INTERNATIONAL STANDARD

ISO 20749

First edition
2017-03

Dentistry — Pre-capsulated dental amalgam

Médecine bucco-dentaire — Amalgame dentaire en capsules prédosées

Reference number
ISO 20749:2017(E)

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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 on 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 the following URL: www.iso.org/iso/foreword.html.

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

Introduction

This is the first edition of this document. Its scope is limited solely to dental amalgam alloy and dental mercury that are supplied pre-capsulated in masses that are sufficient to produce a mass of dental amalgam that is considered to be suitable for a single small or medium size restoration in a single tooth.

Dental amalgam alloy and dental mercury are the essential and only components of dental amalgam restorative material. This document specifies the requirements and the test methods for dental amalgam alloy that is suitable for the preparation of dental amalgam, together with those for the set dental amalgam, those for the capsules themselves and the requirements for packaging and marking.

This document has been developed in response to the UNEP Minamata Convention on Mercury. The objective of the Minamata Convention is to reduce anthropogenic mercury pollution by restricting the use of mercury, products containing mercury and materials that release mercury during use. In this convention, dental amalgam is classified as a "mercury-added product", for which parties to the agreement are to adopt two or more measures from a list of nine. One of these is "restricting the use of dental amalgam to its encapsulated form". In some countries, the term *encapsulated* has been interpreted as the *pre-capsulated* form alone. Given the increased vigilance on the use of dental amalgam products since 2013, when the Minamata Agreement was signed, this document will enable countries that do not allow the use of products other than those that are pre-capsulated to adopt an ISO standard on dental amalgam. Not all of the membership of the UN has signed the Minamata Convention and in non-signatory countries, dental amalgam products outside the scope of this document, but within the scope of ISO 24234, will continue to be marketed. Thus, both standards are required to provide full global coverage for compliance.

Although this document is based on ISO 24234, there have been significant technical changes. Also, the requirements for the capsule that were in ISO 13897 have been transferred to this document, treating a product that falls within the scope as an entity. This document differs technically from ISO 24234 in the following respects:

— The scope of this document is restricted to pre-capsulated products alone.

— A requirement for packaging and capsule to be free from contamination is present.

— The requirement concerning foreign matter in the dental amalgam alloy powder has been removed.

— A requirement for loss of mass from the capsule during mixing has been added.

— A requirement for the yield of dental amalgam from a capsule replaces the requirement for the masses of dental mercury and dental amalgam powder present before mixing.

— A requirement for the consistency in the ratio of dental mercury to dental amalgam alloy powder in capsules has been changed radically. Determination of the effect of variation in this ratio upon properties replaces weighing the dental mercury and the dental amalgam alloy powder.

— Requirements for the capsule have been introduced and revised technically.

A decision was taken not to alter requirements upon which capsulation has no bearing, these being:

— the requirements on chemical composition and purity of the dental amalgam alloy;

— the requirements for the properties of dental amalgam;

— the requirement for the appearance of dental amalgam before setting.

As with ISO 24234, the inclusion of a requirement for corrosion resistance was considered. However, it was agreed that the data available were insufficient to set a corrosion resistance requirement in this edition of this document. A requirement for the corrosion resistance will be set and incorporated at the earliest possible date. It is recommended that in assessing corrosion resistance of a dental amalgam product (relative to other dental amalgam products), reference can be made to ISO/TS 17988.

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 and dental mercury in quantities suitable for the creation of a single dental restoration.

This document specifies the requirements and test methods for dental amalgam alloys that are suitable for the preparation of dental amalgam and the capsule, together with the requirements and test methods for that dental amalgam and the requirements for packaging and marking.

This document is not applicable to dental amalgam alloys supplied as a free-flowing powder in bulk quantities or as powder compressed into tablets, or to dental mercury supplied in sachets or bulk quantities.

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.

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

The scope of 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 within the scope of 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 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 6344-1, *Coated abrasives — Grain size analysis — Part 1: Grain size distribution test*

ISO 7488, *Dental amalgamators*

ISO 13565-2, *Geometrical Product Specifications (GPS) — Surface texture: Profile method; Surfaces having stratified functional properties — Part 2: Height characterization using the linear material ratio curve*

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

Globally Harmonized System of Classification and Labelling of Chemicals (GHS). United Nations, New York and Geneva, 5th Revised Edition, 2013, ISBN 978-92-1-117067-2

UN Recommendations on the Transport of Dangerous Goods, Model Regulations. United Nations, New York and Geneva, 18th Edition, 2013, ISBN 978-92-1-193146-6

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 terminological databases for use in standardization at the following addresses:

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

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

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

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

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* (3.2) are separated by a barrier that is broken immediately prior to mixing to allow their contact. The capsule remains sealed until mixing has been completed.

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

Note 1 to entry: There is another type of design that requires a physical action by the user to rupture the separating barrier for *activation* (3.6) before placing the capsule in the mechanical mixing machine.

