
Dentistry — Corrosion resistance of dental amalgam

*Médecine bucco-dentaire — Résistance à la corrosion des amalgames
dentaires*

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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).

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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).

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

This document sets a requirement, being the acceptable limit, for the reduction in strength of dental amalgam that is a consequence of crevice corrosion when the test is conducted using the procedure specified in this document. It uses one of the three corrosion test procedures present in ISO/TS 17988 for which a requirement is given in this document. The testing protocol is designed to accelerate the effect, such that results are obtained in a time suited to an *in vitro* test. Its purpose is to differentiate acceptable products from those that are not (by using a benchmark value) and not to rank products. It is not intended for use in product comparison claims.

Specific qualitative and quantitative requirements for freedom from biological hazard are not included in this document, but it is recommended that reference be made to ISO 10993-1 and ISO 7405 for assessing possible biological hazards. The test procedure in this document is inappropriate for assessing possible biological hazards.

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Dentistry — Corrosion resistance of dental amalgam

1 Scope

This document specifies the requirements for the permissible reduction in strength resulting from crevice corrosion of dental amalgam products that are within the scope of ISO 24234 or ISO 20749. It provides details of the test procedure for determining this.

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 1942, *Dentistry — Vocabulary*

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

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

ISO 6344-1, *Coated abrasives — Grain size analysis — Part 1: Grain size distribution test*

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

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

ISO 24234, *Dentistry — Dental amalgam*

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:

- ISO Online browsing platform: available at <http://www.iso.org/obp>
- IEC Electropedia: available at <http://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 20749:2017, 3.1]

3.2

dental mercury

mercury supplied for use in the preparation of dental amalgam

[SOURCE: ISO 20749:2017, 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 20749:2017, 3.3]

3.4

dental amalgam alloy tablet

quantity of *dental amalgam alloy* (3.1) powder that has been compressed to form a single entity for the purpose of providing a pre-dosed quantity of the alloy that, when mixed with an appropriate mass of *dental mercury* (3.2), produces 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: During mixing, the tablet is intended to break apart, forming a fine powder.

[SOURCE: ISO/TS 20746:2016, 3.4]

3.5

dental mercury sachet

measured quantity of *dental mercury* (3.2) supplied in a sachet (for use in a reusable mixing capsule) in a mass that, when mixed with an appropriate mass of *dental amalgam alloy* (3.1), produces 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 sachet is intended to rupture during mixing to allow the dental mercury to come into contact with the dental amalgam alloy powder.

Note 2 to entry: A dental mercury sachets may be referred to as a dental mercury pillow.

[SOURCE: ISO/TS 20746:2016, 3.5]

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3.6

hertzian-loading strength-reduction corrosion test

test in which a test-piece is immersed for a defined period of time in a specified solution (at a specified temperature) in a way that creates crevice corrosion conditions on one surface, after which it is removed from the solution and fractured with the force to do this then compared with the force to fracture an identical test-piece subjected to ageing in air at the same temperature

Note 1 to entry: Fracture is initiated from the surface subjected to crevice corrosion conditions and proceeds by radial crack growth.

[SOURCE: ISO/TS 17988: 2014, 3.8]

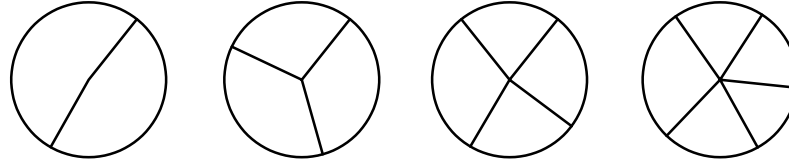
3.7

radial cracking

fracture pattern of a Hertzian-loaded test-piece in which (more or less) planar cracks form along radii, normal to the face of the disc shaped test-piece, thus dissecting it into two or more sectors

Note 1 to entry: Such radial cracks initiate on the test surface of the test-piece and propagate through the disc to produce approximately equiangular dissection in most cases.

