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Dentistry — Corrosion test methods for dental amalgam

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National foreword

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Dentistry — Corrosion test methods for dental amalgam

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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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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 meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 106, *Dentistry*, Subcommittee SC 1, *Filling and restorative materials*.

This is the first edition of ISO/TS 17988, *Dentistry — Corrosion test methods for dental amalgam.* Part of the subject matter in this Technical Specification was formerly contained in two annexes to ISO 24234:2004, *Dentistry — Mercury and alloys for dental amalgam.*

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Introduction

Dental amalgam alloy and dental mercury are the essential and only components of dental amalgam restorative material. This Technical Specification, of which this is the first edition, 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 are not intended to be used directly for any biocompatibility claims, for which their use is inappropriate.

Should other corrosion test procedures emerge as suitable for application to dental amalgam and use in the comparative evaluations of products, they will be included in future editions of this Technical Specification.

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Dentistry — Corrosion test methods for dental amalgam

1 Scope

This Technical Specification gives details of test procedures for evaluating the corrosion resistance of dental amalgam produced from a dental amalgam alloy product.

It is applicable to dental amalgam formed from products that are within the scope of ISO 24234, *Dentistry — Dental amalgam.*

It is not applicable to dental metallic materials that are within the scope of ISO 22674, *Dentistry — Metallic materials for fixed and removable restorations and appliances.*

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

NOTE Dental mercury is at least 99,99 % pure, and as such it is a metallic element of high commercial purity, and not an alloy.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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 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 13897, *Dentistry — Amalgam 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.

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

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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 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.

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.

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, 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.

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

Note 1 to entry: For the present case of dental amalgam, the mercury released as vapour is also relevant.

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, expressed in $C/(cm^2 \cdot d)$

3.8
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.

4 Sampling

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

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For pre-capsulated products, all capsules shall be of the same lot.

For a free-flowing dental amalgam alloy powder in bulk, or dental amalgam alloy tablets, the alloy shall be from a single lot. For use with these, the dental mercury sachets shall be from a single lot that complies with ISO 24234. (Use as many dental mercury sachets as required, according to the mixing ratio recommended by the manufacturer of the dental amalgam alloy product.)

For the immersion corrosion procedure (Clause 6) at least 3 g of dental amalgam alloy is required.

For the potentiostatic corrosion procedure (Clause 7) at least 1 g of dental amalgam alloy is required.

For the Hertzian-loading strength-reduction procedure (Clause 8), at least 35 g of dental amalgam alloy is required.

5 Preparation of dental amalgam test-pieces

5.1 General

5.1.1 Temperature

Prepare test-pieces at (23 ± 2) °C.

5.1.2 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 dental mercury should be that recommended by the manufacturer. Use a capsule (with a pestle, if needed) that complies with 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 allowed.

For pre-capsulated products, use as many capsules as needed. Mix the contents of the capsules either simultaneously using the same number of pieces of equipment of the same type, or sequentially on a single piece of equipment. (The latter is allowed, 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 an amalgamator that complies with ISO 7488 and that is recommended for mixing the amalgam alloy product with dental mercury or mixing the pre-capsulated product. Use the amalgamator setting and mixing time that is recommended by the manufacturer of the dental amalgam alloy or pre-capsulated product (for the mass of dental amalgam alloy that is being mixed).

5.2 Cylindrical test-pieces for use in the immersion and potentiostatic corrosion test procedures

5.2.1 Mixing

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

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

5.2.2 Apparatus for the preparation of dental amalgam cylindrical test-pieces

5.2.2.1 General

Use the apparatus as shown in Figures 1 to 4.

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