3.5
percentage by mass
mass fraction expressed as a percentage

Note 1 to entry: The terminology “mass fraction” is favoured when expressing a composition in which this is measured by mass. However, for *dental amalgam alloys* (3.1), the terminology “by mass” is in general use. Because it is the intention for this document to be user-friendly, the latter has been adopted. In both cases, the composition is expressed as a percentage.

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 drops from the opened and upended capsule

Note 1 to entry: A light tap of the rim of the open capsule on a hard surface may be required to dislodge the pellet and is permitted.

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

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

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

Determine the chemical composition in accordance with 6.2.

The chemical composition shall comply with Table 1.

The total for elements that are not declared by the manufacturer as alloying elements shall not exceed 0,1 % (by mass).

4.3 Large particles in the dental amalgam alloy powder

When compliance with 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 0,1 % (by mass).

4.4 Loss of mass from the capsule during mixing

When compliance with this requirement is determined in accordance with 6.4, the average loss in mass of dental mercury and dental amalgam alloy powder from 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 The yield of amalgam from the capsule

When compliance with this requirement is determined in accordance with 6.5, the average mass of the pellet of dental amalgam obtained from a capsule (for a 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 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 in the capsule.

There may 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 compliance with this requirement is determined in accordance with 6.6, the mean value of the hardness for 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 for a specified number of capsules.

NOTE 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 on all test-pieces.

4.7 Properties of the dental amalgam

Table 2 — Properties of the dental amalgam

Maximum creep %	Permitted dimensional change during hardening %	Minimum compressive strength at 1 h MPa	Minimum compressive strength at 24 h MPa
2,0	−0,10 to +0,15	100	350

4.7.1 Creep

When compliance with 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.

4.7.2 Dimensional changes during hardening

When compliance with 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.

4.7.3 Compressive strength at 1 h

When compliance with 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.

4.7.4 Compressive strength at 24 h

When compliance with 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 the mixed dental amalgam before setting

When compliance with this requirement is determined in accordance with 6.8, when the dental amalgam alloy and dental mercury are 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 plastic mass after packing.

4.9 Length tolerance for the capsule

When compliance with this requirement is determined in accordance with 6.9, 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 containers of capsules of the same lot in packages that have been produced for retail.

NOTE The number of capsules required depends on the masses of dental amalgam alloy 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 during transit is a concern. Such a loss can be detected by visual examination using low power magnification.

6.1.2 Test sample

Test all containers holding the capsules from the sample procured for testing, 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 Expression of the results

Record the observations.

6.1.6 Report

6.1.6.1 General

If contamination is seen on the surface of a container, report this and the number of containers that is contaminated.

If it is the capsule surface that is contaminated, report this and the number of capsules that is contaminated.

6.1.6.2 Compliance

Report whether the product does or does not comply with the requirement for package and capsule 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 dental amalgam alloy powder from a 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 procedure, with a sensitivity adequate to determine the composition of the dental amalgam alloy for the elements declared by the manufacturer in compliance with 4.2.

NOTE Inductively-coupled plasma (ICP) spectroscopy 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.

6.2.5 Expression of results

Record all elements detected in concentrations greater than 0,01 % (by mass) and their proportions as percentages by mass.

For other elements that are detected in concentrations greater than 0,01 % (by mass) and below 0,1 % (by mass), 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 percentage (by mass) of other elements.

6.2.6 Report

6.2.6.1 General

Report the analytical method used. Report any irregularities in the test procedure used.

Report the percentages (by mass) for those elements that are alloying elements according to Table 1 and reported as such by the manufacturer. If any other element is declared by the manufacturer as an alloying element, report this and its percentage (by mass).

Report the sum of the percentages (by mass) of undeclared elements present in concentrations greater than 0,01 % (by mass).

Report each undeclared element that was found in a concentration greater than 0,1 % (by mass) by name and the percentage (by mass).

6.2.6.2 Compliance

Report whether the product does or does not comply with the requirement for composition and purity in accordance with 4.2

6.3 Large particles in the dental amalgam alloy powder

6.3.1 Principle

The large particles (defined as >150 µm in size) separated from the sample (a known mass of dental amalgam powder) are weighted.

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 of 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, ×10 magnification.

6.3.4 Test procedure

Weigh the sample to an accuracy of 1 mg and record this 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. Using the stereomicroscope, inspect the sieve at a magnification of ×10 for any foreign material and remove any that is seen. Then, transfer the dental amalgam alloy particles remaining on the sieve to the balance. Weigh these 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 present as particles that have a size greater than 150 µm (expressed as a percentage of the mass of the sample), as shown in Formula (1):

$$w = \frac{m_r}{m_p} \times 100\ (\%) \qquad (1)$$

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 General

Report any irregularities in the test procedure. Report whether foreign material was found on the sieve.

Report 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.

6.3.6.2 Compliance

Report whether the product does or does not comply with the requirement for 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 may 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 complies with ISO 7488.

NOTE Traditionally, the mechanical mixer for dental amalgam has been called an amalgamator. The latter is now a deprecated term.

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.

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.

