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BSI Standards Publication

Dentistry – Corrosion resistance of dental amalgam

bsi.

National foreword

This British Standard is the UK implementation of EN ISO 23325:2020. It is identical to ISO 23325:2020.

The UK participation in its preparation was entrusted to Technical Committee CH/106/1, Dental restorative and orthodontic materials.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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Médecine bucco-dentaire - Résistance à la corrosion des amalgames dentaires (ISO 23325:2020)

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European foreword

This document (EN ISO 23325:2020) has been prepared by Technical Committee ISO/TC 106 "Dentistry" in collaboration with Technical Committee CEN/TC 55 “Dentistry” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by January 2021, and conflicting national standards shall be withdrawn at the latest by January 2021.

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Endorsement notice

The text of ISO 23325:2020 has been approved by CEN as EN ISO 23325:2020 without any modification.

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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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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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INTERNATIONAL STANDARD ISO 23325:2020

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]

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

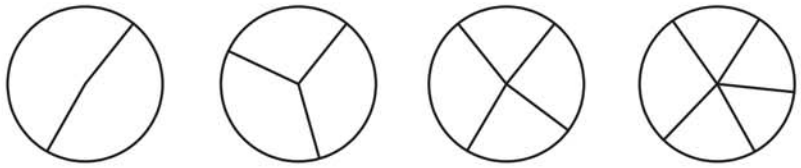
Note 1 to entry: Fracture is initiated from the surface subjected to crevice corrosion conditions and proceeds by radial crack growth.

[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

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 11497. 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.

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 µm when tested in accordance with ISO 4287. The hole shall have a taper of (7 ± 2)° 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 µm (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 ± 2)° is the included angle. The wall of the mould is at an angle of (3,5 ± 1,0)° with the centre line.

It is permissible to use PTFE in the place of steel provided the same dimensional accuracy and surface roughness exists. Steel is selected for better durability. If PTFE is used, the thickness shall be checked frequently and the edges of the tapered hole inspected for significant chipping.

6.4 Packing the mould, removal of test-piece and inspection for surface defects

Place the steel mould on the glass plate with the side that has the greater diameter for the tapered hole in contact with the plate.

NOTE 1 The surface of the glass plate acts as a matrix for the test surface of the test-piece.

Mix a mass of the dental amalgam sufficient to make a disc-shaped test-piece that is 10 mm diameter and 3 mm high after packing into the die shown in Figure 1.

Transfer pieces of the amalgam paste to the mould by using tweezers. Using the hand-instrument for dental amalgam packing (6.2.4), condense the dental amalgam, overfilling slightly. Carve back using the edge of the microscope slide to produce a flat surface (on the dental amalgam) that is level with that of the mould.

A razor blade should not be used for carving back excess amalgam. A microscope slide produces a smoother and more even surface finish.

Allow the dental amalgam to set for 10 min. Carefully eject the test-piece from the mould by applying light finger-pressure to the surface of the test-piece that has been carved back (the top surface), while holding the mould in the other hand. Check visually that the test surface is defect-free everywhere, other than possibly at the margin. Use visual inspection without magnification. Carry out this inspection at an illuminance of at least 1 000 lux and at a distance not exceeding 250 mm. A person making the inspection shall have nominally normal visual acuity [corrective (non-magnifying) non-tinted lenses may be worn]. If a defect is detected, reject that test-piece and make a replacement.

NOTE 2 To prevent any damage to the test surface during ejection, placing a thick soft pad, such as a number of dental napkins, under the mould to "catch" the ejected test-piece is recommended.

After ejection do not grind or polish the surfaces of the test-piece.

