INTERNATIONAL STANDARD

ISO 22112

Second edition
2017-08

Dentistry — Artificial teeth for dental prostheses

Médecine bucco-dentaire — Dents artificielles pour prothèses dentaires

Reference number
ISO 22112:2017(E)

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Foreword

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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).

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For an explanation on 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 the following URL: www.iso.org/iso/foreword.html.

This document was prepared by ISO/TC 106 *Dentistry*, Subcommittee SC 2 *Prosthodontic materials*.

This second edition cancels and replaces the first edition (ISO 22112:2005), which has been technically revised.

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

— clarification of colour and blending requirement for multi-layered teeth (5.1.3);

— clarification of test procedure for surface finishing (7.5);

— for testing of radioactivity of ceramic teeth: gamma spectroscopy system is added (7.8).

Dentistry — Artificial teeth for dental prostheses

1 Scope

This document specifies the classification, requirements, and test methods for artificial teeth such as ceramic teeth and polymer teeth that are industrially manufactured for use in dental prostheses.

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 483, *Plastics — Small enclosures for conditioning and testing using aqueous solutions to maintain the humidity at a constant value*

ISO 1942, *Dentistry — Vocabulary*

ISO 3950, *Dentistry — Designation system for teeth and areas of the oral cavity*

ISO 6344-1, *Coated abrasives — Grain size analysis — Part 1: Grain size distribution test*

ISO 6873:2013, *Dentistry — Gypsum products*

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

ISO 20795-1, *Dentistry — Base polymers — Part 1: Denture base polymers*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 and ISO 20795-1 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://www.iso.org/obp

3.1
artificial teeth
manufactured product designed to simulate and replace natural teeth

3.2
diatoric teeth
teeth designed to be retained by anchorage slots and/or holes

3.3
pin teeth
teeth designed to be retained by headed pins

3.4
set
set of six anterior teeth or eight posterior teeth, as received from the manufacturer

3.5
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

3.6
mould chart
chart representing the form, shape and dimensions of all individual teeth of a set

4 Classification

For the purposes of this document, artificial teeth are classified into the following types:

— Type 1: anterior teeth;

— 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 document, 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

The designation of the teeth shall be as given in ISO 3950.

The dimensions of the teeth when examined in accordance with 7.2 shall not differ by more than 5 % for 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. Multi-layered 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 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 Porosity and other defects

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

Examine the ceramic teeth in accordance with 7.6.

Polymer teeth shall exhibit no porosity or defect, such as rough trimming, rough finish or visible impurities, on the coronal surfaces.

Examine the polymer teeth in accordance with 7.7.

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 $Bq \cdot g^{-1}$ 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 Polymer teeth

5.3.1 Bonding to denture base polymer

All polymer teeth shall be capable of being bonded to heat-polymerizable denture-base materials which conform to ISO 20795-1. 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 specified in 7.11.

NOTE Additional information for another bonding test between polymer teeth and denture base polymer is given in ISO/TS 19736.

5.3.2 Resistance to blanching, distortion and crazing

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 ± 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.

7 Measurement 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 Reagents and/or materials

7.2.1.1 Teeth sample (see Clause 6).

7.2.2 Apparatus

7.2.2.1 Micrometer, accurate to ± 0,01 mm and fitted with parallel anvils.

7.2.2.2 Mould chart.

7.2.3 Procedure

Figure 1 defines the symbols for the dimensions (given in parentheses as l_1 to l_8).