NOTE 1 Although, according to 4.1, the surface should be free from contamination, it is 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 weights (m_S). This and all subsequent weighings are to be accurate to 0,1 mg.

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

NOTE 2 Sharp edges on the metal fork (or similar device) that hold 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 that are recommended by the manufacturer for the mass of dental amalgam alloy that is being mixed. See 7.3.1.

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 may have been produced when the capsule was placed in or removed from the mechanical mixing machine. If any are seen, note these.

Then 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.

6.4.5 Expression of the results

Tabulate the results.

The loss of dental mercury and amalgam alloy during mixing (m_l) is as shown in Formula (2):

$$m_l = (m_s - m_m) \quad (2)$$

If the loss in mass of a capsule 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. Take a replacement capsule and test it using procedure 6.4.4. Record the result.

6.4.6 Report

6.4.6.1 General

Present the results for the loss of mass from each of the 15 accepted capsules (each to 0,1 mg). Present the mean value for these (to 0,01 mg). Present any rejected result and give the reason for rejection. Report any irregularity in the test procedure.

6.4.6.2 Compliance

Report whether the product does or does not comply with the requirement for 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. This amount may 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 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 complies with 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 are to 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 mass of dental amalgam alloy that is being mixed. See 7.3.1. 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 pieces 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 may be necessary to break up the pellet to do this.) Similarly, remove any pestle. 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 in the capsule. They are ruptured on activation.

Repeat this procedure for the 14 other capsules.

6.5.5 Expression of the results

Tabulate the results.

The yield of dental amalgam from the capsule (m_y) is as shown in Formula (3):

$$m_y = (m_a - m_w) \quad (3)$$

6.5.6 Report

6.5.6.1 General

Report the results for the yield of amalgam from each of the 15 capsules tested (to 0,1 mg). Convert these masses to percentages of the sum of the masses of dental amalgam alloy and dental mercury declared by the manufacturer in accordance with 7.2.1 e) and 7.2.1 f). Report the mean value of these percentages.

Report any irregularity in the test procedure.

If seen, report any excessive inclusion of remnants of the membrane or sachet or any pestle in, or with, the dental amalgam pellet.

6.5.6.2 Compliance

Report whether the product does or does not comply with 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 might lead to a significant variation in properties, particularly when the extremes (of the tolerances) are considered. 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 the set dental amalgam. This property and instrumentation are 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 complies with ISO 7488.

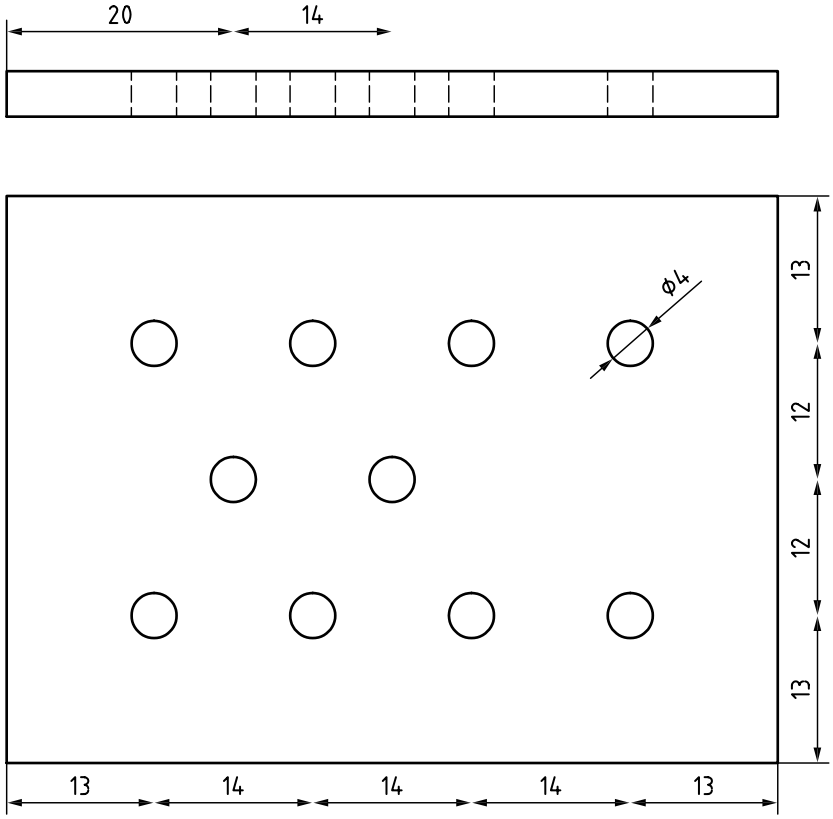
6.6.3.2 Materials and tolerances of the mould

Make the mould of poly(methyl methacrylate) or polycarbonate sheet that is 3,0 mm thick. Drill 10 holes that are 4,0 mm in diameter, spaced no closer than 10 mm to each other. A suitable mould is shown in Figure 1.

NOTE 1 This simple and low-cost mould can be considered to be consumable.

