
Dentistry — Compatibility testing —

Part 1:

Metal-ceramic systems

Médecine bucco-dentaire — Essais de compatibilité —

Partie 1: Systèmes métallo-céramiques



Reference number
ISO 9693-1:2012(E)



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Foreword

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International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 9693-1 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthetic materials*.

This first edition of ISO 9693-1, together with ISO 9693-2¹⁾, cancels and replaces ISO 9693:1999. It also incorporates the Amendment ISO 9693:1999/Amd 1:2005.

ISO 9693 consists of the following parts, under the general title *Dentistry — Compatibility testing*:

— *Part 1: Metal-ceramic systems*

The following parts are under preparation:

— *Part 2: Ceramic-ceramic systems*

1) Under preparation.

Introduction

Dental metallic materials and ceramics are suitable for use in the fabrication of metal-ceramic dental restorations.

Dentistry — Compatibility testing —

Part 1: Metal-ceramic systems

1 Scope

This part of ISO 9693 specifies test methods for determining the compatibility of metallic and ceramic materials used for dental restorations by testing the composite structure.

The requirements given in this part of ISO 9693 are applicable to metallic materials and ceramics when used in combination, and are not applicable to either metallic materials or ceramics when used alone.

NOTE Requirements for metallic materials are given in ISO 22674; requirements for ceramic materials are given in ISO 6872.

2 Normative references

The following referenced documents are indispensable for the application 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 6872:2008, *Dentistry — Ceramic materials*

ISO 22674:2006, *Dentistry — Metallic materials for fixed and removable restorations and appliances*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942, ISO 6872 and ISO 22674 apply.

4 Requirements

4.1 Biocompatibility

Specific qualitative and quantitative test methods for demonstrating freedom from unacceptable biological risks are not included in this part of ISO 9693, but it is recommended that, for the assessment of such biological risks, reference be made to ISO 10993-1 and ISO 7405.

4.2 Properties of metal-ceramic system

The debonding/crack-initiation strength of the metallic material and at least one specified (named) ceramic present shall be greater than 25 MPa. The debonding/crack-initiation strength of the ceramic and at least one specified (named) metallic material present shall be greater than 25 MPa.

Testing shall be carried out in accordance with 6.4.

5 Sampling

5.1 Metallic material

The sample shall be adequate for preparing the test specimens in accordance with 6.4.2. All of the metallic materials procured shall be unused and obtained from the same batch.

5.2 Ceramic

Take a sufficient amount of ceramic (see 6.4.2) to carry out the necessary tests in accordance with this part of ISO 9693. If there is more than one shade of opaque, dentine and enamel ceramics, take equal quantities of each shade.

6 Test methods

6.1 Linear thermal expansion

6.1.1 Ceramic materials

Test methods for ceramic materials shall be in accordance with ISO 6872:2008, 7.4.

6.1.2 Metallic materials

Test methods for metallic materials shall be in accordance with ISO 22674:2006, 8.8.

6.2 Glass transition temperature

Test methods for glass transition temperature shall be in accordance with ISO 6872:2008, 7.5.

6.3 Young's modulus

Test methods for Young's modulus shall be in accordance with ISO 22674:2006, 5.4.4.

6.4 Metal-ceramic bond characterization (Schwickerath crack-initiation test)

6.4.1 Apparatus

6.4.1.1 Flexural-strength testing machine for three-point bending, having a span of 20 mm between supports and which is capable of attaining a cross-head-speed of $(1,5 \pm 0,5)$ mm/min. The supports and bending piston shall be rounded to a radius of 1,0 mm.

6.4.2 Preparation of test specimens

Prepare six alloy/metal specimens of (25 ± 1) mm \times $(3 \pm 0,1)$ mm \times $(0,5 \pm 0,05)$ mm in accordance with the manufacturer's procedure for processing the substructures for metal-ceramic prostheses. Condition the specimens, observing the manufacturer's instructions (e.g. cleaning, sandblasting, oxidation).

Before applying the ceramic to the test specimens, calibrate the furnace according to the manufacturer's recommendation and test-fire the ceramic material to obtain the appropriate firing grade and surface gloss of both opaque and dentine ceramic. If necessary, adjust the firing temperatures or holding times.

In accordance with the manufacturer's instructions, apply opaque ceramic over a length of $(8 \pm 0,1)$ mm symmetrically on one 3 mm-wide side of each specimen.

Add dentine ceramic to each specimen to form a total ceramic thickness of $(1,1 \pm 0,1)$ mm after firing (see Figure 1). The ceramic layer shall have a rectangular shape.

If necessary, add additional dentine ceramic to obtain the required thickness and shape, and fire it. Carefully trim the rectangular shape with a disc. If necessary, remove ceramic from the side of the metal strip.

Submit each specimen to a glaze firing in accordance with the manufacturer's instructions.

