# INTERNATIONAL STANDARD

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## Dentistry — Artificial teeth for dental prostheses

Art dentaire — Dents artificielles pour prothèses dentaires

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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.

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 22112 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthodontic materials*.

This first edition cancels and replaces ISO 3336:1993, ISO 4824:1993 and ISO 4824:1993/Amd. 1:1997 which have been technically revised. (standards.iteh.ai)

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## **Dentistry** — Artificial teeth for dental prostheses

### 1 Scope

This International Standard specifies the classification, requirements, and test methods for synthetic polymer and ceramic teeth that are manufactured for use in prostheses used in dentistry.

#### 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 483 <sup>1)</sup>, Plastics — Small enclosures for conditioning and testing using aqueous solutions to maintain the humidity at a constant value

ISO 1567:1999, Dentistry — Denture base polymers

ISO 1942 <sup>2)</sup>, Dentistry — Vocabulary (standards.iteh.ai)

ISO 3950:1984, Dentistry — Designation system for teeth and areas of the oral cavity https://standards.itch.a/catalog/standards/sist/64b9910e-c0db-4955-a1ed-

ISO 6873:1998, Dental gypsum products 65c59806c/iso-22112-2005

ISO 7491:2000, Dental materials — Determination of colour stability

#### 3 Terms and definitions

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

#### 3.1

#### diatoric teeth

teeth designed to be retained by anchorage slots and/or holes

#### 3.2

#### pin teeth

teeth designed to be retained by headed pins

#### 3.3

#### set

set of six anterior teeth or eight posterior teeth, as received from the manufacturer

<sup>1)</sup> To be published. (Revision of ISO 483:1988)

<sup>2)</sup> To be published. [Revision of ISO 1942 (all parts):1989]

#### 3.4

#### half-set

three teeth on one side of a set of anterior teeth or four teeth on one side of a set of posterior teeth

#### 3.5

#### mould chart

chart representing the form, shape and dimensions of all individual teeth of a set

#### 4 Classification

Artificial teeth are grouped in accordance with the following classification:

- a) Type 1: anterior teeth;
- b) Type 2: posterior teeth.

#### 5 Requirements

#### 5.1 General

#### 5.1.1 Biocompatibility

Specific qualitative and quantitative requirements for freedom from biological hazard are not included in this International Standard, but it is recommended that, in assessing possible biological or toxicological hazards, reference be made to ISO 10993-1 and ISO 7405.

#### 5.1.2 Dimensions of teeth

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The dimensions of the teeth when examined in accordance with 7025 shall not differ by more than 5 % for synthetic polymer teeth and 7 % for ceramic teeth from the values shown in the manufacturer's mould chart.

#### 5.1.3 Colour and blending of shades

When tested in accordance with 7.3, sets of anterior and posterior teeth shall exhibit no perceptible colour difference compared with the manufacturer's shade guide (8.2.2) or nominated shade guide. Blended teeth shall show no line of demarcation between incisal and cervical portions on the facial aspects of the teeth.

NOTE This requirement is not intended to disallow especially designed demarcations placed to simulate borders of restorations or enamel imperfections found in natural teeth.

#### 5.1.4 Surface finish

When inspected visually in accordance with 7.1, the teeth as received (excluding retention areas) shall have a smooth, lustrous, non-porous surface.

When ceramic teeth are tested in accordance with 7.4, the processing shall not have impaired the original finish of the teeth, and the teeth shall be capable of being ground and polished.

When synthetic polymer teeth are tested in accordance with 7.5, the teeth shall be capable of being polished to restore the original finish.

#### 5.1.5 Freedom from porosity and other defects

Ceramic teeth shall not show more than a total of 16 pores of diameter greater than 30  $\mu$ m on the four test surfaces when tested in accordance with 7.6. No more than six of those pores shall have diameters ranging from  $\geqslant$  40  $\mu$ m and  $\leqslant$  150  $\mu$ m. There shall be no pores of diameter greater than 150  $\mu$ m.

Synthetic polymer teeth, when examined in accordance with 7.7, shall exhibit no porosity or defect, such as rough trimming, rough finish or visible impurities, on the coronal surfaces.