NOTE 2 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.

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

6.6.4 Test-piece production

6.6.4.1 General

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

Produce a total of 10 test-pieces using the procedure set out in 6.6.4.2.

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

6.6.4.2 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 mass of dental amalgam alloy that is being mixed. See 7.3.1. 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 and 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 with 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 unclear. 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, according to ISO 6344-1. 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.

NOTE This surface can be achieved 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 the test-piece to equilibrate with the ambient test temperature [(23 ± 2) °C].

6.6.5 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 products for which the hardness differs by 50 MPa. Use the same load for all products. Use a dwell time that is consistent.

NOTE 1 For example: For the Vickers hardness of dental amalgam at 24 h, an applied load between 0,5 kgf and 1 kgf is suitable and recommended. Such loads produce indentations with diagonal lengths between 79 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. 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 shall 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 may 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 2 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, multiply that value by 9,81. To convert to a value that has GPa units, multiply that number by $9,81 \times 10^{-3}$.

6.6.6 Expression 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. Note whether or not each test-piece mean value is greater than 85 % of the overall mean value.

6.6.7 Report

6.6.7.1 General

Report the microhardness test method used — Vickers or Knoop.

Present these results:

a) for each test-piece, the values for all 10 hardness measurements and their mean value ("the test-piece mean value");

b) the overall mean hardness value, calculated using all 100 hardness measurements ("the overall mean value");

c) the hardness value that is 85 % of the overall mean value.

Report any irregularity in the specimen production and the test procedure used.

6.6.7.2 Compliance

Report whether the product does or does not comply with 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 of these properties 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.

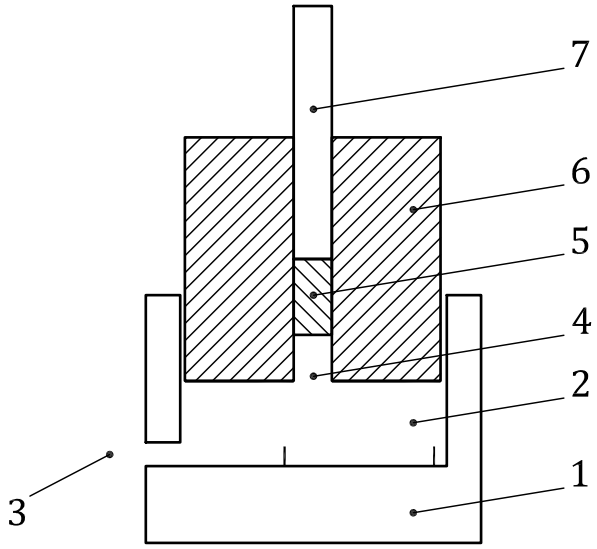
6.7.2 Sample

Select at random sufficient capsules to produce the required number of test-pieces for each property determination.

6.7.3 Mould for the preparation of cylindrical test-pieces for determining creep, dimensional change during hardening and compressive strength

