INTERNATIONAL STANDARD

ISO 6872

Second edition
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Dental ceramic

Céramique dentaire

Reference number
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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.

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.

International Standard ISO 6872 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthodontic materials*.

This second edition cancels and replaces the first edition (ISO 6872:1984), of which it constitutes a technical revision.

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Introduction

Specific qualitative and quantitative requirements of freedom from biological hazard are not included in this International Standard but it is recommended that, in assessing possible biological or toxicological hazards, reference should be made to ISO 10993-1:1992, *Biological evaluation of medical devices — Part 1: Guidance on selection of tests* or to ISO/TR 7405:1984, *Biological evaluation of dental materials*, or any more recent edition.

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Dental ceramic

1 Scope

This International Standard specifies the requirements and the corresponding test methods for dental ceramic materials for all fixed ceramic restorations.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 3696:1987, *Water for analytical laboratory use — Specification and test methods.*

ISO 4799:1978, *Laboratory glassware — Condensers.*

3 Definitions

For the purposes of this International Standard, the following definitions apply.

3.1 air-fired dental ceramic: Dental ceramic fired under ambient atmospheric pressure.

3.2 batch; lot: Defined quantity of starting material, packaging material or product processed in one process or series of processes so that it could be expected to be homogeneous.

3.3 castable dental ceramic: Dental ceramic specially prepared to be cast using a lost wax process.

3.4 class of dental ceramic: Classification of a dental ceramic according to its intended use.

3.5 condensation of dental ceramic: Any process by which a dental ceramic is compacted before firing.

3.6 core dental ceramic: Dental ceramic which provides a supporting structure for building up a ceramic restoration.

3.7 dental ceramic: Material specially prepared for the fabrication of ceramic prostheses and restorations.

3.8 dental ceramic stain: Highly pigmented dental ceramic used for a ceramic restoration or prosthesis to simulate details of colour and/or appearance of a natural tooth.

3.9 dental dentine ceramic: Slightly translucent, pigmented dental ceramic used to give the overall shape and basic colour of a dental ceramic restoration or prosthesis.

3.10 dental enamel ceramic: Translucent, lightly pigmented dental ceramic, for use on a core or a base

of dentine ceramic to simulate the natural tooth enamel.

3.11 glass-ceramic: Partly crystalline product whose final microstructure is obtained via the controlled crystallization of a glass.

3.12 glass-infiltrated dental ceramic: Initially sintered, i.e. porous, dental ceramic, subsequently infiltrated with glass.

3.13 injectable dental ceramic: Type of dental ceramic specially prepared to be injected, in the fused state, into a mould.

3.14 medium glaze: Surface appearance obtained when the glaze is clinically and aesthetically acceptable.

3.15 modelling fluid: Liquid (other than water) with which a dental ceramic may be intended to be mixed prior to condensation.

3.16 sintering of ceramic: Act or process of heating at a predetermined temperature a finely powdered dental ceramic material, resulting in its densification and bonding.

3.17 vacuum-fired dental ceramic: Dental ceramic which is formulated to be fired at much less than atmospheric pressure.

4 Types, classes and their identification

Dental ceramics are designated in two types. Type I includes ceramic products which are provided as a powder: type II includes all other forms of ceramic product. Ceramics shall be divided into classes according to their intended use. If a colour is added to a ceramic powder in order to identify the class of the powder, the colour coding given in table 1 is recommended.

Type II, class 1 ceramics are used for the fabrication of the supporting structure for crowns, veneers, inlays and onlays, thus referring to materials which are intended to be layered with material from one or more of type I ceramics, classes 2 to 8. Type II, class 2 ceramics are used for the fabrication of veneers, inlays and onlays.

5 Requirements

5.1 Uniformity

The inorganic pigment(s) used to produce the colour of a fired dental ceramic and any dye(s) shall be uniformly dispersed throughout the dental ceramic material, and, in powdered ceramic products, no segregation of the pigment(s) shall take place when the powder is mixed as in 8.1.3. Check by visual inspection (see clause 7).