EXAMPLE Some radial fracture patterns in disc shaped test-pieces are illustrated here:



[SOURCE: ISO/TS 20746:2016, 3.8]

3.8

top surface

surface of the disc shaped test-piece that has been produced by carving back unset amalgam that is above the level of the mould until the surface of the test-piece is flat and level with that mould surface

[SOURCE: ISO/TS 20746:2016, 3.6]

3.9

test surface

surface of the disc shaped test-piece that has been produced by contact with the polished glass plate when the mixed amalgam is packed into the mould

[SOURCE: ISO/TS 20746:2016, 3.7]

3.10

mixing machine for dental amalgam

DEPRECATED: amalgamator

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

[SOURCE: ISO/TS 17988: 2014, 3.12]

4 Sampling

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Products shall be procured in packages that have been produced for retail.

For pre-capsulated dental amalgam products, procure a sufficient number of capsules from a single lot.

For dental amalgam alloy in the form of a powder supplied in bulk or in tablets, procure sufficient dental amalgam alloy and a sufficient number of dental mercury sachets from single lots. The dental mercury sachets shall conform to ISO 24234.

NOTE In this context, “sufficient” is deemed to be the quantity to make the required number of test-pieces and the maximum number of test-pieces allowed to replace any that are rejected.

At least 3,0 g of dental amalgam alloy is required per test-piece.

5 Requirement

When tested in accordance with [Clauses 6, 7, 8](#) and [9](#) the mean value (in newton) of 10 valid results for corrosion test-pieces shall not be less than 80 % of the mean value (in newton) of 10 valid results for control test-pieces.

6 Preparation of the dental amalgam test-piece

6.1 General

6.1.1 Temperature

Prepare test-pieces at (23 ± 2) °C.

6.1.2 Mixing

For a dental amalgam alloy product supplied either as tablets or as a free-flowing powder in bulk, the ratio by mass of the dental amalgam alloy to the mass of dental mercury shall be that recommended by the manufacturer. Use a reusable mixing-capsule (with a pestle, if needed) that conforms to ISO 13897. Use any other mixing accessory that is required, as recommended by the manufacturer. If more than one mix is required to make the test-piece, produce these mixes simultaneously using equipment of the same type for each mix. However, if the last mix can be produced within the working time of the first mix, mixing these masses sequentially on a single piece of equipment is permitted.

For pre-capsulated products, use as many capsules as needed. Mix the contents of the capsules either simultaneously using the same number of mixing machines for dental amalgam of the same type, or sequentially on a single mixing machine for dental amalgam (the latter is permitted, provided the mixing of the last capsule is completed before the end of the working time of the first). If necessary, use only a portion of the dental amalgam mix from one of these capsules.

Use a mixing machine for dental amalgam that conforms to ISO 7488 and that is recommended for mixing the dental amalgam alloy product with dental mercury or mixing the pre-capsulated product. Use the mixing machine settings and mixing time that are recommended by the manufacturer of the dental amalgam alloy or pre-capsulated product (for the mass of dental amalgam alloy that is being mixed).

6.2 Apparatus for the preparation of the dental amalgam test-piece

6.2.1 **Mould**, as shown in [Figure 1](#).

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6.2.2 **Flat glass plate**, with a polished scratch-free surface and square with an edge length greater than 30 mm.

6.2.3 **Microscope slide**, glass, to provide a straight edge to carve back the dental amalgam.

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

6.2.5 **Tweezers**, steel.

6.3 Materials and tolerances for construction of the mould

The mould shall be made of hardened tool steel or hardened stainless steel. The upper and lower surfaces shall be flat and parallel, and have an arithmetic mean roughness (R_a) not greater than $6,3 \mu\text{m}$ when tested in accordance with ISO 4287. The hole shall have a taper of $(7 \pm 2)^\circ$ to allow the amalgam disc to be ejected without undue force when this is applied to the face that has the smaller diameter. The tapered surface shall be smooth enough not to impede the ejection of the test-piece. For example, it may be honed to an arithmetic mean roughness (R_a) of $6,3 \mu\text{m}$ (when tested in accordance with ISO 4287).

NOTE 1 For convenience, to distinguish between the two surfaces during test-piece production, a small engraved mark (set away from the hole) can be made on one of the mould faces.

NOTE 2 The angle of the taper, $(7 \pm 2)^\circ$ is the included angle. The wall of the mould is at an angle of $(3,5 \pm 1,0)^\circ$ with the centre line.