Dimensions in millimetres

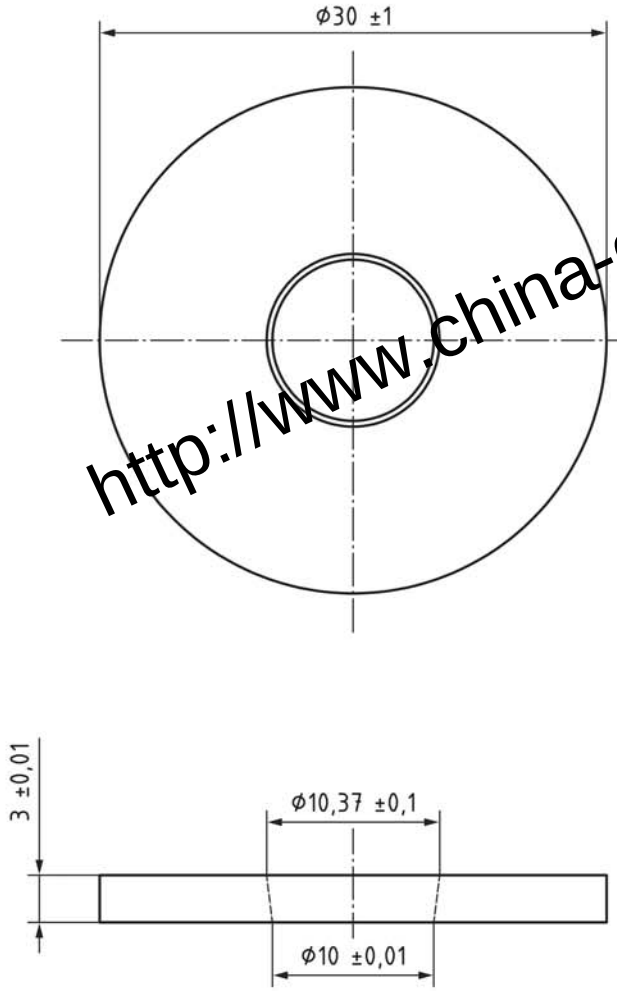


Figure 1 — Mould to produce disc-shaped test-pieces for the Hertzian-loading strength-reduction corrosion test

7 Test solution (artificial saliva)

7.1 Reagents

All reagents are to be analytical grade with the exception of lactic acid which is to be ≥85 %.

7.1.1 Sodium dihydrogen phosphate.

7.1.2 Potassium chloride.

7.1.3 Sodium chloride.

7.1.4 Ammonium chloride.

7.1.5 Trisodium citrate dihydrate.

7.1.6 Lactic acid solution.

7.1.7 Urea.

7.1.8 Uric acid.

7.1.9 Sodium hydroxide.

7.1.10 Potassium thiocyanate.

7.1.11 Hydrochloric acid.

7.1.12 Water to Grade 2, as specified in ISO 3696.

7.2 Stock solutions

Make the following three stock solutions using water to Grade 2, as specified in ISO 3696. Store these separately in a refrigerator at (4 ± 2) °C.

7.2.1 Stock Solution A

7.2.1.1 Sodium dihydrogen phosphate, 28,0 g/l.

7.2.1.2 Potassium chloride, 86,8 g/l.

7.2.1.3 Sodium chloride, 7,2 g/l.

7.2.1.4 Ammonium chloride, 11,0 g/l.

7.2.1.5 Trisodium citrate dihydrate, 1,1 g/l.

7.2.1.6 Lactic acid solution, 3,5 g/l.

7.2.2 Stock Solution B

7.2.2.1 Urea, 5,0 g/l.

7.2.2.2 Uric acid, 0,375 g/l.

7.2.2.3 Sodium hydroxide, 0,1 g/l.

7.2.3 Stock Solution C

7.2.3.1 Potassium thiocyanate, 12,0 g/l.

7.3 Test solution

Immediately before making the dental amalgam test-pieces make the test solution by placing 500 ml of water (to Grade 2, as specified in ISO 3696) into a 1 L volumetric flask. To this, add in turn 20 ml of Solution A, 40 ml of Solution B, and 20 ml of Solution C, followed by a further addition of water (to Grade 2, as specified in ISO 3696) to make up the volume to within 20 ml of the mark. If necessary, adjust to pH 6,2 by using sodium hydroxide or hydrochloric acid, as required. Then finally, make up to the mark with water (to Grade 2, as specified in ISO 3696).

8 Procedure for test-piece conditioning

8.1 Apparatus

8.1.1 Air oven or incubator maintained at (37 ± 2) °C.

8.1.2 Measuring cylinder with a minimum measuring capacity of 25 ml and accurate to 1 ml (or similar volume measuring piece of equipment).

8.1.3 Micrometre screw gauge or similar measuring instrument, to measure test-piece thickness to an accuracy of 0,01 mm.

8.1.4 Blood dilution vial, polystyrene with a snap cap that seals the vial[1]. The vial shall have a flat interior base (without any protuberance), 25 ml capacity. Thirty of these are required.

