INTERNATIONAL STANDARD

ISO 1567

Third edition
1999-02-15

Dentistry — Denture base polymers

Art dentaire — Polymères pour base de prothèses dentaires

Contents

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Printed in Switzerland

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 1567 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthodontic materials.*

This third edition cancels and replaces the second edition (ISO 1567:1988), which has been technically revised.

Significant differences between this third edition and the second edition are:

— two new categories of material (light-activated and microwave-cured) have been added as Type 4 and Type 5 to Classification (clause 4);

— requirements and tests previously identified as transverse deflection properties are now identified as "flexural strength" (5.2.7 and 8.5.3.5) and "flexural modulus" (5.2.8 and 8.5.3.5); the determination of flexural strength and flexural modulus require force per unit area calculations;

— a requirement and tests for residual methyl methacrylate monomer content (5.2.10 and 8.7) have been added.

Annex A forms an integral part of this International Standard. Annex B is for information only.

Introduction

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.

Dentistry — Denture base polymers

1 Scope

1.1 This International Standard classifies denture base polymers and copolymers and specifies their requirements. It also specifies the test methods to be used in determining compliance with these requirements. It further specifies requirements with respect to packaging and marking the products and to the instructions to be supplied for use of these materials.

1.2 Although this International Standard does not require manufacturers to declare details of the composition, attention is drawn to the fact that some national or international authorities require such details to be provided.

1.3 This International Standard applies to denture base polymers such as those listed below.

a) Poly(acrylic acid esters);

b) poly(substituted acrylic acid esters);

c) poly(vinyl esters);

d) polystyrene;

e) rubber-modified poly(methacrylic acid esters);

f) polycarbonates;

g) polysulfones;

h) poly(dimethacrylic acid esters);

i) polyacetals (polyoxymethylene);

j) copolymers or mixtures of the polymers listed in a) through i).

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 463: —[1)], *Geometrical product specifications (GPS) — Dimensional measuring instruments: Dial gauges — Design and metrological requirements.*

ISO 1942-1:1989, *Dental vocabulary — Part 1: General and clinical terms.*

[1)] To be published. (Revision of ISO 463:1988)

ISO 1942-2:1989, *Dental vocabulary — Part 2: Dental materials.*

ISO 1942-5:1989, *Dental vocabulary — Part 5: Terms associated with testing.*

ISO 336:1993, *Dentistry — Synthetic polymer teeth.*

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

ISO 7491:1985, *Dental materials — Determination of colour stability of dental polymeric materials.*

ISO 8601:1988, *Data elements and interchange formats — Information interchange — Representation of dates and times.*

3 Definitions

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

3.1
autopolymerizable polymers
products having polymerization initiated by chemical means and not requiring application of verifiable temperatures above 65 °C to complete the process

3.2
capsulated material
material consisting of two or more components supplied in a container which keeps them separated until the time they are mixed together and dispensed for use directly from the container

3.3
denture
artificial substitute for missing natural teeth and adjacent tissues, to include also any additions needed for optimum function

3.4
denture base
that part of a denture which rests on soft tissue foundations and to which teeth are added

3.5
heat-polymerizable polymer
product requiring application of verifiable temperatures above 65 °C to complete polymerization

3.6
immediate container
container which is in direct contact with the denture base materials

3.7
liquid
monomeric fluid to be mixed with polymeric particles to form a mouldable dough or fluid resin mixture used for forming denture bases

3.8
outer packaging
labelled container or wrapping within which other containers are packed

3.9
packing
⟨of a denture⟩ the act of filling a denture base mould with a material (using a compression, pour or injection technique) to form a denture base

3.10
initial packing time
time after mixing, or other preparation, at which a denture base material mixture first reaches packing consistency

3.11
final packing time
the last time, after reaching the initial packing time, at which a denture base material mixture retains packing consistency

3.12
processing
procedure of preparing a solid denture base polymer plate and/or specimen by polymerization or injection moulding

3.13
thermoplastic, adj.
characteristic of a hard polymeric material that allows it to be softened by application of heat to make it mouldable, and then return to the hardened state upon cooling

3.14
translucency
capacity of a body of material to allow the passage of light, yet diffusing the light so as not to render objects lying beyond the body clearly visible

4 Classification

Denture base polymers covered by this International Standard are categorized into the following Types and Classes:

Type 1 : Heat-polymerizable polymers

Class 1 : Powder and liquid

Class 2 : Plastic cake

Type 2 : Autopolymerizable polymers

Class 1 : Powder and liquid

Class 2 : Powder and liquid pour-type resins

Type 3 : Thermoplastic blank or powder

Type 4 : Light-activated materials

Type 5 : Microwave cured materials

5 Requirements

5.1 Unpolymerized material

5.1.1 Liquid component

5.1.1.1 General

The liquid shall consist essentially of monomeric material compatible with the powder.