5.2 Freedom from extraneous materials

5.2.1 Dental ceramic materials, powdered as well as non-powdered products, shall be free from extraneous materials, when assessed by visual inspection (see clause 7).

5.2.2 Dental ceramic materials shall have a radioactive emission of not more than 0,2 $Bq \cdot g^{-1}$. This value does not include that of potassium-40. Test in accordance with 8.2.

5.3 Mixing and condensation properties, type I ceramics

When mixed as in 8.1.3 with water or the modelling fluid recommended by the manufacturer, a dental ceramic powder shall not form lumps or granules when assessed by visual inspection (see clause 7).

The paste so formed shall be suitable for making jacket-crowns, and inlay and onlay restorations by condensation of successive layers. When the paste is condensed as in 8.1.4, it shall not crack or crumble, when assessed by visual inspection (see clause 7) during the drying cycle recommended by the manufacturer.

5.4 Physical and chemical properties

The physical and chemical properties of ceramic test specimens tested in accordance with the relevant methods, detailed for the dissimilar types of ceramics in clause 8, shall comply with the requirements specified in table 2.

5.5 Biocompatibility

See the Introduction for guidance on biocompatibility.

Table 1 — Colours for dental ceramic powders, type I

Class	Material	Colour coding
1	Core ceramic	Yellow or none
2	Dentine/body ceramic	Pink
3	Enamel ceramic	Blue
4	Neck material	Green
5	Transparent material	None
6	Stains	None
7	Add-on material	None
8	Glaze material	None

Table 2 — Physical and chemical properties

Property	Requirement				
	Type I class			Type II class	
	1	2 to 5	6 to 8	1	2
Flexural strength, MPa, min.	100	50	—	100	30
Chemical solubility: loss in mass, $\mu g \cdot cm^{-2}$, max.	2 000	100	100	2 000	100

6 Sampling

6.1 Type I ceramics

Take a sufficient amount of ceramic to carry out the necessary tests. Where there is more than one shade in a class of dental ceramic, take equal quantities of each shade.

Sufficient quantities of essential modelling fluids shall be obtained, if their use is recommended by the manufacturers. The quantities shall be those recommended by the manufacturer concerned. If the shades of a class of ceramic comply with clause 4, 5.1 and 5.2.1, form a pool of powder of that material by taking samples of equal mass from each shade, using a core sampler or an apparatus of similar capability. The total mass of the pool of powder shall be sufficient to carry out the necessary tests.

6.2 Type II ceramics

All of the material procured for testing in accordance with this International Standard shall be of the same lot.

7 Inspection

Use visual inspection to assess compliance of each sample, taken in accordance with clause 6, with clause 4, 5.1, 5.2.1 and 5.3.

8 Test methods

8.1 Preparation of test specimens

For detailed instructions, see the individual test methods.

For type I specimens and unless otherwise stated or inconsistent with the text, the apparatus detailed in 8.1.2 and 8.1.4.1, and the conditions for mixing, condensation and firing apply to all test methods.

8.1.1 Components of test specimens, type I ceramics

The liquid used in the preparation of test specimens shall be water that complies with the requirements for grade 3 water, ISO 3696 or, when applicable, the modelling fluid recommended by the manufacturer of the dental ceramic powder. The required amount of powder shall be taken from the appropriate pool of powder obtained in accordance with 6.1.

8.1.2 Apparatus for mixing

All apparatus for mixing shall be clean and dry.

8.1.2.1 Glass slab or mixing palette.

8.1.2.2 Spatula, made from a non-metallic material that is not readily abraded by the dental ceramic powder (glass is recommended). Instruments used for the mixing procedure shall be made of materials which do not contaminate the ceramic material.

8.1.3 Method of mixing

Combine the mixing liquid and the ceramic powder in the proportions recommended by the manufacturer. Avoid vigorous mixing which will tend to incorporate air bubbles with the paste and, both during and after mixing, examine for compliance with 5.1 and 5.2.1.

