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INTERNATIONAL ORGANIZATION FOR STANDARDIZATION

ISO RECOMMENDATION
R 1567

DENTURE BASE POLYMER

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June 1970

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BRIEF HISTORY

The ISO Recommendation R 1567, *Denture base polymer,* was drawn up by Technical Committee ISO/TC 106, *Dentistry,* the Secretariat of which is held by the British Standards Institution (BSI).

Work on this question led to the adoption of Draft ISO Recommendation No. 1567, which was circulated to all the ISO Member Bodies for enquiry in December 1968. It was approved, subject to a few modifications of an editorial nature, by the following Member Bodies :

Australia
Belgium
Brazil
Canada
Czechoslovakia
Denmark
France
Greece
India
Israel
Korea, Rep. of
Netherlands
New Zealand
Peru
Poland
South Africa, Rep. of
Spain
Sweden
U.A.R.
United Kingdom
U.S.A.
Yugoslavia

The following Member Body opposed the approval of the Draft :

Switzerland

This Draft ISO Recommendation was then submitted by correspondence to the ISO Council, which decided to accept it as an ISO RECOMMENDATION.

ISO Recommendation R 1567 June 1970

DENTURE BASE POLYMER

INTRODUCTION

This ISO Recommendation is technically identical with F.D.I.* Specification No. 3, the only difference being in the wording and layout to bring the text into standard ISO form. Further studies are being undertaken to provide, if necessary, for a future revision of this ISO Recommendation in the light of technological advances supported by well-documented data.

NOTE. – Throughout this ISO Recommendation the figures for SI units are approximate conversions of the technical metric units using the conversion factors 1 N = 0.102 kgf and 1 MN/m^2 = 10.2 kgf/cm^2.

1. SCOPE

This ISO Recommendation gives the classification of and requirements for denture base polymer, together with the test methods to be employed to determine compliance with these requirements.

2. FIELD OF APPLICATION

This ISO Recommendation is applicable to the following denture base polymers :

(*a*) poly(acrylic acid esters);
(*b*) poly(substituted acrylic acid esters);
(*c*) poly(vinyl esters);
(*d*) polystyrene;
(*e*) copolymers or mixtures of the foregoing.

3. CLASSIFICATION

Denture base polymer covered by this ISO Recommendation should be of the following types, classes and colours.

3.1 Type I : Heat-curing polymers

3.1.1 *Class 1.* Powder and liquid
Colour A – Pink
Colour B – Clear

3.1.2 *Class 2.* Plastic cake 5 ± 3 mm thick
Colour A – Pink
Colour B – Clear

3.1.3 *Class 3.* Mouldable blank or powder
Colour A – Pink
Colour B – Clear

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* Fédération Dentaire Internationale.

3.2 Type II : Cold-curing polymers

Colour A – Pink
Colour B – Clear

4. REQUIREMENTS

4.1 Liquid

The liquid should be water-clear and free from deposits or sediment.

4.1.1 *Stability.* The liquid should not thicken when heated in the absence of light in a closed container at 60 ± 2 °C for 24 hours.

4.1.2 *Discolouration.* The liquid should not discolour when exposed in a closed clear glass container to bright diffuse daylight for 24 hours.

4.2 Solids

The powder, plastic cake, or precured blank should be free of extraneous material such as dirt and lint.

4.3 Uncured polymer – Classes 1 and 2

4.3.1 *Class 1 polymer.* This material when mixed as directed in the manufacturer's instructions accompanying the package should be considered ready for packing when the plasticity is such that the polymer separates cleanly from the walls of the glass mixing jar.

The polymer should be ready for packing not more than 40 minutes from the start of the mixing. 5 minutes later the polymer, when subjected to the test described in clause 7.2.1, should be capable of being intruded into at least two holes of the die (see Fig. 1) to a depth of not less than 0.5 mm.