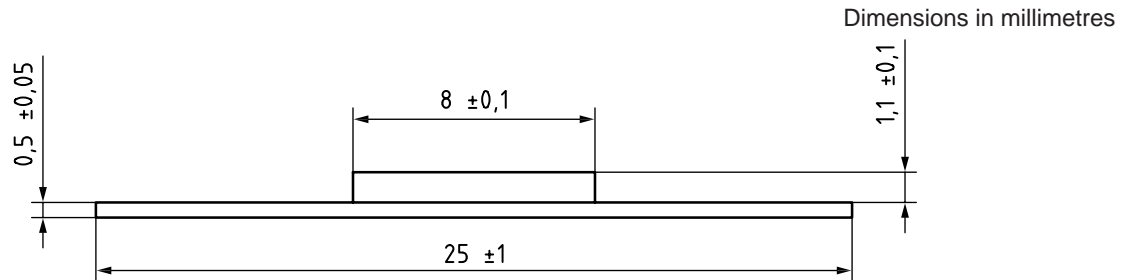


Figure 1 — Test specimen configuration

6.4.3 Procedure

6.4.3.1 General

The fired specimens are placed in the bending apparatus [the distance between the centres of the supports is $(20 \pm 0,1)$ mm and the radius of the bending piston is $(1,0 \pm 0,1)$ mm] with the ceramic positioned symmetrically on the side opposite the applied load. The force is applied at a constant rate of $(1,5 \pm 0,5)$ mm/min and recorded up until failure. The fracture force, F_{fail} , expressed in newtons, is measured for specimens that fail as a result of a debonding crack occurring at one end of the ceramic layer. Specimens failing as a result of cracks in the middle of the ceramic layer shall be replaced until six appropriate specimens are obtained.

6.4.3.2 Assessment of results

The debonding/crack-initiation strength, τ_b , is calculated using the following equation:

$$\tau_b = k \times F_{fail}$$

The coefficient, k , is a function of the thickness of the metal substrate, d_M , [$(0,5 \pm 0,05)$ mm], and the value of Young's modulus, E_M , (determined in accordance with ISO 22674), of the used metallic material. Coefficient k can be read from Figure 2. To read the value k for a certain thickness d_M , first pick the curve for the proper value of E_M , then read the value k from the picked curve for the thickness d_M .

If four specimens out of six (66 %), or more, comply, the system passes the test. If only two, or fewer, comply, the system fails. If three pass, repeat the test with another six specimens. If five or six of the new specimens pass, the system complies.

6.4.4 Alternative procedure

6.4.4.1 General

The debonding/crack-initiation strength, τ_b , can also be calculated numerically on the basis of the flow chart shown in Figure 3.

6.4.4.2 Assessment of results

The metal-ceramic system passes the test if four or more specimens comply with the requirement specified in 4.2.

If four specimens out of six (66 %), or more, comply, the system passes the test. If only two, or fewer, comply, the system fails. If three pass, repeat the test with another six specimens. If five or six of the new specimens pass, the system complies.

Dimensions in millimetres

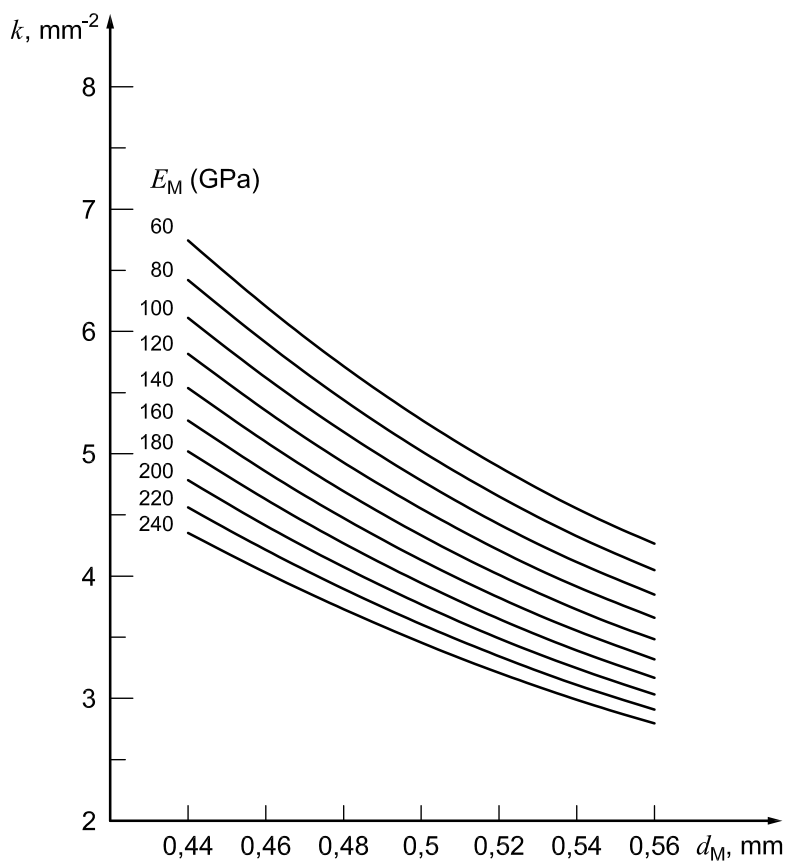


Figure 2 — Diagram to determine the coefficient k as a function of metal substrate thickness, d_M , and Young's modulus, E_M , of the metallic material

