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Dentistry — Corrosion test methods for dental amalgam

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National foreword

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Médecine bucco-dentaire — Essais de 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).

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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*.

This second edition cancels and replaces the first edition (ISO/TS 17988:2014), which has been technically revised. The main changes to the previous edition are as follows:

— The scope has been extended to include products that are within the scope of ISO 20749.

— Clause 3 includes additional terms and definitions.

— Clause 4: quantities required for the production of test-pieces for each of the three test procedures are given now as the mass of dental amalgam alloy per test-piece, in place of the total mass of dental amalgam alloy for the complete test (i.e. the estimated quantity for all test-pieces including permitted replacements).

— 5.2.2.2 and 5.3.2: the parameter R_a has replaced R_k to specify surface roughness on steel moulds.

— 5.3.2: the surface roughness of the tapered hole in the Hertzian-indentation strength-reduction test-piece mould has been revised.

— 8.3.1.1 and 8.3.1.2: two additional items have been added to the list of apparatus.

— 8.3.1.4: blood dilution vials without protuberances on the interior base surface might not be available. A means by which the required flat surface can be created has been added.

— 8.3.4 and 8.4.2.2: a technical addition has been made to the procedure. Instructions are given for replacing test-pieces from which invalid results had been produced. Also, advice is given to make the maximum number of permitted replacements at the time that the actual test-pieces are made (to avoid a possible 31-day delay should a result be invalid and a replacement test-piece be required).

— 8.4.2.2: instructions are given to inspect the substrate disc and to replace it if damage is observed.

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Introduction

This document gives the practical details of three test methods for the measurement of the resistance to corrosion of dental amalgam. These corrosion test methods are laboratory procedures for evaluating the relative performances of dental amalgam alloy products. They are designed to produce a measurable effect (and differences between products) within a relatively short time period, a time period appropriate for a comparative laboratory evaluation.

The results of these tests should not be used for any biocompatibility claims, for which their use is inappropriate.

Should other corrosion test procedures emerge in time as suitable for application in comparative evaluations of dental amalgam products, they will be included in future editions of this document.

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Dentistry — Corrosion test methods for dental amalgam

1 Scope

This document gives the details of test procedures for evaluating the corrosion resistance of dental amalgam formed from products that are within the scopes of ISO 24234 and ISO 20749.

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

2 Normative references

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

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

ISO 1942, *Dentistry — Vocabulary*

ISO 3585, *Borosilicate glass 3.3 — Properties*

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 https://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 produces a dental amalgam for dental restoration

[SOURCE: ISO 20749:2017, 3.1]

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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 powder and dental mercury 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 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, 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 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 powder, 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: The dental mercury sachet is also known as a dental mercury pillow.

[SOURCE: ISO/TS 20746:2016, 3.5, modified — Note 2 to entry added.]

3.6
immersion corrosion test
test in which a test-piece of known surface area is immersed in a specified solution (at a specified temperature) for a defined period of time to determine quantitatively the elemental release into the solution and thereby allow a comparison of the corrosion resistance between this and other products of a similar type

3.7
potentiostatic corrosion test
test in which a test-piece of known surface area is immersed in a specified electrolyte (at a specified temperature) with a set potential applied for a defined period of time during which the corrosion current is recorded, integrated and then normalized by the anodic surface area and time to produce the total charge transported per unit of area in a unit of time [units $C/(cm^2.d)$]

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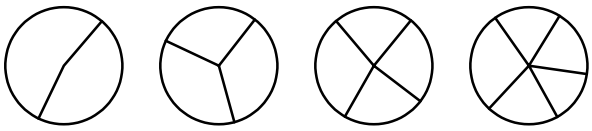
3.8
Hertzian-loading strength-reduction test
test in which a test-piece is immersed for a defined period of time in a specified solution (at a specified temperature) in a way that creates crevice corrosion conditions on one surface, after which it is removed from the solution and fractured with the force 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.

3.9
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]

3.10
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]

3.11
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]

3.12
mixing machine for dental amalgam
DEPRECATED: amalgamator
electrically powered mixing machine that operates using an oscillating action for mixing dental amalgam alloy and dental mercury (in a capsule) to produce a dental amalgam

4 Sampling

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 as dental amalgam alloy 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.

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