8.1.4 Condensation

8.1.4.1 Apparatus

8.1.4.1.1 Open multipart mould (figure 1 or 2) from which the condensed specimen may be removed without distortion.

8.1.4.1.2 Vibration system (table or mechanical brush) with 50 Hz to 60 Hz frequency or in accordance with the manufacturer's instructions.

Dimensions in millimetres

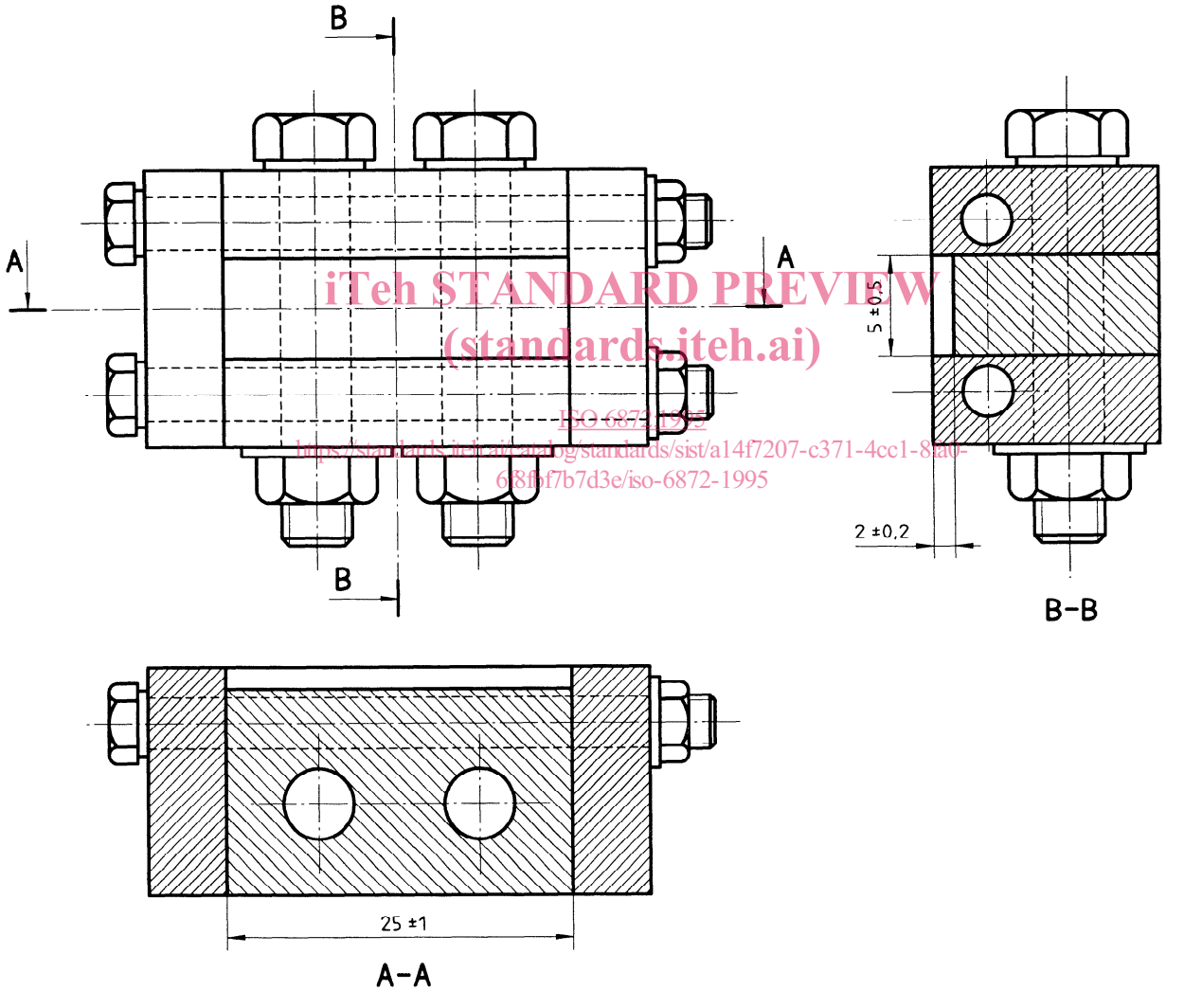
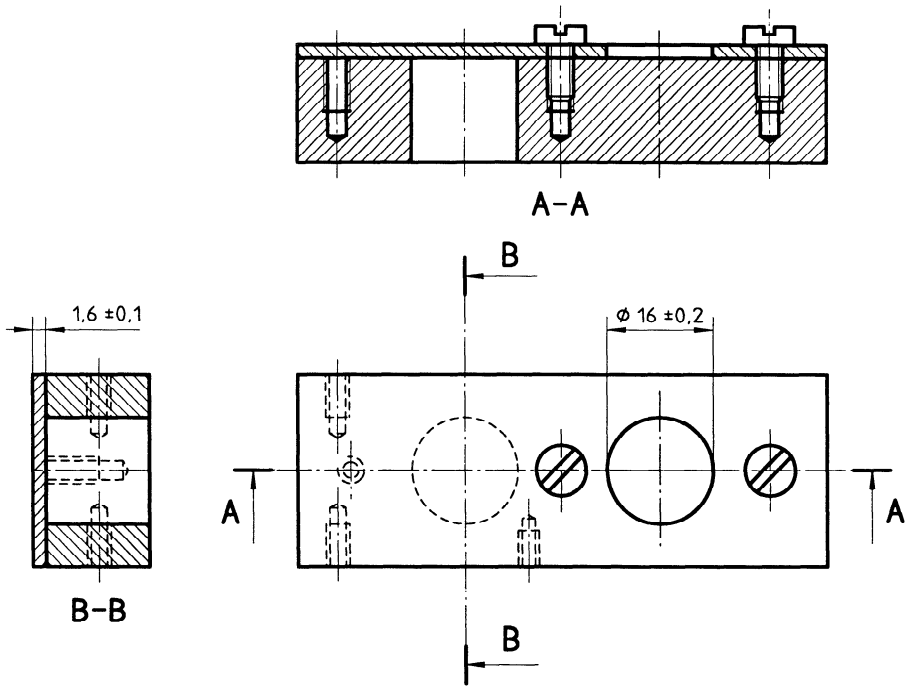