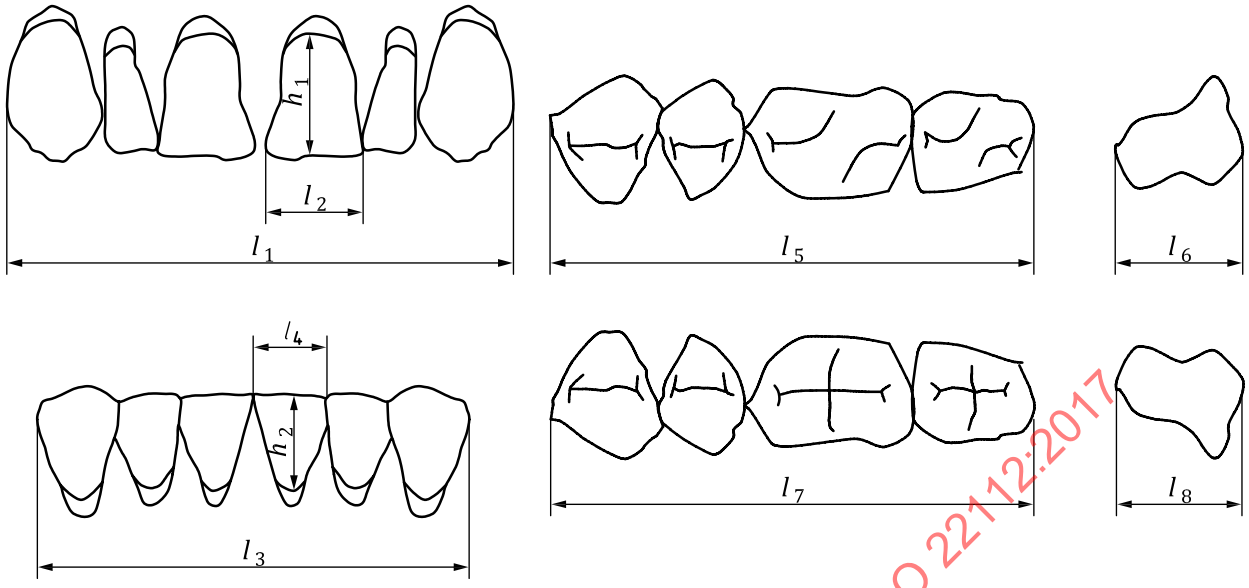
Use a micrometer (7.2.2.1) for the following measurements.

Measure the maximum mesio-distal dimension of each upper (l_1, l_5) and lower (l_3, l_7) set of teeth (7.2.1.1) in the in-line plane.

NOTE The numerical tooth designations (given in parentheses) are in accordance with ISO 3950.

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).

Check the measured values for conformity to the mould chart dimensions (see 5.1.2).



a) Dimensions of Type 1 teeth

b) Dimensions of Type 2 teeth

Figure 1 — Dimensions of teeth

7.3 Comparison with shade guide

7.3.1 Reagents and/or materials

7.3.1.1 Teeth sample (see Clause 6).

7.3.2 Apparatus

7.3.2.1 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.

If there is no perceptible colour difference, the tooth complies with 5.1.3.

7.4 Surface finish of ceramic teeth

7.4.1 Reagents and/or materials

7.4.1.1 Denture base polymer, heat-polymerizable, complying with ISO 20795-1.

7.4.1.2 Dental gypsum, for investment, complying with ISO 6873:2013, Type 2 or Type 3.

7.4.1.3 Dental modelling wax.

7.4.1.4 Lathe wheel, 300 grit silicon carbide, of diameter (63 ± 3) mm and thickness (4,7 ± 0,3) mm, capable of being rotated at (1 700 ± 300) r/min.

7.4.2 Apparatus

7.4.2.1 Dental laboratory equipment, for denture flasking and deflasking, processing, finishing and wet polishing.

7.4.3 Processing

7.4.3.1 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). Use dental laboratory equipment (7.4.2.1) and accepted denture compression packing techniques and follow the manufacturer's instructions. Use dental gypsum (7.4.1.2) and a suitable dental modelling wax (7.4.1.3).

7.4.3.2 Procedure

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

After this 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 dental laboratory equipment used in processing.

7.4.4 Grinding

7.4.4.1 Preparation of specimens

Use the wet lathe wheel (7.4.1.4) and carefully grind the occlusal surfaces of posterior teeth or the incisal edges of anterior teeth from the sample of the processed teeth from 7.4.3. Remove a layer of ceramic material approximately 1 mm thick. Rotate the wheel at (1 700 ± 300) r/min. Take care to avoid overheating the teeth during grinding.