If the only vials that are available have a protuberance on the interior base, the required flat surface may be created by inserting a poly(methylmethacrylate) disc [between 2 mm and 3 mm thick with a diameter 0,5 mm less than the interior diameter of the vial] into the vial. This should be produced by trephining from a scratch-free polymer plate that has a polished surface. Thirty of these discs are required.

Although a trephined disc is preferred, lathe cutting the disc from a rod is permitted as an alternative production method. The flat surfaces of such discs should be made smooth by wet grinding on coated abrasive sheets that shall comply with P1200 (in accordance with ISO 6344-1).

8.2 Control test-pieces

If required, place a poly(methylmethacrylate) disc in each of 10 blood dilution vials to produce a flat protuberance-free surface on the interior base.

Make the test-piece, in accordance with Clause 6. As soon as it is made, measure the thickness to an accuracy of 0,01 mm. Take care not to mark the surfaces when the test-piece is placed between the anvils of the micrometre and they are closed onto the surfaces. If the thickness is outside the range (3,00 ± 0,02) mm, reject this test-piece and replace it with another.

NOTE 1 To minimize the possibility of surface marking, a micrometre that has flat anvils at least 6 mm in diameter is recommended.

NOTE 2 This tolerance for thickness, ±0,02 mm, is necessary to limit the variation in fracture force as a consequence of differences in test-piece thickness to an acceptable value.

After removing the test-piece from the micrometre, inspect the test surface (i.e. the surface that has been in contact with the glass plate, 6.2.2) to determine whether it has been marked during measurement. Carry out this inspection at an illuminance of at least 1 000 lux and at a distance not exceeding 250 mm. A person making the inspection shall have nominally normal visual acuity [corrective (non-magnifying) non-tinted lenses may be worn]. If marking is seen, reject and replace the test-piece.

Immediately after this inspection, place the test-piece in its own blood dilution vial with the test surface upward. Cap the vial and place it in an air oven or incubator maintained at (37 ± 2) °C.

Make 10 test-pieces to be the "control test-pieces". Store these control test-pieces for a period of (30,0 ± 0,1) days.

After the storage period of 30 days, remove the vials from the oven (or incubator). Then, remove the test-pieces from the vials, taking care not to touch the test surface.

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1) V130 blood dilution vial; Simport, Beloeil QC, Canada is an example. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of this product.

Place the control test-pieces with the test surface upwards on a sheet of absorbent paper and hold at ambient temperature.

8.3 Corrosion test-pieces

If required to produce the flat protuberance-free surface, place a poly(methylmethacrylate) disc in each of the 10 of the remaining blood dilution vials.

Take the test solution and add (15 ± 1) ml to each of these 10 blood dilution vials.

Make 10 test-pieces, in accordance with 6, to be the "corrosion test-pieces". Immediately after removing a test-piece from the mould, measure its thickness, following the procedure given in 8.2, rejecting any unacceptable test-piece using the same criteria and then replacing it.

As soon as a test-piece is measured (and inspected), place it in its own test solution-containing vial with the test surface downward on the base (or disc). Cap the vial. Inspect the vial to see whether there is an air bubble trapped between the dental amalgam test-piece and the vial base (or disc). If an air bubble is seen, remove it by a gentle swirl of the vial. (A crevice filled with the test solution is produced between the dental amalgam and the flat surface.) Without delay, place the vial in the air oven or incubator maintained at (37 ± 2) °C.

Store these 10 corrosion test-pieces for a period of (30,0 ± 0,1) days, leaving them completely undisturbed throughout that time.

After the storage period of 30 days, remove the vials from the oven (or incubator). Then remove the test-pieces from the vials, taking care not to touch the test surface.

Rinse these corrosion test-pieces with water (to Grade 2, as specified in ISO 3696), taking care not to disturb the adherent corrosion product layer. Do not dry, but rest the test-pieces with the test surface upward on a sheet of absorbent paper and hold at ambient temperature.