6.7.3.1 General

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



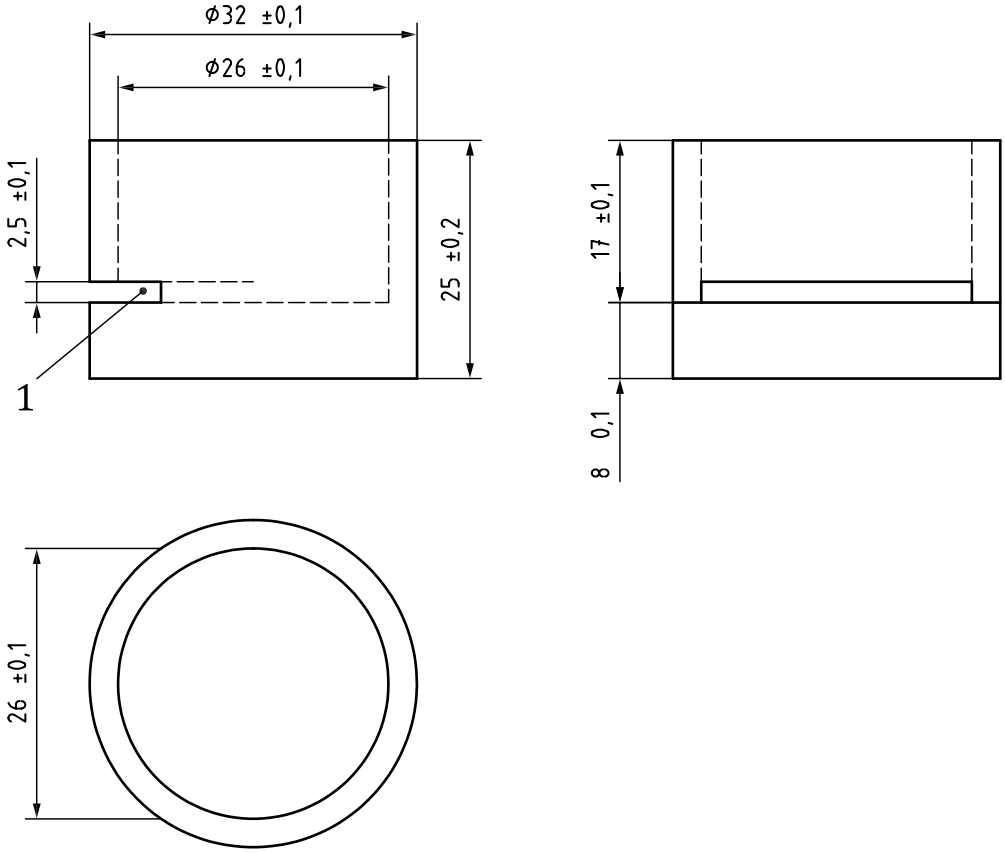
Key

1	holder	5	test-piece
2	Spacer No. 1	6	die
3	Spacer No. 2	7	Plunger No. 1
4	Plunger No. 2		

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

Dimensions in millimetres



Key

1 slot

Figure 3 — Holder

Dimensions in millimetres

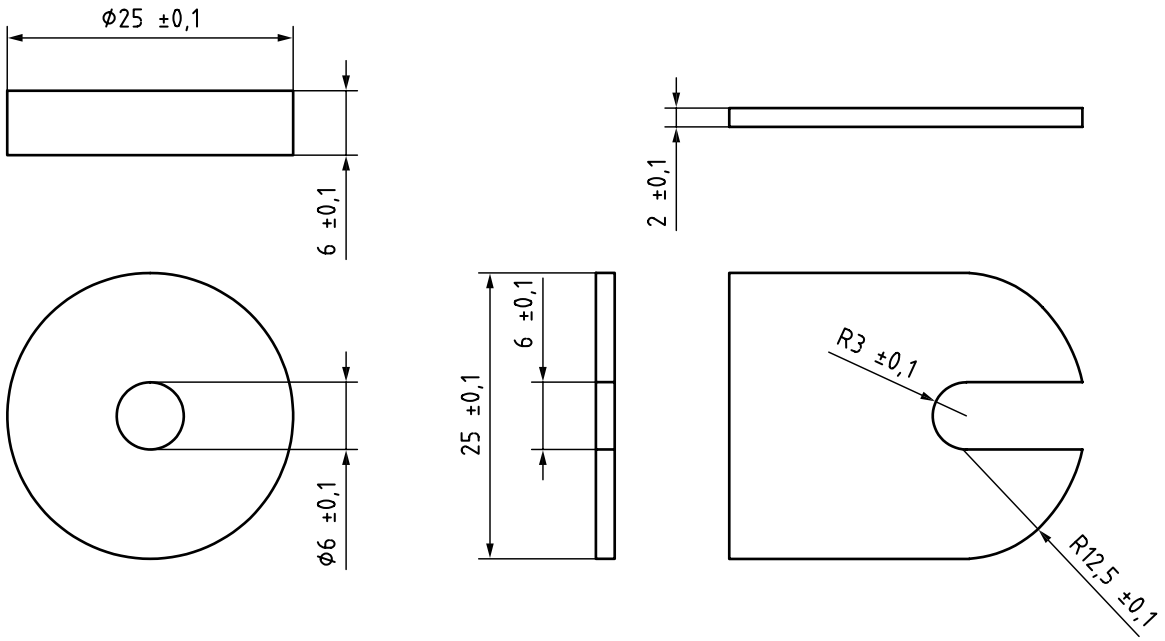


Figure 4 — Spacer No. 1 (left) and Spacer No. 2 (right)