#### 5.2 Ceramic teeth

#### 5.2.1 Radioactivity

When tested in accordance with 7.8, ceramic teeth shall have an activity concentration of no more than 1,0 Bq·g<sup>-1</sup> of uranium–238.

#### 5.2.2 Anchorage

All ceramic diatoric teeth, examined in accordance with 7.9, shall provide a means of positive retention and have holes all of which shall be open and unsealed.

#### 5.2.3 Resistance to thermal shock

Ceramic teeth shall, when tested in accordance with 7.10, show no signs of cracking.

#### 5.3 Synthetic polymer teeth

#### 5.3.1 Bonding to denture base polymers

All synthetic polymer teeth shall be capable of being bonded to heat-polymerized denture-base materials (Type 1), which conform to ISO 1567:1999. For five out of the six test specimens, the bond formed between the ridge lap portion of the teeth and the denture base polymer shall pass the test described in 7.11.

#### 5.3.2 Resistance to blanching, distortion and crazing

https://standards.itch.ai/catalog/standards/sist/64b9910e-c0db-4955-a1ed-When tested in accordance with 7.12 no teeth shall exhibit blanching or distortion. No teeth shall exhibit crazing with the exception of the ridge lap surfaces and the cervical portion of the teeth up to the cervical line.

#### 5.3.3 Colour stability

When tested in accordance with 7.13, there shall be no perceptible colour change between the exposed and unexposed halves of the tooth and the unexposed tooth.

#### 5.3.4 Dimensional stability

When tested in accordance with 7.14, the dimensional change of a tooth shall be within  $\pm$  2 % of its original mesio-distal dimension.

### 6 Sampling

The sample shall consist of six groups, each comprising sets of mandibular and maxillary anterior and posterior teeth (if available).

For comparisons with the manufacturer's shade guide, all available shades of anterior teeth and five shades of available posterior teeth shades shall be included.

Five mould sizes shall be included covering the range of mould sizes shown by the manufacturer's mould chart. The teeth shall be representative of the physical dimensions of the brand and type.

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#### 7 Inspection and test methods

#### 7.1 Visual inspection

Visually examine without magnification all the teeth in each set for compliance with the requirements given in 5.1.3 and 5.1.4.

#### 7.2 Dimensions of teeth

#### 7.2.1 Apparatus

**7.2.1.1 Micrometer**, accurate to  $\pm$  0,01 mm and fitted with parallel steel face pieces.

#### 7.2.2 Procedure

Measure the maximum mesio-distal dimension of each upper  $(l_1, l_5)$  and lower  $(l_3, l_7)$  set of teeth (see Clause 6) in the in-line plane for conformity to the mould chart dimensions (see 5.1.2). Measure the maximum mesio-distal  $(l_2, l_4)$  and cervico-incisal  $(h_1, h_2)$  dimensions of the upper and lower left central incisors (21, 31), and the overall facio-lingual  $(l_6, l_8)$  dimensions of the crowns of the upper and lower left first molars (26, 36), using a micrometer (7.2.1.1). See Figure 1 for these dimensions given in parentheses. The numerical tooth designations given in parentheses are in accordance with ISO 3950:1984.

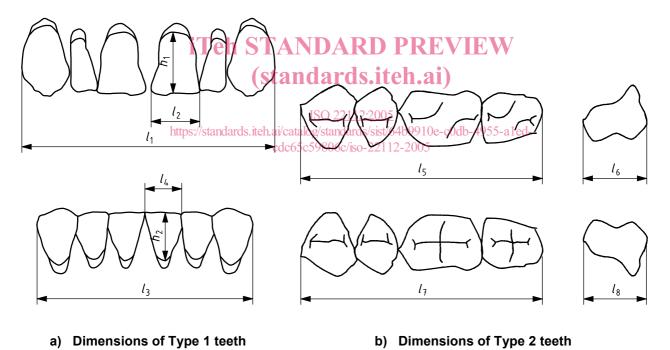


Figure 1 — Dimensions of teeth to be measured

#### 7.3 Comparison with shade guide

Select a maxillary central incisor of all available anterior shades and/or a maxillary premolar tooth (see Clause 6) from each of the five different posterior tooth shades for evaluation. Evaluate in accordance with ISO 7491:2000, 3.2.3. Compare the labial surfaces of each tooth to be tested to the shade guide by holding the tooth alongside and in the same plane as the corresponding shade guide tooth, with the test tooth first on one side of the shade guide tooth and then on the other. The tooth complies with 5.1.3 if there is no perceptible colour difference.

