2 to 6.

6.7.4.2.7 **Apparatus to apply (176 ± 13) N to the mould plunger no. 1**.

6.7.4.2.8 **Air oven or incubator** set to maintain a temperature of (37 ± 1) °C.

6.7.4.3 Mixing

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 dental amalgam cylinder of 4 mm in diameter and 8 mm in length is approximately 1,2 g.

If the content of more than one capsule is required to make the test piece, mix the content of these capsules simultaneously using equipment of the same type for each capsule. However, if the last mix can be produced within the working time of the first mix, mixing these capsules sequentially on a single piece of equipment is permitted.

Use the setting on the dental amalgam mixing machine and the mixing time (for the combined mass of dental amalgam alloy powder and dental mercury in the capsule) that are recommended by the manufacturer of the product under test [see 8.4 b)].

6.7.4.4 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.

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

If the cap (see Figure 6) 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.

If the cap (see Figure 6) 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.

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 can be worn. If the test piece is defective, replace it.

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

6.7.5 Procedure for the determination of creep

6.7.5.1 Apparatus

6.7.5.1.1 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 to 0,01 mm.

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

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

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

6.7.5.2 Test pieces

Make five test pieces. After ejection from the mould and inspection (see 6.7.4.4) 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, i.e. (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 in air maintained at (37 ± 1) °C.

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 storage, it will be necessary to stagger the production of test pieces if fewer than three sets of creep test apparatus are available.

6.7.5.3 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 6.7.5.4, test both the remaining test pieces.

6.7.5.4 Treatment 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, expressed in millimetres to an accuracy of 0,01 mm;

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

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

If two or all three test pieces fail to meet 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 two remaining 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.

6.7.5.5 Report

6.7.5.5.1 Test report

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

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

b) name and address of the manufacturer;

c) the International Standard used (i.e. ISO 20749:2023);

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 6.7.5.4);

g) any unusual features observed;

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

i) date of testing.

6.7.5.5.2 Conformity

Report whether the product does or does not conform to the requirement for creep, in accordance with 4.7.2.

6.7.6 Procedure for the determination of dimensional change during hardening

6.7.6.1 Apparatus

6.7.6.1.1 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. The instrument is to maintain the test piece at a temperature of (37,0 ± 0,5) °C during the test period.

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

6.7.6.1.3 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.)

6.7.6.2 Test pieces

Make five test pieces.

6.7.6.3 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, i.e. (8 ± 1) mm, reject the result and replace the test piece. Using this replacement test piece, repeat preceding test procedure in 6.7.6.3.

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 can remain in the measuring instrument and the change in length monitored continuously, or it can 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.

6.7.6.4 Treatment 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 the result:

$$\varepsilon_d = \frac{\Delta l_d}{l_d} \times 100$$

where

Δl_d is the dimensional change between 5 min and 24 h, expressed in millimetres;

l_d is the length at 24 h, expressed in millimetres.

6.7.6.5 Report

6.7.6.5.1 Test report

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

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

b) name and address of the manufacturer;

c) the International Standard used (i.e. ISO 20749:2023);

d) the test method used;

e) any irregularity during test piece production or testing;

f) results for all test pieces (see 6.7.6.4);

g) any unusual features observed;

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

i) date of testing.

6.7.6.5.2 Conformity

Report whether the product does or does not conform to the requirement for dimensional change during hardening in accordance with 4.7.3.

6.7.7 Procedure for the determination of compressive fracture stress

6.7.7.1 Apparatus

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

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

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

6.7.7.2 Test pieces

Make 20 test pieces.

6.7.7.3 Procedure

6.7.7.3.1 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 force is applied to it. 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 for not less than 20 min 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 fracture stress 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.

6.7.7.3.2 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.

6.7.7.3.3 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.

6.7.7.4 Treatment of the results

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

6.7.7.5 Report

6.7.7.5.1 Test report

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

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

b) name and address of the manufacturer;

c) the International Standard used (i.e. ISO 20749:2023);

d) the test method used;

e) any irregularity in the test piece production or testing;

f) results for all test pieces that were loaded to failure (see 6.7.7.4);

g) any unusual features observed;

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

i) date of testing.

6.7.7.5.2 Conformity

Report whether the product does or does not conform to the requirement for compressive fracture stress at 2 h, in accordance with 4.7.4.