Dimensions in millimetres

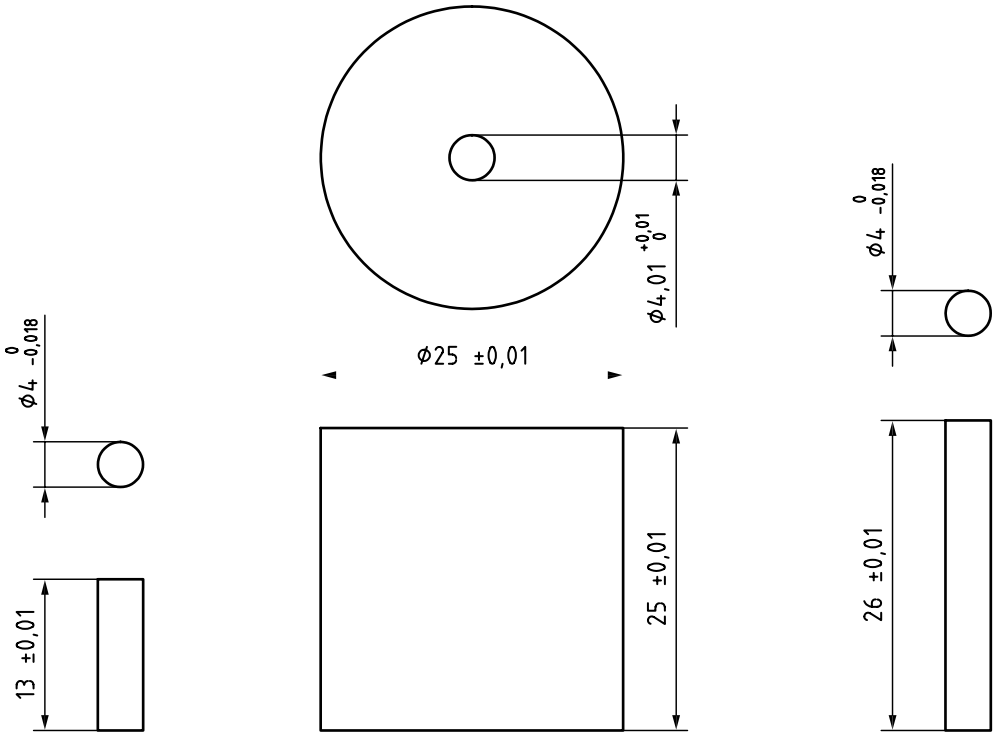


Figure 5 — Plunger No. 2 (left), the die (centre) and Plunger No. 1 (right)

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) is to be in contact with the dental amalgam. Though such datum lines are not mandatory, their use is recommended.

The diameters of the plungers are 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 is to be between 4,010 mm and 4,020 mm.

6.7.3.2 Materials and tolerances 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 a core roughness depth (R_k) not greater than 6,3 µm when tested in accordance with ISO 13565-2. Set the limits of clearance between the die and the plungers at F7 and h7, respectively, in accordance with ISO 286-2.

6.7.3.3 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) may 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.

Dimensions in millimetres

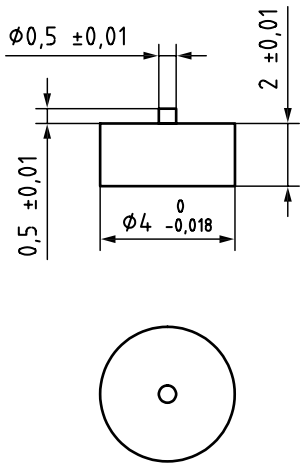


Figure 6 — Cap used for the production of test-pieces used for the measurement of dimensional change during hardening

6.7.4 Preparation of cylindrical test-pieces to determine compliance with the requirements for creep, dimensional change during hardening and compressive strength

6.7.4.1 Apparatus

6.7.4.1.1 Mould, shown in Figures 2 to 6. As specified for construction material, dimensions and finish in 6.7.3.

6.7.4.1.2 Mechanical mixing machine for dental amalgam, that is recommended by the manufacturer and complies with ISO 7488.

6.7.4.1.3 Hand-instrument for amalgam packing, slightly less than 4 mm in diameter.

6.7.4.1.4 Timer, resolution and accuracy 1 s.

6.7.4.1.5 Light source, with an illuminance ≥1 000 lx.

6.7.4.1.6 Apparatus to apply (176 ± 13) N to the mould plunger.

6.7.4.1.7 Coated abrasive, complies with microgrit size P1200, according to ISO 6344-1, as required.

6.7.4.2 Temperature

Prepare test-pieces at (23 ± 2) °C.

6.7.4.3 Mixing

Mix a mass of dental amalgam sufficient to make a cylindrical test-piece (8 ± 1) mm in length after packing into the mould shown in Figure 2.

Use as many capsules as needed to produce a test-piece. Simultaneously, mix the contents of the capsules using the same number of mechanical mixing machines of the same brand and model, or sequentially mix the content of the capsules on a single mechanical mixing machine. (The latter is allowed, provided the mixing for the last capsule is completed, the mould is filled and force applied before the end of the working time of the first capsule.) If necessary, use only a portion of the dental amalgam mix from one of these capsules.

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

Use the setting on the mechanical mixing machine and mixing time that are recommended by the manufacturer for the mass of dental amalgam alloy that is being mixed. See 7.3.1.

6.7.4.4 Packing

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 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

Time in seconds

Procedure	Time
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 mercury and eject the test-piece at	120

NOTE 1 If the cap (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.

NOTE 2 If the cap (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 lx 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.

Inspect the ends of the test-piece. In general, the ends of a test-piece will not have flash and will be perfectly flat and orthogonal to the cylinder axis, producing an acceptable test-piece. If necessary, remove any flash with a gentle rub on wet, coated abrasive that complies with microgrit size P1200, according to ISO 6344-1. Do not grind. After this, check that the ends are still flat and parallel. If the ends are no longer flat and parallel, replace the test-piece.

NOTE 3 Excessive abrasion produces uneven removal and as a consequence the need to replace the test-piece.

6.7.5 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 for a period greater 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.

6.7.5.1.2 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 [(8 ± 1) mm]. If it is acceptable, return it to the oven or incubator. If it is not, reject and replace this test-piece.

NOTE 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 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 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.

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 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 shown in Formula (4):

$$\varepsilon_c = \frac{\Delta l}{l_o} \times 100\ (\%) \tag{4}$$

where

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

l_0 is the original length, to an accuracy of 0,01 mm.