4.3.2 *Class 2 polymer.* This material when treated according to the manufacturer's instructions should be capable of being intruded into at least two holes of the die (see Fig. 1) to a depth of not less than 0.5 mm.

4.4 Cured polymer

4.4.1 *Working qualities.* The polymer when processed according to the manufacturer's instructions should produce a satisfactory denture base material.

4.4.1.1 GLOSSY SURFACE AND DEFECTS. The polymer should have a glossy surface and should show no defects when cured in a gypsum mould lined with tin foil.

4.4.1.2 POLISH. The polymer should present a smooth surface having a high gloss when polished by the conventional dental methods.

4.4.1.3 TOXICITY. The polymer should not be toxic when used as a denture base material.

4.4.2 *Colour.* The depth of colour of the cured polymer should be as specified by the purchaser with reference to the manufacturer's shade guide. The material may be uniformly coloured or mottled. Clear polymer should be colourless and a specimen plate prepared in accordance with clause 7.2.4.1 should be sufficiently transparent to read this paragraph clearly though the plate.

4.4.3 *Translucency.* The coloured polymer, when prepared in accordance with clause 7.2.4.1, should be translucent.

4.4.4 *Porosity.* The polymer, when cut as described in clause 7.2.4.1, should not show bubbles or voids.

4.4.5 *Sorption.* The increase in mass of the polymer should not be more than 0.7 mg/cm^2 of surface after immersion in water for 24 hours at 37 ± 1 °C as described in clause 7.2.2.

4.4.6 *Solubility.* The loss in mass of the polymer should not be more than 0.04 mg/cm^2 of surface when tested in accordance with clause 7.2.3.

4.4.7 *Transverse deflection.* The polymer, in water at 37 ± 1 °C, tested in accordance with clause 7.2.4 should meet the requirements shown in Table 1.

TABLE 1 – **Deflection limits of specimens in transverse test of denture base polymer**

Polymer types	Deflection in millimetres		
	at 35.0 N load*	at 50.0 N load*	
	Maximum	Minimum	Maximum
I and II	2.5	2.0	5.5

* Deflections should be measured from an initial load of 15.0 N to the load indicated.

4.4.8 *Colour stability.* The polymer should not show more than a slight change in colour after 24 hours when tested in accordance with clause 7.2.5.

4.4.9 *Manufacturer's instructions.* Instructions for storing and processing should accompany each package.

(*a*) TYPE I, CLASSES 1 AND 2 POLYMERS

The instructions should include the following, as applicable : powder-liquid ratio, the length of the time for mixing, the time at which the polymer attains the proper plasticity at 23 ± 2 °C, the temperature of the flask when the polymer is packed, the length of time necessary to bring the flask to the recommended curing temperature, the length of time to hold at curing temperature, the method of cooling the flask and the time when the flask may be released.

The manufacturer's instructions should conform to those details mentioned in clause 6.2, and in addition to, but not replacing those described in clause 6.2, the manufacturer may provide one alternative set of instructions. The manufacturer should certify that the polymer will meet the requirements of this ISO Recommendation when it is processed according to the alternative method as well as according to the prescribed method.

(*b*) TYPE I, CLASS 3, AND TYPE II POLYMERS

The instructions for Type I, Class 3, and Type II polymers should be those prescribed by the manufacturer. The manufacturer's instructions should include a method for the repair of the polymer concerned.

5. SAMPLING

The method of procurement and amount of the polymer needed for testing should be the subject of agreement between the parties concerned.

6. PREPARATION OF TEST SPECIMENS

6.1 Mixing

Class 1 polymers should be mixed in accordance with the manufacturer's instructions accompanying the package, except that the mixing temperature should be 23 ± 2 °C.

Likewise, Class 2 polymers should be brought to this temperature prior to testing. Class 1 polymers should be considered ready for packing when the plasticity is such that the polymer separates cleanly from the walls of the glass mixing jar.

