TECHNICAL SPECIFICATION

ISO/TS 17988

Second edition 2020-03

Dentistry — Corrosion test methods for dental amalgam

lédec.
dentaire. Médecine bucco-dentaire — Essais de corrosion des amalgames



Reference number ISO/TS 17988:2020(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 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.
- <u>Clause 4</u>: 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.
- <u>5.3.2</u>: 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.

a test p. amalgam p. 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]