If all three results meet 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 meet the requirement for creep and 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. If the results for both of these meet the requirement in Table 2, the product meets the requirement for creep.

Test no more than five test-pieces.

6.7.5.5 Report

6.7.5.5.1 General

Present the results for all test-pieces that were subjected to creep loading. Report any irregularity during test-piece production or testing.

6.7.5.5.2 Compliance

Report whether the product does or does not comply with the requirement for creep in accordance with 4.7.1.

6.7.6 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.

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.

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.

6.7.6.3 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.

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 test procedure 6.7.6.3.

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.

6.7.6.4 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 shown in Formula (5):

$$\varepsilon_d = \frac{\Delta l_d}{l_d} \times 100\ (\%) \tag{5}$$

where

Δl_d is the dimensional change between 5 min and 24 h;

l_d is the length at 24 h.

6.7.6.5 Report

6.7.6.5.1 General

Present the results for all test-pieces. Report any irregularity during test-piece production or testing.

6.7.6.5.2 Compliance

Report whether the product does or does not comply with the requirement for dimensional change during hardening in accordance with 4.7.2.

6.7.7 Determination of compressive strength

6.7.7.1 Apparatus

6.7.7.1.1 Universal mechanical testing machine, configured for compression testing, 10 kN frame and load cell capacity, and resolution and accuracy better than 10 N.

6.7.7.1.2 Micrometer screw gauge, or 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 Test procedure

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 strength to the nearest 5 MPa.

6.7.7.3.1 Compressive strength at 1 h

Determine the compressive strength of five test-pieces at (60 ± 2) min after mixing.

If only three test-pieces meet the requirement in Table 2 for compressive strength at 1 h, determine the compressive strength of five more test-pieces.

Test no more than 10 test-pieces at 1 h.

6.7.7.3.2 Compressive strength at 24 h

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

If only three test-pieces meet the requirement in Table 2 for the compressive strength at 24 h, determine the compressive strength of five more test-pieces.

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

6.7.7.4 Expression of the results

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

6.7.7.5 Report

6.7.7.5.1 General

Present the results for all test-pieces that were loaded to failure. Report any irregularity during test-piece production or testing.

6.7.7.5.2 Compliance

Report whether the product does or does not comply with the requirement for compression strength at 1 h in accordance with 4.7.3.

Report whether the product does or does not comply with the requirement for compression strength at 24 h in accordance with 4.7.4.

6.8 Appearance of the mixed dental amalgam before setting

6.8.1 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.

6.8.2 Apparatus

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

6.8.2.2 Mould and ejection components, comprising Spacer No. 1, the die and Plunger No. 1 of the mould for making cylindrical dental amalgam test-pieces that are specified in Figures 4 and 5.

6.8.2.3 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.

6.8.2.4 Mechanical mixing machine for dental amalgam, that is recommended by the manufacturer and that complies with ISO 7488.

6.8.2.5 Light source, giving an illuminance of at least 1 000 lx.

6.8.3 Test procedure

Place Spacer No. 1 on the glass plate. Upend Plunger No. 1 in the centre hole of Spacer No 1. Place the die over the protruding end of Plunger No. 1, thereby creating a 5 mm deep cavity into which the dental amalgam is packed.

Prepare the test-piece at (23 ± 2) °C.

Use the setting on the mechanical mixing machine and the mixing time (for the mass of dental amalgam alloy and dental mercury present in the capsule) that are recommended by the manufacturer of the product under test (see 7.3.1). Mix and use as many capsules as needed to produce a dental amalgam cylinder that is 4 mm in length. If more than one capsule is required, simultaneously mix the contents of the capsules using the same number of mechanical mixing machines (of the same brand and model) or sequentially mix the content of the capsules on a single mechanical mixing machine. (The latter is allowed, provided mixing of the last capsule is completed and the amalgam it contains is packed in the mould before the end of the working time of the first capsule.)

NOTE The mass of a 4 mm diameter dental amalgam cylinder 4 mm in length is approximately 0,6 g.

Use visual inspection without magnification under an illuminance of at least 1 000 lx and at a distance not exceeding 250 mm to determine the appearance of the surface of the mixed dental amalgam and whether a coherent mass exists. A person making the inspection shall have nominally normal visual acuity. Corrective (non-magnifying) non-tinted lenses may be worn.

Mix the contents of the first capsule and empty the amalgam pellet onto the glass plate. Examine the amalgam immediately to determine whether a coherent mass exists initially. Determine whether the surface is shiny. Record these findings.

At 30 s after the end of mixing, place a piece of the dental amalgam pellet from the first capsule on the top of the mould, over the cavity. Pack this, then further pieces (from this and, if required, other capsules) until the mould is filled to the required level. Pack immediately with 10 thrusts within a period of 10 s using the hand-instrument for amalgam packing. The amount placed should be sufficient to fill the cavity to the extent that, after packing, approximately 1 mm of the cavity above the dental amalgam surface will remain unfilled. Eject the test-piece at 120 s after the end of mixing by removing the spacer and then pressing down on the die so that the plunger forces out the test-piece.