7.4.4.2 Procedure

Use dental laboratory equipment and techniques and polish the ground surfaces. Examine for compliance with 5.1.4.

7.5 Surface finish of polymer teeth

7.5.1 Reagents and/or materials

7.5.1.1 Teeth sample (see Clause 6).

7.5.1.2 Denture base polymer, heat-polymerizable, complying with ISO 20795-1.

7.5.1.3 Precipitated calcium carbonate (chalk), of a dental polishing grade.

7.5.1.4 Muslin wheel, soft, 18- to 36-ply, capable of rotating at a circumferential speed of (650 ± 350) m/min.

NOTE A wheel with a diameter of 70 mm rotating at 1 500 r/min has a circumferential speed of 330 m/min.

7.5.1.5 Grinding wheel, silicon carbide or silicon carbide impregnated rubber, of less than 65 µm grit, approximately 20 mm diameter and 5 mm width.

7.5.1.6 Pumice powder, medium grain size.

7.5.2 Apparatus

7.5.2.1 Dental laboratory equipment, for denture flasking and deflasking, processing, finishing, and wet polishing.

7.5.2.2 Timer, accurate to ± 1 s.

7.5.3 Processing

7.5.3.1 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 (7.5.1.2), following manufacturer's instructions for the denture base polymer.

7.5.3.2 Procedure

Cure and deflask the tooth/polymer specimen by using dental laboratory equipment (7.5.2.1). Then polish the teeth for no longer than 1 min. Use wet chalk (7.5.1.3) and the muslin wheel (7.5.1.4) at a circumferential speed of (650 ± 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 and the incisal edge of one of the processed anterior teeth with the grinding wheel (7.5.1.5). Be careful to avoid excessive temperature rise. Then polish for 1 min the ground surface using pumice powder (7.5.1.6). Then polish with chalk (7.5.1.3) and the muslin wheel (7.5.1.4) for no longer than 1 min.

After polishing, examine the teeth for compliance with 5.1.4.

7.6 Porosity of ceramic teeth and other defects

7.6.1 Reagents and/or materials

7.6.1.1 Teeth sample (see Clause 6).

7.6.1.2 Diamond wheel, with lubricant.

7.6.1.3 Mounting material, such as autopolymerizing PMMA (polymethylmethacrylate).

7.6.1.4 Silicon carbide paper for grinding, 240 to 600 grit, in accordance with ISO 6344-1.

7.6.1.5 Diamond paste or powder, of 3,0 µm grade.

7.6.2 Apparatus

7.6.2.1 Equipment for the preparation of polished sections.

7.6.2.2 Optical microscope, capable of 100 × magnification.

7.6.2.3 Photomicrographic equipment.

7.6.3 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 (7.6.1.2). Embed the four halves, exposing the cut surfaces, in the mounting material (7.6.1.3). Polish the exposed surfaces 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 µm 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 (7.6.2.2).

7.6.4 Procedure

Examine each of the four specimens in the following way. View the section under the optical microscope (7.6.2.2) 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 (7.6.2.3) with a final enlargement of approximately 100 ×; 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 40 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 polymer teeth and other defects

7.7.1 Reagents and/or materials

7.7.1.1 Teeth sample (see Clause 6).

7.7.1.2 Abrasive paper, of mean grit particle size 8 µm to 20 µm, corresponding to grit grade 1 000, in accordance with ISO 6344-1.