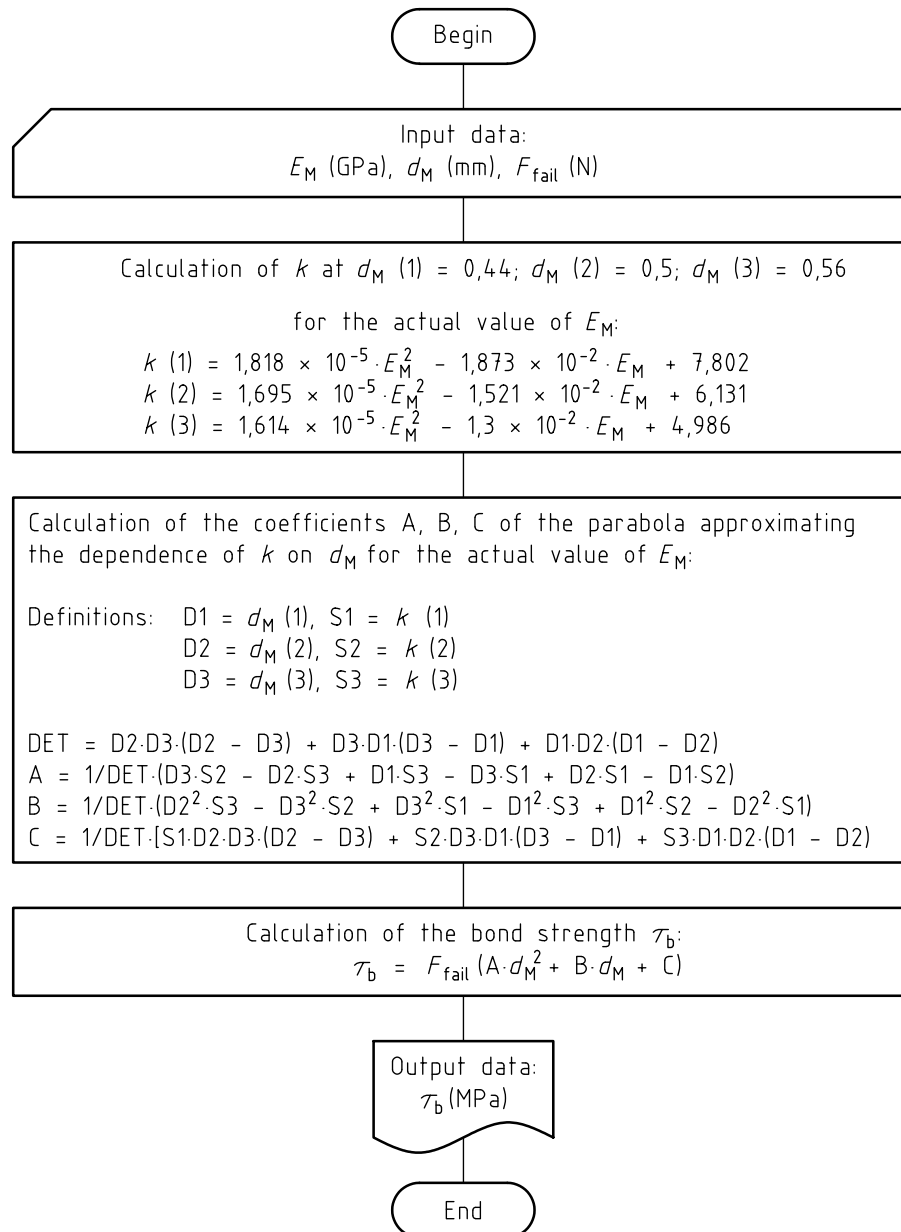


Figure 3 — Flow chart for numerical calculation of debonding/crack-initiation strength

7 Test report

The test report shall include at least the following information:

- tested materials;
- results obtained from the crack-initiation test, in MPa;
- linear thermal expansion of the tested materials;
- glass transition temperature of the ceramic(s) tested;
- name of the responsible person and the testing laboratory;
- date of the test report and signature of the responsible person.

Bibliography

- [1] ISO 7405, *Dentistry — Evaluation of biocompatibility of medical devices used in dentistry*
- [2] ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*
- [3] ISO 6892-1:2009¹⁾, *Metallic materials — Tensile testing — Part 1: Method of test at room temperature*

1) Cancels and replaces ISO 6892:1998.

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