Use visual inspection under the same conditions as the initial inspection to determine whether a coherent mass has been maintained during packing. Record this.

6.8.4 Expression of the results

Record the observations.

6.8.5 Report

6.8.5.1 General

Report any irregularity in the production of the test-piece. If remnants of the membrane or sachet are seen as inclusions in the dental amalgam pellet, report this.

6.8.5.2 Compliance

Report whether the product does or does not meet the requirement for the appearance of the mixed dental amalgam before setting in accordance with 4.8.

6.9 Length tolerance for the capsule

6.9.1 Principle

To ensure that all capsules will be held securely in the mechanical mixing machine for dental amalgam, the capsule length should be consistent, within an acceptable tolerance. To determine compliance with 4.9, the length of capsules in a sample is measured to an accuracy that is an order of magnitude lower than the tolerance.

6.9.2 Test sample

10 capsules selected at random.

6.9.3 Apparatus

Micrometer screw gauge, or similar measuring instrument, with an accuracy of 0,05 mm.

6.9.4 Test procedure

For self-activating capsules, measure the length of the capsule to an accuracy of 0,05 mm. Measure the lengths of all 10 capsules and record these values.

For other capsules that require a physical action by the user to rupture the separating barrier to activate the capsule before placing it in the mechanical mixing machine, activate the capsule as instructed by the manufacturer. Do not mix. Measure the length of the activated capsule to an accuracy of 0,05 mm. Measure the lengths of all 10 activated capsules and record these values.

6.9.5 Expression of the results

Tabulate the 10 values. Consult the marking and labelling information for the capsule length, given by the manufacturer according to 7.2.1 k). Determine whether any of the recorded capsule lengths differ by more than 1 mm from the length given by the manufacturer.

6.9.6 Report

6.9.6.1 General

Present the results for all measured capsule lengths. Report any irregularity in testing.

6.9.6.2 Compliance

Report whether the product does or does not comply with the requirement for length tolerance for the capsule in accordance with 4.9.

7 Marking, labelling and packaging

7.1 Packaging

The capsules are to be packed in containers that, under normal conditions of shipment, ensure that the capsules remain intact so as to prevent spillage of the dental amalgam alloy or the dental mercury.

7.2 Marking and labelling

7.2.1 Information

The following information is to be present on the surface of the package or included as part of accompanying printed literature:

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 intended mass of dental amalgam alloy in one capsule;

f) the intended mass of dental mercury in one capsule;

g) the number of capsules in each package;

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

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

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

k) the length of the capsule to an accuracy of 1 mm;

l) 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 Labelling of Chemicals (GHS)* (United Nations).

7.2.2 Labelling of a package for dental mercury

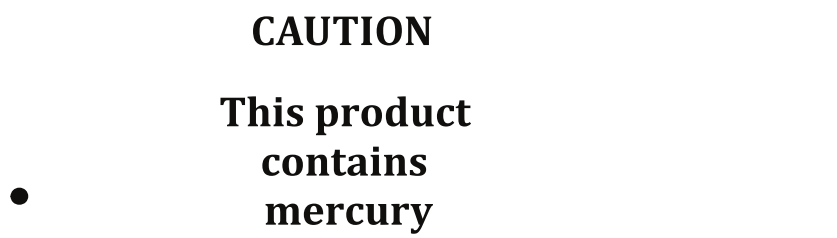


Figure 7 — Cautionary label — Registration number: ISO 7000-0434A

Mark with the label given in Figure 7. 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, presented as follows:

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

— text information “CAUTION This product contains mercury” shall be printed in black;

— 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 information required by 7.2.1 l) and the precautionary notes contained in the manufacturer’s instructions (see 7.3.2).

7.2.3 Labelling of the outer surface of package or container used for shipping

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

NOTE 1 Whereas 7.2.2 is information intended for the user, 7.2.3 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.

7.3 Manufacturer’s instructions

7.3.1 General instructions

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

a) a specified brand and model number or name of a mechanical mixing machine for dental amalgam complying with ISO 7488 that is recommended for mixing capsules of the product;

b) the machine setting(s) and the time required for the mixing of a capsule of dental amalgam using the mechanical mixing machine for dental amalgam specified in 7.3.1 a);

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

7.3.2 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

“Waste material and all primary containers that have held mercury shall be disposed of following appropriate management practice”.

Bibliography

[1] ISO 1942, *Dentistry — Vocabulary*

[2] ISO 7405, *Dentistry — Evaluation of biocompatibility of medical devices used in dentistry*

[3] ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

[4] ISO 13897, *Dentistry — Amalgam capsules*

[5] ISO 24234, *Dentistry — Dental amalgam*

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

[7] UNEP Minamata Convention on Mercury. United Nations, New York, 2015. United Nations Treaty Collection C.N. 244.2015 TREATIES XXVII-17

ICS 11.060.10

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