

This is a preview of "ISO 24234:2021". [Click here to purchase the full version from the ANSI store.](#)

Third edition
2021-08

Dentistry — Dental amalgam

Médecine bucco-dentaire — Amalgame dentaire



Reference number
ISO 24234:2021(E)

© ISO 2021



COPYRIGHT PROTECTED DOCUMENT

© ISO 2021

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

This is a preview of "ISO 24234:2021". [Click here to purchase the full version from the ANSI store.](#)

Contents

	Page
Foreword	v
Introduction	vii
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 Requirements	3
4.1 Chemical composition and purity of the dental amalgam alloy.....	3
4.2 Purity of the dental mercury.....	3
4.3 Foreign material and large particles in the dental amalgam alloy powder.....	3
4.4 Accuracy and variability of pre-proportioned masses.....	4
4.4.1 For dental mercury sachets.....	4
4.4.2 For dental amalgam alloy tablets.....	4
4.5 Properties of the dental amalgam.....	4
4.5.1 General.....	4
4.5.2 Creep.....	4
4.5.3 Dimensional changes during hardening.....	4
4.5.4 Compressive fracture stress at 2 h.....	4
4.5.5 Compressive fracture stress at 24 h.....	4
4.6 Appearance of the mixed dental amalgam before setting.....	4
4.7 Corrosion resistance of the dental amalgam.....	5
5 Sampling	5
6 Test methods	5
6.1 Chemical composition and purity of the dental amalgam alloy.....	5
6.1.1 Principle.....	5
6.1.2 Test sample.....	5
6.1.3 Apparatus.....	5
6.1.4 Procedure.....	5
6.1.5 Expression of results.....	5
6.1.6 Report.....	6
6.2 Purity of the dental mercury.....	6
6.2.1 Principle.....	6
6.2.2 Sample.....	6
6.2.3 Apparatus.....	6
6.2.4 Procedure.....	7
6.2.5 Expression of results.....	7
6.2.6 Report.....	7
6.3 Foreign material and large particles in the dental amalgam alloy powder.....	7
6.3.1 Principle.....	7
6.3.2 Test sample.....	7
6.3.3 Apparatus.....	8
6.3.4 Test procedure.....	8
6.3.5 Expression of the results.....	8
6.3.6 Report.....	9
6.4 Determination of the accuracy and variability of pre-proportioned masses.....	9
6.4.1 Principle.....	9
6.4.2 Test sample.....	9
6.4.3 Apparatus.....	9
6.4.4 Test procedure.....	9
6.4.5 Treatment of data.....	10
6.4.6 Report.....	10
6.5 Properties of the dental amalgam.....	11
6.5.1 Principle.....	11

This is a preview of "ISO 24234:2021". [Click here to purchase the full version from the ANSI store.](#)

6.5.2	Mould for the preparation of test-pieces for determining creep, dimensional change during hardening and compressive fracture stress.....	11
6.5.3	Sample.....	14
6.5.4	Test-piece production.....	14
6.5.5	Procedure for the determination of creep.....	16
6.5.6	Procedure for the determination of dimensional change during hardening.....	17
6.5.7	Procedure for the determination of compressive fracture stress.....	19
6.6	Appearance of the mixed dental amalgam before setting.....	20
6.6.1	Principle.....	20
6.6.2	Apparatus.....	20
6.6.3	Test procedure.....	21
6.6.4	Expression of the results.....	21
6.6.5	Report.....	22
6.7	Corrosion resistance of the dental amalgam.....	22
6.7.1	Principle.....	22
6.7.2	Sampling.....	22
6.7.3	Test procedure.....	23
6.7.4	Treatment of results.....	23
6.7.5	Report.....	23
7	Report.....	24
8	Marking and labelling.....	24
8.1	Information.....	24
8.1.1	General.....	24
8.1.2	Dental amalgam alloy products.....	24
8.1.3	Dental mercury.....	25
8.2	Labelling for a package containing dental mercury.....	25
8.3	Labelling of the outer surface of package or container used for shipping dental mercury.....	26
8.4	Manufacturer's instructions.....	26
8.5	Precautionary notes.....	26
	Bibliography.....	27

This is a preview of "ISO 24234:2021". [Click here to purchase the full version from the ANSI store.](#)

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 third edition cancels and replaces the second edition (ISO 24234:2015), which has been technically revised.

The main changes compared to the previous edition are as follows.

- Pre-capsulated dental amalgam products have been removed from the scope of this document.
- A requirement for corrosion resistance has been added.
- In previous editions of this document, the presence of a limited number of foreign body particles in the dental amalgam alloy powder was permitted. Now, as a requirement, foreign body particles are not permitted to be present in the dental amalgam alloy powder.
- The roughness parameter used to specify the finish required on working surfaces of test-piece moulds has been changed from R_k to R_a .
- An instruction to lightly abrade the ends of the cylindrical test-pieces, if required for removing flash, has been deleted.
- The requirement for early compression strength has been altered. Measurement of the value is made at 2 h and not at 1 h.
- An additional four items of information have been added to each of the test reports.
- The edition number of the manufacturer's instructions and information, and the date of its introduction have been added as a requirement to the manufacturer's instructions.
- For each test method used to determine conformity to a requirement, a new subclause, "Principle", has been added in which a brief summary is present to explain the method adopted.

This is a preview of "ISO 24234:2021". [Click here to purchase the full version from the ANSI store.](#)

- For each test method used to determine conformity to a requirement, a new subclause, "Test report", has been added.
- A new clause "7 Report" has been added which provides details of the evaluation that are to accompany a statement or claim of conformity to this document overall.

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.

This is a preview of "ISO 24234:2021". [Click here to purchase the full version from the ANSI store.](#)

Introduction

Continuing concern about the use of dental mercury and a move in some countries to limit its use to pre-capsulated products led to the development of ISO 20749. The scope of ISO 20749 is restricted to pre-capsulated products alone. Consequently, it is appropriate to remove pre-capsulated dental amalgam products from the scope of this document.

Dental amalgam alloy supplied as a free-flowing powder and as tablets remain in use in some countries. For their use, dental mercury is required and the supply of dental mercury sachets (also referred to as pillows) continues to be consistent with the objective to restrict the supply of dental mercury only in sealed capsules containing a mass suitable for a single restoration. All such products are within the scope of this revision.

NOTE In some jurisdictions only pre-capsulated products are allowed to be used. ISO TC 106, *Dentistry*, must consider global use and not restrict the standards it produces to the position prevailing in individual states or regional blocks. For as long as product types within the scope of this document are in legal use in other nations, this standard will continue to be required.

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