6.2 Processing of specimens, for sorption, solubility, transverse deflection and colour stability tests

Specimens of Type I, Classes 1 and 2 polymers should be processed in accordance with the following schedule :

10 minutes after the proper plasticity as specified in clause 4.3.1 has been reached, the specimen (see Fig. 2) having been flasked should then be held in a flask clamp without springs, submerged in water at 73 ± 1 °C for 1 $\frac{1}{2}$ hours and finally immersed in boiling water for 30 minutes.

When this heating schedule has been completed, the flask in the clamp should be cooled in air at 23 ± 10 °C for 30 minutes and immersed in water at 23 ± 10 °C for 15 minutes.

For Type I, Class 3, and Type II polymers, the manufacturer's instructions should be followed.

7. TEST METHODS

7.1 Visual inspection

Visual inspection should be used in determining compliance with the requirements outlined in clauses 4.1, 4.2, 4.4.1.1, 4.4.1.2, 4.4.2, 4.4.3, 4.4.4, 4.4.8 and 4.4.9, and section 8.

7.2 Physical tests

7.2.1 *Packing test.* The packing test for Class 1 polymers should be started 5 minutes after the proper plasticity has been reached. A layer approximately 5 mm thick (6 to 10 g) of Class 1 or 2 polymer should be placed on the perforated brass die (see Fig. 1). The die and specimen should be transferred immediately to an air chamber in which all the equipment has been preheated to within ± 5 °C of the packing temperature specified in the manufacturer's instructions.

A glass plate approximately 5 mm thick and 50 mm square and a 5 kg weight should be placed immediately on the specimen. A sheet of polyethylene should be used as a separator between the glass plate and the specimen. 10 minutes later, the die and the specimen should be removed from the air chamber and the polymer stripped from the die. The depth of intrusion should be measured using a steel scale and magnifying glass or with a dial gauge.

7.2.2 *Sorption*

7.2.2.1 PREPARATION OF TEST SPECIMENS. The water sorption test should be made on two specimen disks 50 ± 1 mm in diameter and 0.5 ± 0.1 mm thick. These specimens should be made using a stainless steel mould (see Fig. 3). The mould should be mounted with gypsum in the flask in the same relative position as the specimen plate shown in Figure 2.

The gypsum in the shallow half of the flask should be poured against a glass plate to obtain a smooth plane surface. The polymer should then be mixed and trial packing conducted with a sheet of polyethylene used as a separator. Before final closure of the flask and processing (see clause 6.2), a sheet of tin foil should be substituted for the polyethylene. All surfaces of the disk should be smooth and the top and bottom surfaces should be flat.

7.2.2.2 PROCEDURE. The specimen disks, prepared as detailed in clause 7.2.2.1, should be dried in a desiccator containing thoroughly dry anhydrous calcium sulphate ($CaSO_4$) or silica gel (freshly dried at 130 °C) at 37 ± 2 °C for 24 hours, removed to a similar desiccator at room temperature for 1 hour, and then weighed with a precision of ± 0.2 mg. This cycle should be repeated until a constant mass is attained, that is, until the mass loss of each specimen disk is not more than 0.5 mg between successive weighings.

The specimen disks should then be immersed in distilled water at 37 ± 1 °C for 24 hours, after which time they should be removed from the water with tweezers, wiped with a clean dry hand towel until free from visible moisture, waved in the air for 15 seconds and weighed 1 minute after removal from the water.

The value for water sorption should be calculated as follows for each disk :

$$\text{Sorption (mg/cm}^2\text{)} = \frac{\text{Mass after immersion (mg)} - \text{Conditioned mass (mg)}}{\text{Surface area (cm}^2\text{)}}$$

The average of the determined values for the two disks should be recorded to the nearest 0.01 mg/cm^2. The final value, the average of two determinations, should be rounded to the nearest 0.1 mg/cm^2.

When the final value falls midway between two numbers the even number should be recorded.