#### 7.4 Surface finish of ceramic teeth

#### 7.4.1 Apparatus and materials

- **7.4.1.1 Denture base polymer**, Type 1, complying with ISO 1567:1999.
- **7.4.1.2 Dental laboratory equipment**, for denture flasking, processing, finishing and wet polishing.
- **7.4.1.3 Dental gypsum for investment**, complying with ISO 6873:1998 (Type 2 or Type 3).
- 7.4.1.4 Dental modelling wax.
- **7.4.1.5** Wet 300 grit silicon carbide lathe wheel, of diameter  $(63 \pm 3)$  mm and thickness  $(4,7 \pm 0,3)$  mm, capable of being rotated at  $(1 700 \pm 300)$  r/min.

#### 7.4.2 Processing

#### 7.4.2.1 Preparation of specimens

Process a group of three teeth from different moulds of Type 1 teeth and likewise from Type 2 teeth to a denture base polymer (7.4.1.1), using the dental laboratory equipment (7.4.1.2) and accepted denture compression packing techniques, and following the manufacturer's instructions. Use a gypsum product (7.4.1.3) and a suitable modelling wax (7.4.1.4).

## 7.4.2.2 Procedure iTeh STANDARD PREVIEW

After deflasking, using dental laboratory equipment and techniques, remove any surplus denture base material from those surfaces of the teeth that are normally exposed. Polish the teeth with dental laboratory equipment (7.4.1.2) taking care to keep the polishing tools wet where appropriate.

After polishing, examine the teeth visually for compliance with 5.1.4 and for evidence of any damage suffered in processing, excluding accidental damage by the equipment used in processing.

#### 7.4.3 Grinding

#### 7.4.3.1 Preparation of specimens

Using the lathe wheel (7.4.1.5), carefully grind the occlusal surfaces of posterior teeth or the incisal edges of anterior teeth from the sample of the processed teeth from 7.4.2, removing a layer of ceramic material approximately 1 mm thick. Rotate the wheel at  $(1\ 700\pm300)\ r/min$ . Take care to avoid overheating the teeth during grinding.

#### 7.4.3.2 Procedure

Using dental laboratory equipment and techniques (7.4.1.2), polish the ground surfaces and examine for compliance with 5.1.4.

#### 7.5 Surface finish of synthetic polymer teeth

#### 7.5.1 Apparatus and materials

- **7.5.1.1 Denture base polymer**, Type 1, complying with ISO 1567:1999.
- **7.5.1.2 Dental laboratory equipment**, for denture flasking, processing, finishing, and wet polishing.
- **7.5.1.3** Timer, accurate to  $\pm 1$  s.

- **7.5.1.4** Precipitated calcium carbonate (chalk), of a dental polishing grade.
- **7.5.1.5** Soft 18- to 36-ply muslin wheel, capable of rotating at a circumferential speed of  $(650 \pm 350)$  m/min.
- NOTE A wheel with a diameter of 70 mm rotating at 1 500 r/min will have a circumferential speed of 330 m/min.
- **7.5.1.6** Silicon carbide wheel or silicon carbide impregnated rubber wheel, of less than 65  $\mu$ m grit, approximately 20 mm diameter and 5 mm width.
- **7.5.1.7 Pumice powder**, medium grain size.

#### 7.5.2 Processing

#### 7.5.2.1 Preparation of specimens

Bond a group of three teeth from different moulds of Type 1 teeth and likewise from Type 2 teeth to a denture base polymer (7.5.1.1), following the manufacturer's instructions for the denture base polymer.