7.7.2 Apparatus

7.7.2.1 Low-speed cooled saw or **wet-grinding equipment**.

7.7.2.2 Micrometer, accurate to ± 0,01 mm and fitted with parallel anvils.

7.7.2.3 Magnifying instrument, capable of 10 × magnification.

7.7.3 Procedure

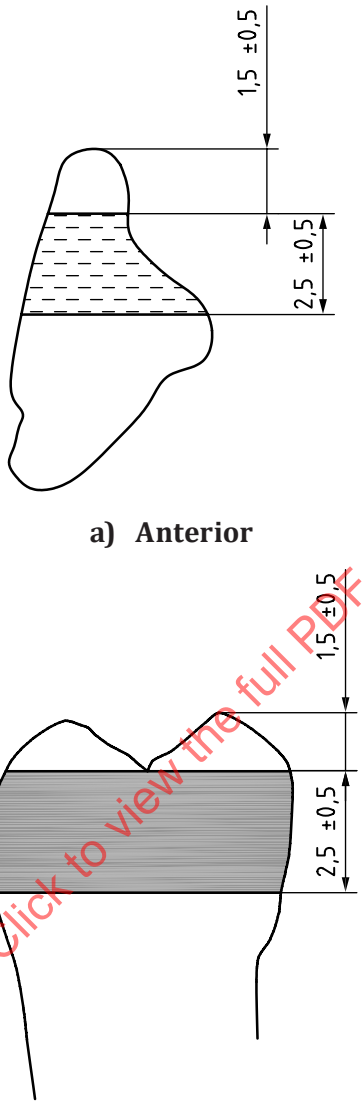
Provide a flat surface (1,5 ± 0,5) mm from the incisal edge or cusp tips of two anterior teeth from different moulds and two posterior teeth from different moulds using either a low-speed cooled saw or by wet grinding (7.7.2.1). Produce another approximately parallel surface, by removing of the lower coronal region and fitting surface, to provide a specimen thickness of (2,5 ± 0,5) mm (see Figure 2) using abrasive paper (7.7.1.2).

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

Measure the dimensions with the micrometer (7.7.2.2).

Examine the tooth specimen surfaces with the magnifying instrument (7.7.2.3) for compliance with 5.1.5.

Dimensions in millimetres



a) Anterior

b) Posterior

Figure 2 — Specimen tooth thickness for the porosity test (see 7.7)

7.8 Radioactivity of ceramic teeth

7.8.1 Reagents and/or materials

7.8.1.1 Teeth sample (see Clause 6).

7.8.2 Apparatus

7.8.2.1 Mill, made of tungsten carbide or alumina ceramic.

7.8.2.2 Sieve, mesh width of 75 µm, capable of sieving particles less than 75 µm.

7.8.2.3 Equipment for neutron activation.

7.8.2.4 Gamma spectrometry system.

7.8.3 Sample preparation

If the ceramic teeth contain pins, crush lightly to remove pins, and then continue milling in a mill (7.8.2.1). Sieve the powder with a sieve (7.8.2.2) and obtain 10 g of powder with particle size less than 75 µm.

Containers and equipment in contact with the ceramic teeth material shall be free of radioactivity when testing.

7.8.4 Counting procedure

Use a sample volume of 10 g bulk powder. Determine the activity concentration of uranium-238 by neutron activation (7.8.2.3) or gamma spectroscopy (7.8.2.4).

7.8.5 Assessment of results

The sample tested shall comply with the requirements in 5.2.1.

7.9 Anchorage of ceramic teeth to denture base polymers

7.9.1 Reagents and/or materials

7.9.1.1 Teeth sample (see Clause 6).

7.9.2 Apparatus

7.9.2.1 Stiff wire, of at least (1,0 ± 0,1) mm diameter.

A stainless steel wire with high tensile is suitable.

7.9.3 Procedure

Visually examine each tooth of two sets of diatoric teeth (16 teeth) and ascertain whether the anchorage slots and/or holes are capable of providing positive retention for the denture base material. If holes are provided, probe with the stiff wire (7.9.2.1) to a depth of at least 0,5 mm.

Check for compliance with 5.2.2.

7.10 Resistance of ceramic teeth to thermal shock

7.10.1 Reagents and/or materials

7.10.1.1 Teeth sample (see Clause 6).

7.10.1.2 Cleansing solution.

A 10 g/l solution of household detergent is suitable.