8.4 Replacement test-pieces

After fracture, inspection of a test-piece may lead to the rejection of its result. The results of up to five control test-pieces and up to five corrosion test-pieces may be rejected and replacement test-pieces made and tested. Thirty-one days elapse between the making of a test-piece and its fracture. It is convenient to make all test-pieces (i.e. the 20 specified and the 10 possible replacements) at the same time in case any results are rejected (15 are to be air stored and 15 are to be stored in the corrosive solution; that is the maximum permitted). This action (producing more than the total of 20 test-pieces specified in 8.2 and 8.3) is advisory since none may be required. However, by doing this, a lengthy possible delay is avoided if one (or more) result is rejected.

9 Mechanical testing

9.1 Apparatus for mechanical testing

9.1.1 Universal mechanical testing machine with compression testing attachments. Load cell capacity 5 kN. Data acquisition rate: 100 data points/s, as a minimum rate.

9.1.2 Chrome steel ball bearing, 700 to 900 VHN, polished surface, 20 mm diameter.

9.1.3 Cylindrical rod, Young's Modulus = (10 ± 1) GPa[2)], 10 mm diameter cut to a 5,00 mm thick disc. The flat surfaces of the disc should be made by wet-ground under light pressure, if necessary to remove

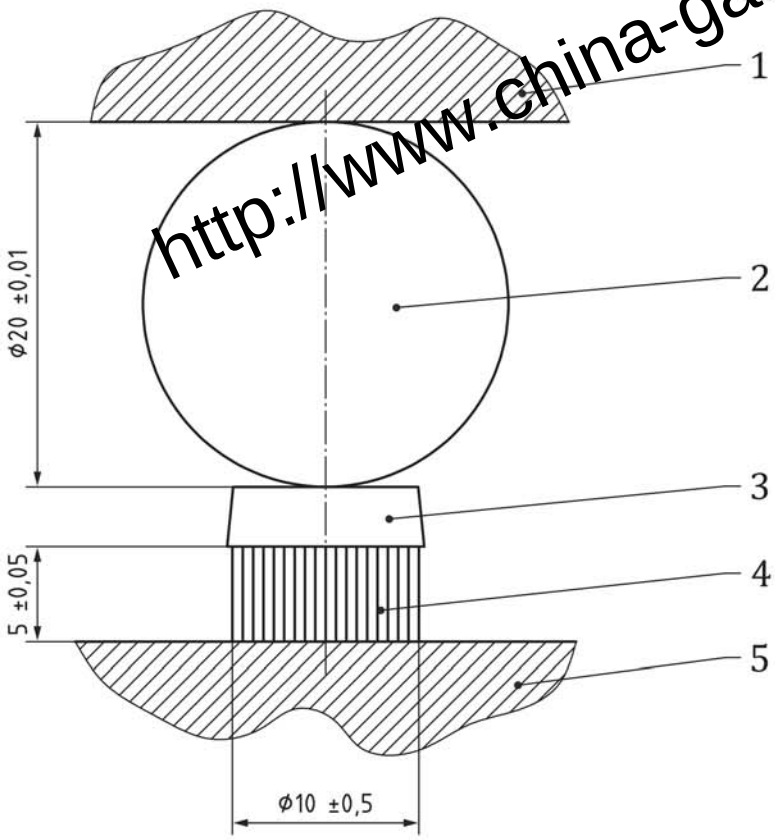
2) Polyamide — Nylon 6,6 — 30 % Glass Fibre Reinforced — Rod. (PA 6,6 30 % GFR). Goodfellow Cambridge, Huntington, England. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of this product.

any lathe turning marks, on coated abrasives with micro-grit size P1200. The coated abrasive sheets shall comply with ISO 6344-1.

9.2 Procedure

9.2.1 Loading arrangement

Dimensions in millimetres



Key

1 universal mechanical testing machine compression upper platen
2 chrome steel ball
3 dental amalgam test-piece (see Figure 1 for the dimensions and dimensional tolerances for this)
4 disc with Young's Modulus = (10 ± 1) GPa
5 universal mechanical testing machine compression lower platen

Figure 2 — Loading arrangement for the Hertzian-loading strength-reduction test

(60 ± 10) min after a test-piece is removed from the oven (or incubator), place it with its test surface downward on the [Young's Modulus = (10 ± 1) GPa] disc, which is on the lower compression platen of the universal mechanical testing machine, i.e. the test surface is to be in contact with that disc. The chrome steel loading ball is positioned centrally on the upper surface of the dental amalgam test-piece (see Figure 2).