5.1.1.2 Homogeneity

The liquid shall be free of deposit or sediment that can be observed by visual inspection (8.1).

5.1.2 Solid components

The solid or semisolid components shall be free of extraneous material that can be observed by visual inspection (8.1).

5.1.3 Packing plasticity

When Type 1 Class 1, Type 1 Class 2, Type 2 Class 1, Type 2 Class 2, Type 4 and Type 5 materials are tested in accordance with 8.2, at the initial packing time recommended by the manufacturer, they shall be capable of being intruded into at least two holes in the die (see figure 1) to a depth of not less than 0,5 mm (8.2.3.1.1). Type 1 Class 1, Type 1 Class 2, Type 4 and Type 5 materials shall also meet the requirements when tested at the final packing time (8.2.3.1.2)

5.2 Polymerized material

5.2.1 Biocompatibility

See the Introduction for guidance on biocompatibility

5.2.2 Surface characteristics

When processed in the manner and against materials recommended by the manufacturer, denture base specimens prepared in accordance with 8.4.3, 8.7.2.2 and 8.8.3 should have a smooth, hard and glossy surface.

The specimens for colour stability, the specimens for residual methyl methacrylate monomer and the specimens for sorption and solubility testing shall retain their form without visible distortion after processing.

When polished in accordance with 8.5.1.3, the specimen plates shall present a smooth surface with a high gloss (8.1).

When prepared in accordance with the manufacturer's instructions, all types of denture base polymers shall produce a test specimen plate (8.5.1) with defined edges after deflasking (see figure 3).

5.2.3 Colour

A specimens strip shall show no more than a slight difference when compared with the corresponding shade of the shade guide, when tested in accordance with 8.3 and inspected in accordance with 8.1.

The manufacturer shall provide a shade guide on request.

Coloured denture base polymers shall be translucent (5.2.5 and 8.5.2) and evenly pigmented and/or, where applicable, evenly fibred.

Clear denture base polymers shall be clear and colourless.

5.2.4 Colour stability

When tested in accordance with 8.4 and inspected in accordance with 8.1, test specimens shall not show more than a slight change in colour, perceptible with difficulty.

5.2.5 Translucency

When tested in accordance with 8.5.2.3 the shadow of the illuminated opaque disc shall be visible from the opposite side of the test specimen plate.

5.2.6 Freedom from porosity

When prepared in accordance with 8.5.3.3, specimens strips shall not show voids (8.1) that can be observed by visual inspection.

5.2.7 Flexural strength

When determined in accordance with 8.5.3.5, the flexural strength shall be not less than 65 MPa for Type 1, Type 3, Type 4 and Type 5 polymers and not less than 60 MPa for Type 2 polymers when tested in water at (37 ± 1) °C (see table 1).

5.2.8 Flexural modulus

When determined in accordance with 8.5.3.5, the flexural modulus of the processed polymer shall be at least 2 000 MPa for Type 1, Type 3, Type 4 and Type 5 polymers and at least 1 500 MPa for Type 2 polymers when tested in water at (37 ± 1) °C (see table 1).

5.2.9 Bonding to synthetic polymer teeth

Denture base polymers intended for use with synthetic polymer teeth shall meet one of the following requirements.

a) The polymer shall, when tested in accordance with 8.6, be capable of bonding to polymer teeth complying with the bonding requirements of ISO 3336.

b) If there are problems of achieving bonding, the outer packages and containers shall contain information about special treatments necessary to achieve bonding and/or indicate that further information is provided in the manufacturer's instructions [8.6.3, 9.2.1 k), 9.2.2 k), and 9.3 h)].

5.2.10 Residual methyl methacrylate monomer

When prepared and tested in accordance with 8.7, the following shall apply (see table 1).

The upper limit (maximum) for residual methyl methacrylate is 2,2 % mass fraction for denture base polymers of Type 1, Type 3, Type 4 and Type 5.

The upper limit (maximum) for residual methyl methacrylate is 4,5 % mass fraction for denture base polymers of Type 2.