7.10.2 Apparatus

7.10.2.1 Perforated container, of non-corrodible metal of suitable capacity to contain at least 28 teeth.

7.10.2.2 Oven, maintained at (100 ± 2) °C.

7.10.2.3 Timer, accurate to ± 1 s.

7.10.2.4 Metal container, with ice water at (1 ± 1) °C, sufficiently large to enable the perforated container to be completely immersed.

7.10.2.5 Light source, of minimum illuminance of 1 000 lx, suitable for transillumination.

7.10.2.6 Magnifying instrument, capable of 10 × magnification.

7.10.3 Preparation of specimens

Use the cleansing solution (7.10.1.2) and thoroughly clean two sets of Type 1 and Type 2 teeth of the same mould and shade. Remove all traces of adherent wax. Rinse the teeth with water.

7.10.4 Procedure

Place the teeth in the perforated container (7.10.2.1) and transfer it to the oven (7.10.2.2) at (100 ± 2) °C. After (20 ± 1) min, remove the perforated container and immediately (within 3 s) immerse it in the metal container with ice water (7.10.2.4). After immersion for no less than 30 s, remove the perforated container and return it to the oven at (100 ± 2) °C for further (15 ± 1) min. Remove the perforated container and allow to cool to (23 ± 2) °C.

Use high-intensity transillumination (7.10.2.5) and examine each tooth with the magnifying instrument (7.10.2.6) for compliance with 5.2.3.

7.11 Bonding of polymer teeth to denture-base polymers

7.11.1 Reagents and/or materials

7.11.1.1 Teeth sample (see Clause 6).

7.11.1.2 Dental mounting wax.

7.11.1.3 Denture base polymer, heat-polymerizable, complying with ISO 20795-1.

7.11.1.4 Dental gypsum, for investment, complying with ISO 6873:2013, Type 2 or Type 3.

7.11.1.5 Tap water.

7.11.2 Apparatus

7.11.2.1 Metal former, of the design illustrated in Figure 3 a) which incorporates a trough 5 mm wide by 1,5 mm deep for use in mounting the teeth.