Figure 1 — Mould (25 mm × 5 mm × 2 mm) for use in flexural strength test

Dimensions in millimetres



Materials: PMMA sheet
PTFE rod
Brass or steel screws

Figure 2 — Mould (16 mm diameter × 1,6 mm) for use in chemical solubility test

8.1.4.2 Procedure

Over-fill the mould with dental ceramic paste, and vibrate. When excess liquid appears at the free surface of the specimen, place a paper tissue (or similar absorbent material) on the surface of the specimen, and remove the excess liquid continually by replacing the tissue as soon as it becomes saturated with liquid. Continue vibration and absorption until no further liquid can be removed, and then level the free surface of the condensed specimen by means of a suitable instrument (a bevelled glass microscope slide is ideal for this purpose). After removing the specimen from the mould, place it on a firing tray, dry it in accordance with the manufacturer's instructions [see 9.1.1 a)], and check for compliance with 5.3.

8.1.5 Firing

Position the specimens in the furnace so that they will be uniformly fired, and on a substrate to which they will not adhere and from which there will be no pick-up of material. The manufacturer shall provide specific information for the firing of test specimens. Fire the ceramic specimens according to these instructions.

8.2 Radioactivity of dental ceramic

8.2.1 Preparation of samples

8.2.1.1 Type I ceramics

A 50 g sample as-manufactured is suitable.

8.2.1.2 Type II ceramics

Mill in a tungsten-carbide mill. Sieve and produce 50 g of powder $\leqslant$ 75 µm.

8.2.2 Counting procedure

Use a sample volume of 60 ml bulk powder and determine the radioactive emission by an appropriate technique.

8.2.3 Assessment of results

Each sample tested shall comply with the requirement in 5.2.2.