

Dentistry — Denture base polymers

The European Standard EN ISO 1567:2000 has the status of a
British Standard

ICS 11.060.10

National foreword

This British Standard is the official English language version of EN ISO 1567:2000. It is identical with ISO 1567:1999. It supersedes BS EN ISO 1567:1995 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/51, Prosthodontic materials, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this committee can be obtained on request to its secretary.

Cross-references

The British Standards which implement these international or European publications may be found in the BSI Standards Catalogue under the section entitled “International Standards Correspondence Index”, or by using the “Find” facility of the BSI Standards Electronic Catalogue.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

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This British Standard, having been prepared under the direction of the Health and Environment Sector Committee, was published under the authority of the Standards Committee and comes into effect on 15 September 2001

Summary of pages

This document comprises a front cover, an inside front cover, the EN ISO title page, the EN ISO foreword, the ISO title page, pages ii to iv, pages 1 to 27, the annex ZA page, an inside back cover and a back cover.

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(ISO 1567:1999)

Zahnheilkunde - Prothesenkunststoffe (ISO 1567:1999)

This European Standard was approved by CEN on 1 March 2000.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

The text of the International Standard from Technical Committee ISO/TC 106 "Dentistry" of the International Organization for Standardization (ISO) has been taken over as an European Standard by Technical Committee CEN/TC 55 "Dentistry", the secretariat of which is held by DIN.

This European Standard replaces EN ISO 1567:1995

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by October 2000, and conflicting national standards shall be withdrawn at the latest by October 2000.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 1567:1999 has been approved by CEN as a European Standard without any modification.

NOTE: Normative references to International Standards are listed in annex ZA (normative).

INTERNATIONAL STANDARD

**ISO
1567**

Third edition
1999-02-15

Dentistry — Denture base polymers

Art dentaire — Polymères pour base de 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.

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, *Prosthetic 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 3336:1993, *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.