7.11.2.2 Dental laboratory equipment, for denture flasking and processing.

7.11.2.3 Water bath(s), capable of being maintained at (70 ± 3) °C and at boiling water temperature (100 ± 1) °C.

7.11.2.4 Timer, accurate to ± 1 s.

7.11.2.5 Tensile testing apparatus, with the specially designed grips illustrated in Figure 3 c).

7.11.3 Procedure

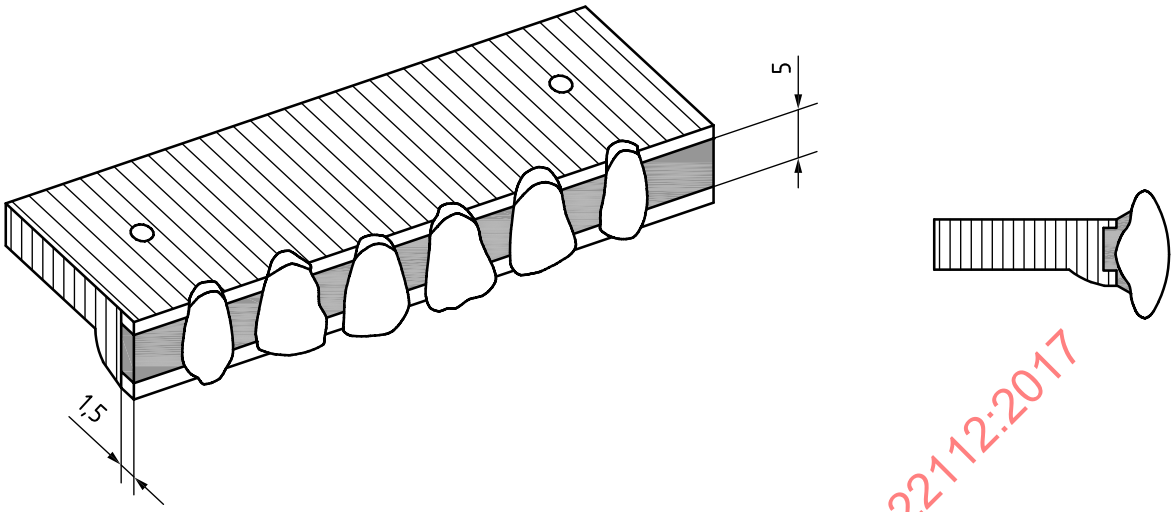
Take six maxillary anterior teeth from at least two different moulds. Mount these teeth on a metal former (7.11.2.1) with dental mounting wax (7.11.1.2), as illustrated in Figure 3 a), so that about one-half of the lingual surface of the incisal portion of the tooth and about one-half of the tooth projects beyond the metal former. Use a denture flask (7.11.2.2), set the mounted teeth in dental gypsum (7.11.1.4) [see Figure 3 b)]. Remove the metal mount and then flush the wax from the teeth with boiling tap water. Process the denture base polymer (7.11.1.3) to the teeth (see 8.3). After proper plasticity has been reached, submerge the clamped flask in water at (70 ± 3) °C in the water bath (7.11.2.3) for (90 ± 1) min and finally immerse in boiling water in the water bath for (30 ± 1) min. When this heating procedure has been completed, cool the denture flask in the clamp in air until room temperature (23 ± 2) °C is reached. Test the plastics-mounted teeth in a tensile testing apparatus (7.11.2.5) designed to permit a direct pull on the incisal part of the lingual surface in a labial direction at a consistent height above the denture base polymer bar [see Figure 3 c)]. Use equipment that does not permit lateral deflection or change of position. Load each tooth, as illustrated in Figure 3 c), at a displacement rate in the range 0,5 mm/min to 10 mm/min, until fracture occurs.

The bond passes the test if the mode of fracture is cohesive within the tooth or the denture base polymer, i.e. there are remnants of tooth remaining bonded to the denture base polymer or there are remnants of denture base polymer remaining bonded to the tooth.

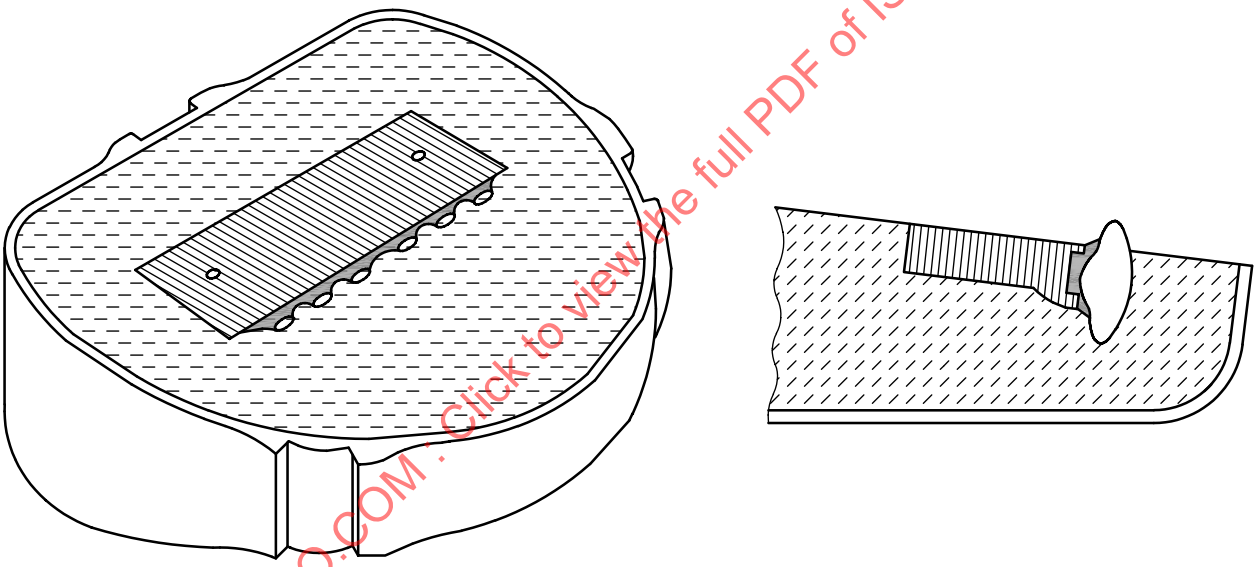
Only pure adhesive interfacial fracture indicates a failure to meet the requirement.