If lower percentages of residual methyl methacrylate monomer are claimed by the manufacturer, the content shall not be more than 0,2 % higher than that stated by the manufacturer.

5.2.11 Sorption

When the processed polymer is tested in accordance with 8.8, the increase in volumic mass (water sorption) shall not exceed 32 µg/mm^3 for Type 1, Type 2, Type 3, Type 4 or Type 5 polymers (see table 1).

5.2.12 Solubility

When the processed polymer is tested in accordance with 8.8, the loss in volumic mass (soluble matter) shall not exceed 1,6 µg/mm^3 for Type 1, Type 3, Type 4 or Type 5 polymers, and shall not exceed 8,0 µg/mm^3 for Type 2 polymers (see table 1).

Table 1 — Summary of the limits for requirements described in 5.2.7, 5.2.8, 5.2.10, 5.2.11 and 5.2.12

Requirement	Flexural strength [MPa] min.	Flexural modulus [MPa] min.	Residual methyl methacrylate monomer Percent mass fraction max.	Sorption [µg/mm³] max.	Solubility [µg/mm³] max.
Type 1,3,4,5	65	2000	2,2	32	1,6
Type 2	60	1500	4,5	32	8,0

6 Sampling

The test sample shall consist of a retail package or packages, containing sufficient material to carry out the specified tests, plus an allowance for any necessary repetition of the tests. If more than one package is required, all material shall be of the same batch.

7 Preparation of test specimens

7.1 Laboratory environment

Unless otherwise specified in this International Standard or the manufacturer's instructions, the test specimens shall be prepared and tested at (23 ± 2) °C and (50 ± 10) % relative humidity.

7.2 Procedures

Unless otherwise specified in this International Standard, the materials used for making the specimens shall be prepared, manipulated and processed using the equipment and procedures recommended in the manufacturer's instructions (9.3)

A separate mix shall be made for each specimen prepared from a material requiring mixture of two or more ingredients.

7.3 Special equipment

Any special equipment specified by the manufacturer for processing a material shall be made available by the manufacturer (or the manufacturer may prepare injection-moulded specimens, and submit them to the test laboratory).

8 Test methods

8.1 Inspection for compliance determination

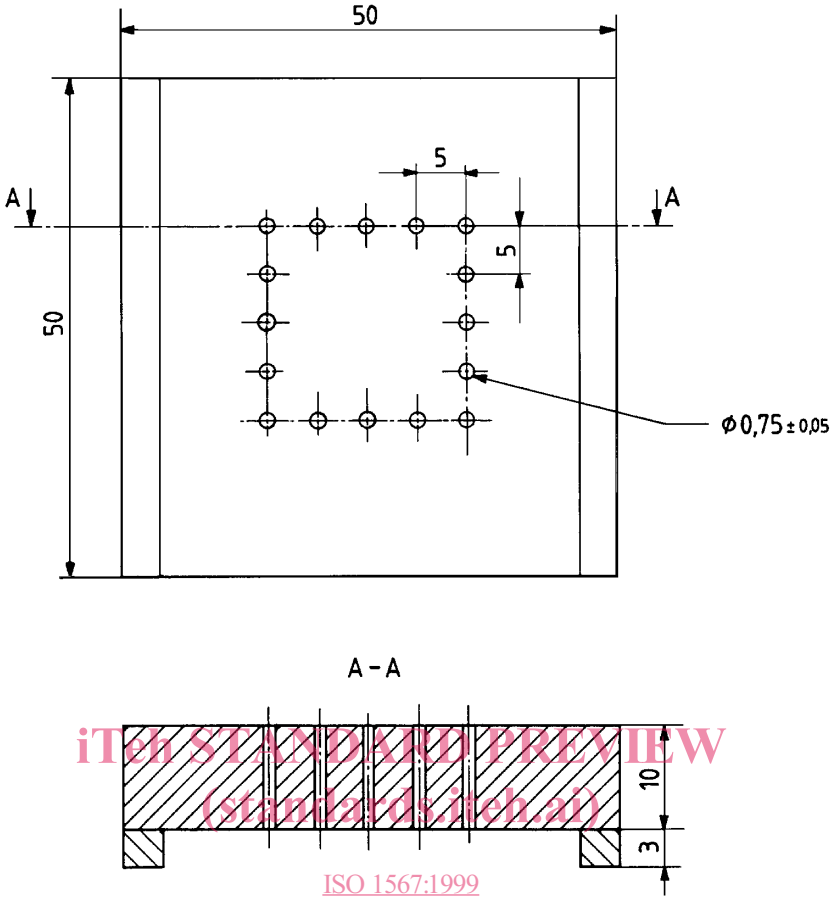
Observe the test samples by visual inspection to determine compliance with the requirements laid down in 5.1.1.2, 5.1.2, 5.2.2, 5.2.3**,** 5.2.4, 5.2.5, 5.2.6 and clause 9. [Inspect for colour (5.2.3) and colour stability (5.2.4) in accordance with ISO 7491].