NOTE The presence of this disc provides a substrate that has an elastic compliance closer to that of dentine than that produced by steel, the material of the compression lower platen.

The designs of mechanical testing machines are various. For this reason, the means by which the ball is accurately located and fixed to the upper platen (and centred on the test-piece) is not prescribed. Adopt an appropriate solution. However, the arrangement should have a high axial stiffness.

9.2.2 Force application and fracture

Apply force to the test-piece using a cross-head speed of 0,2 mm/min, collecting the force versus displacement values digitally at an acquisition rate of at least 100 data points/s. Record the force at which the fracture occurs.

It is possible that incomplete separation occurs in a failed test-piece. In such a circumstance, use gentle finger-pressure to complete the separation (after the test-piece is removed from the testing machine).

NOTE 1 In the absence of explosive fracture, the continued presence of material under the ball maintains a finite force. In such a circumstance, there are several methods available to determine the fracture force — acoustic emission, load-cell ringing, a clear force drop, or a discontinuity in the force versus displacement output in the case of a "silent" fracture.

Collect and piece together the test-piece fragments. Determine whether radial dissection has occurred by ascertaining, using visual inspection without magnification, whether bottom-initiated radial cracking has taken place. Carry out this inspection at an illuminance of at least 1 000 lux and at a distance not exceeding 250 mm. A person making the inspection shall have nominally normal visual acuity. Corrective (non-magnifying) non-tinted lenses may be worn. If it has not, the result shall be rejected.

Fracture of a test-piece can produce between two and five fragments. The result is still valid if more than two fragments are produced, provided bottom-initiated radial cracking has taken place.

Load all 10 control test-pieces and all 10 corrosion test-pieces to fracture. For each test-piece, record the force at which fracture occurs and whether failure is valid or not.

If there are one or more test-pieces for which the result has been rejected because the failure was not valid, make and test replacement test-pieces to that number. If any replacement test-piece does not produce a valid result, make and test a second replacement. Make no more than 15 test-pieces in total for each type (i.e. 15 control test-pieces and 15 corrosion test-pieces).

NOTE 2 A sufficient number of replacement test-pieces are already available if the advisory action given in 8.4 has been adopted. The instructions given in 9.2 to make replacements following rejection is given for users who have chosen not to take up this advice.

9.3 Treatment of data

Record all test results. Include any result that has not been accepted with the reason for this rejection.

Calculate and record the mean values for the accepted results for the control test-pieces and for the corrosion test-pieces. Calculate and record the difference between these means, this being the reduction in fracture force resulting from corrosion.

Use the unpaired student *t*-test to determine the level of significance (*P*-value) for the difference between the two sets of values.

Calculate and record the variance for the accepted results of the control test-pieces. Calculate the variance for the accepted results for the corrosion test-pieces. Calculate the variance ratio (F-test statistic). Determine whether the variance ratio is significant (it should not be significant).

Calculate and record the mean value (in newton) of 10 valid results for corrosion test-pieces as a percentage of the mean value (in newton) of 10 valid results for control test-pieces.

Record whether this percentage reduction in fracture force results in the product conforms, or does not, with the requirement given in Clause 5.

10 Test report

A test report shall be prepared. At least the following information shall be included:

a) name of dental amalgam alloy;

b) name and address of manufacturer;

c) the International Standard used (including its year of publication);

d) any deviations from the procedure;

e) any unusual features observed;

f) all test results; include any result that has not been accepted with the reason for this rejection;

g) the mean value for the accepted results for the control test-pieces;

h) the mean value for the accepted results for the corrosion test-pieces;

i) the variance for the control test-pieces;

j) the variance for the corrosion test-pieces;

k) the variance ratio (F-test statistic) and if this is significant;

l) the difference (in newton) between these mean values, being the reduction in fracture force resulting from corrosion;

m) the level of significance (P-value), obtained using the student *t*-test, for the difference between the two sets of values;

n) the mean value (in newton) of the 10 valid results for corrosion test-pieces as the percentage of the mean value (in newton) of the 10 valid results for control test-pieces;

o) whether the product conforms to the requirement for corrosion resistance given in Clause 5;

p) name of the testing laboratory, with its address;

q) date of test report.

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389 Chiswick High Road London W4 4AL UK

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