#### 7.5.2.2 Procedure

After curing and deflasking (7.5.1.2) the tooth/polymer specimen, polish the teeth for no longer than 1 min (7.5.1.3) using wet chalk (7.5.1.4) and the muslin wheel (7.5.1.5) at a circumferential speed of  $(650 \pm 350)$  m/min. Maintain a distance of at least 10 mm between the outer diameter of the wheel and the stitching or other reinforcement. Examine the teeth for compliance with 5.1.4/

After completion of the first polishing step, grind the occlusal surface of one of the processed posterior teeth or the incisal edge of the processed anterior teeth with the silicon carbide wheel (7.5.1.6) being careful to avoid excessive temperature rise. Then polish the ground surface using pumice powder (7.5.1.7) for 1 min (7.5.1.3). Then polish with chalk (7.5.1.4) and the muslin wheel (7.5.1.5) for no longer than 1 min (7.5.1.3). After polishing, examine the teeth for compliance with 5:1.4 and ards/sist/64b9910e-c0db-4955-aled-cdc65c59806c/iso-22112-2005

#### 7.6 Porosity of ceramic teeth

#### 7.6.1 Apparatus and materials

- 7.6.1.1 Diamond wheel with lubricant.
- **7.6.1.2 Mounting material** such as autopolymerizing poly(methyl methacrylate) (PMMA).
- 7.6.1.3 Equipment for the preparation of polished sections.
- **7.6.1.4** Silicon carbide paper for grinding, 240 to 600 grit.
- **7.6.1.5 Diamond paste** or **powde**r, of 3,0 µm grade.
- **7.6.1.6 Optical microscope**, capable of 100× magnification, with photographic equipment.

#### 7.6.2 Preparation of specimens

Cut two Type 1 teeth and two Type 2 teeth of a set in their long axis, using a diamond wheel under lubrication (7.6.1.1). Embed the four halves, exposing the cut surfaces, in the mounting material (7.6.1.2). Polish the exposed surfaces (7.6.1.3) by progressively grinding with wet silicon carbide paper (7.6.1.4), commencing with 240 grit and finishing with 600 grit paper. Use 3,0  $\mu$ m grade diamond paste or powder (7.6.1.5) for the final polish such that a clear definition in each half of the tooth is visible using the optical microscope (7.6.1.6).

#### 7.6.3 Procedure

Examine each of the four specimens in the following way. View the section under the microscope (7.6.1.6) using incident reflected light and select the area with the highest porosity (but not in the region of the core, if present). Prepare a photomicrograph with a final enlargement of approximately  $100\times$ ; a gauge mark should be included to facilitate determination of pore diameters. Inspect the photomicrograph and again select the region with the highest porosity. Count the pores in a circular area representing 1 mm diameter on the specimen, and record the following:

- a) the number of pores with diameters between 30 µm and 40 µm;
- b) the number of pores with diameters between 41 μm and 150 μm;
- c) whether or not any pore has a diameter greater than 150 µm.

Examine the results for compliance with 5.1.5.

Alternative methods such as scanning electron microscopy or image analysis may be used in place of optical microscopy.

### 7.7 Porosity of synthetic polymer teeth and other defects

#### 7.7.1 Apparatus and materials

- 7.7.1.1 Low-speed cooled saw or wet-grinding equipment.
- **7.7.1.2 Abrasive paper**, of mean grit particle size 8 μm to 20 μm, corresponding to grit grade 1 000.
- **7.7.1.3 Micrometer**, accurate to  $\pm$  0,01 mm and fitted with parallel steel face pieces.

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7.7.1.4 Instrument capable of 8x to 10x magnification 910e-c0db-4955-a1ed-

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#### 7.7.2 Procedure

Provide a flat surface  $(1.5 \pm 0.5)$  mm from the incisal edge or cusp tips of two anterior teeth from different moulds and two posterior teeth from different moulds using either a low-speed cooled saw or by wet grinding (7.7.1.1). Produce another approximately parallel surface, by removal of the lower coronal region and fitting surface, to provide a specimen thickness of  $(2.5 \pm 0.5)$  mm (see Figure 2) using abrasive paper (7.7.1.2). Measure the dimensions with the micrometer (7.7.1.3).

Examine the tooth specimen surfaces with the magnifying instrument (7.7.1.4) for compliance with 5.1.5.

NOTE Ground surfaces are at right angles to the long axes of the teeth.