8.2 Packing plasticity

8.2.1 Apparatus

8.2.1.1 Perforated brass die, having the dimensions shown in figure 1, with perforations having a diameter of (0,75 ± 0,05) mm.

Dimensions in millimetres



NOTE Dimensional tolerances not specified shall be ± 1 mm

Figure 1 — Perforated brass die for packing plasticity test (see 8.2)

8.2.1.2 Glass plate, (60 ± 5) mm x (60 ± 5) mm x (5 ± 1) mm.

8.2.1.3 Weight, capable of exerting a force of (50 ± 1) N.

8.2.1.4 Polyethylene or polyester film, 0,035 mm to 0,050 mm thick and approximately 50 mm by 50 mm.

8.2.1.5 Dial gauge, complying with ISO 463, or **linear gauge** accurate to 0,01 mm, equipped with a probe capable of entering holes in the brass die for measuring depth of penetration of the material into the die.

8.2.2 Test conditions

The perforated brass die (8.2.1.1) and glass plate (8.2.1.2) shall be maintained at conditions specified in 7.1, except where otherwise specified by the manufacturer.

8.2.3 Procedure

8.2.3.1 For Type 1 Class 1, Type 1 Class 2, Type 4 and Type 5

8.2.3.1.1 Initial packing time

Prepare a sample of the material having a mass of 16 g to 20 g. Immediately prior to the manufacturer's recommended initial packing time [9.3 e)], shape one-half of the sample into a cake approximately 5 mm thick,

place it on the upper surface of the brass die (8.2.1.1) and cover it with a plastic sheet (8.2.1.4). At the recommended initial packing time, place the glass plate (8.2.1.2) and the weight (8.2.1.3) on the plastic-covered resin cake. After 10 min ± 30 s, remove the weight. When the material is firm, introduce the measuring instrument probe into each hole from the other side of the brass die, to contact the penetrating material to determine the depth in the hole not penetrated.

Calculate the depth of penetration for each hole according to the following formula:

$$DP = d - d'$$

where

DP is the depth of penetration, in millimetres;

d is the thickness of the brass die, in millimetres;

d' is the the depth not penetrated, in millimetres.

8.2.3.1.2 Final packing time

Immediately before the final packing time [9.3 e)] recommended by the manufacturer, shape the second half of the sample into a cake and test this portion according to 8.2.3.1.1.

8.2.3.2 For Type 2, Class 1

Prepare a sample having a mass 8 g to 10 g. Shape this increment and test it according to the procedure described in 8.2.3.1.1

8.2.3.3 For Type 2, Class 2

Prepare a sample having a mass 8 g to 10 g. Introduce this increment onto the top surface of the brass die at the time recommended by the manufacturer [9.3d)] for pouring the fluid mix into the mould. Determine the depth of penetration values according to the procedure in 8.2.3.1.1

8.2.4 Pass/fail determinations

If the first specimen fails to comply with the requirement stated in 5.1.3, test two additional specimens. If the second and third specimens comply with the requirement, the product passes.

8.2.5 Expression of results

Report the number of holes penetrated to a depth of not less than 0,5 mm by each specimen, and whether the material passes or fails.

8.3 Colour

Compare a specimen strip prepared in accordance with 8.5.3.3, and inspected in accordance with 8.1, with the shade guide for compliance with 5.2.3.

8.4 Colour stability

8.4.1 Materials

8.4.1.1 Sheet of polyester film, having a thickness of (50 ± 25) µm, to cover the steel mould (8.4.2.1).

8.4.1.2 Aluminium foil.

8.4.2 Apparatus

8.4.2.1 Stainless steel mould and cover (Type 1 and Type 2 materials), having the dimensions shown in figure 2, mounted in gypsum in separate halves of a denture flask.