Report the number of teeth for which the bond passes the test and examine for compliance with 5.3.1.

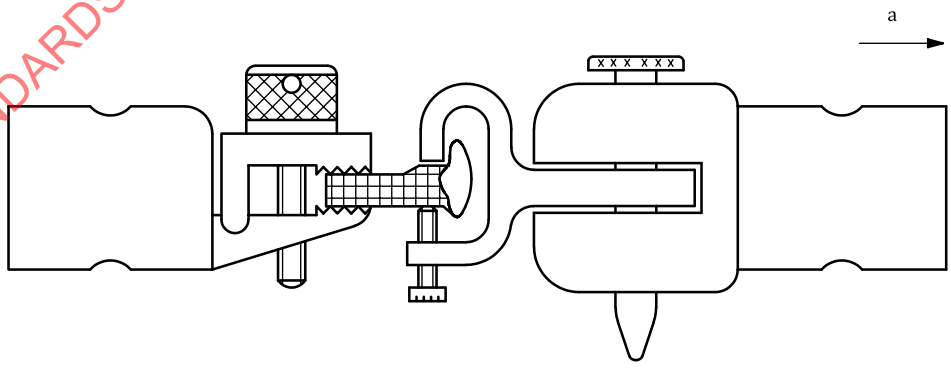
Dimensions in millimetres



a) Teeth mounted on metal former



b) Mounted teeth set in gypsum



c) Tensile-testing apparatus

Key

wax | mould | denture base polymer | tooth | gypsum

a pull

Figure 3 — Apparatus and mould for bonding test

7.12 Resistance to blanching, distortion and crazing of polymer teeth

7.12.1 Sampling

Select two groups of teeth, one group as a control for the other group. One tooth from each of five different sets of five different shades, as defined in Clause 6, shall comprise one group; the counterpart tooth from each of the same five sets shall comprise the other group. This procedure involves exposure of both the test group and the control group to monomer, but the control group is used in the "as received" condition and the test group is used after the conditioning cycle described in 7.12.4. Before exposure to monomer or conditioning, examine each tooth for blanching, distortion or crazing following the procedure in 7.12.5. Teeth that exhibit blanching, distortion or crazing at this stage shall be judged as failing.

7.12.2 Reagents and/or materials

7.12.2.1 Teeth sample (see Clause 6).

7.12.2.2 Methylmethacrylate monomer (without cross linking agent).

7.12.2.3 Absorbent paper tissues.

7.12.2.4 Tap water.

7.12.3 Apparatus

7.12.3.1 Test tube, large, with a stand, for immersion in the water bath.

7.12.3.2 Water bath, capable of being maintained at boiling-water temperature (100 ± 1) °C.

7.12.3.3 Timer, accurate to ± 1 s.

7.12.3.4 Non-absorbent towel.

7.12.3.5 Desiccator, charged with a solution capable of maintaining a relative humidity of (50 ± 5) %, in accordance with ISO 483.

The required conditions may be achieved with a solution of calcium nitrate [$Ca(NO_3)_2$] in the closed desiccator to which an excess of the hydrate [$Ca(NO_3)_2\ 4H_2O$] has been added at least 24 h prior to testing and stored at room temperature. A conditioned room or laboratory with controlled relative humidity (50 ± 5) % can be used instead of the desiccator.

7.12.3.6 White-light inspection unit, flexible fibre-optic.

7.12.3.7 Lighting units, designed as an adjunct to optical microscopy are appropriate.

7.12.3.8 Magnifying instrument, capable of × 10 magnification.