7.2.3 *Solubility in water.* After the final weighing described in clause 7.2.2.2, the disks should be reconditioned to constant mass in the desiccator at 37 ± 2 °C as described in clause 7.2.2.2.

The soluble matter lost during immersion should be determined to the nearest 0.01 mg/cm^2 as follows for each disk :

$$\text{Solubility (mg/cm}^2) = \frac{\text{Conditioned mass (mg)} - \text{Reconditioned mass (mg)}}{\text{Surface area (cm}^2)}$$

where the "conditioned mass" is the mass measured after the conditioning described in the first paragraph of clause 7.2.2.2.

The final value, the average of two determinations, should be rounded to the nearest 0.01 mg/cm^2.

When the final value falls midway between two numbers the even number should be recorded.

7.2.4 *Transverse deflection*

7.2.4.1 PREPARATION OF TEST SPECIMEN. A plate of polymer should be processed in a gypsum mould (see Fig. 2) lined with tin foil. Specimens for the transverse deflection test should be machined from this plate to the dimensions shown in Figure 4 by the following method :

The plate (see Fig. 2) should be sawn lengthwise into five equal strips with a band saw operated at a speed of approximately 100 m/min. For Type II polymers the plate should be at least 2 days old prior to sawing. The strips may then be sanded slightly on the moulded surfaces, if necessary, to remove imperfections.

All subsequent milling operations should be with a 50 mm diameter flycutter, operating at a spindle speed of approximately 1800 rev/min and at a table feed of about 150 mm/min. Rough cuts should be approximately 0.08 mm deep, and finish cuts should be 0.03 mm deep.

The strips should be mounted side by side in a vice and the edges machined parallel in order to remove all band saw marks. The strips at this stage should be over-size in width.

One or more strips should be mounted in a vice and the faces milled to the required thickness of 2.50 ± 0.03 mm. All five strips should then be clamped face to face in a vice and the faces milled to the required width of 10.00 ± 0.03 mm.

The specimens should be stored in distilled water at 37 ± 1 °C for 2 days immediately before testing.

7.2.4.2 PROCEDURE. Specimens prepared as detailed in clause 7.2.4.1 should be mounted in an appropriate apparatus, such as is shown in Figure 4. An initial load of 15.0 N, consisting of the free-moving parts of the apparatus with any necessary additional lead shot, should be placed on the specimen.

The specimen should then be loaded, and dial readings made, according to the schedule shown in Table 2. Each 5.0 N increment in loading should be applied at a uniform rate during the last 30 seconds of each minute.

TABLE 2 – **Schedule of loading and reading for transverse deflection test of denture base polymer**

Time		Load	Dial reading*
min	s	N	mm
0	00	15.0	
0	30	15.0	*A*
1	00	20.0	
1	30	20.0	
2	00	25.0	
2	30	25.0	
3	00	30.0	
3	30	30.0	
4	00	35.0	
4	30	35.0	*B*
5	00	40.0	
5	30	40.0	
6	00	45.0	
6	30	45.0	
7	00	50.0	
7	30	50.0	*C*

* Dial readings should be made to the nearest 0.01 mm.

Deflection at 35.0 N = $B - A$
Deflection at 50.0 N = $C - A$

The difference between the deflections at the initial 15.0 N load and at the specified loads should be taken as the deflection of the specimen. The recorded deflections should be reported to the nearest 0.1 mm. When the determined value falls midway between two numbers the even number should be recorded.

The polymer should be considered satisfactory if three out of five specimens meet the requirements.

7.2.5 *Colour stability.* One of the disks used in the tests described in clauses 7.2.2 and 7.2.3 should be exposed to the radiation of a lamp (see Fig. 5) with an S-I bulb which has been in use not less than 50 hours or more than 400 hours. The light source (S-I bulb) should be a combination tungsten filament/mercury-arc enclosed in corex D or other glass which has a low transmission below 280 nm. The lamp should be rated at 400 W.

The specimen, carried on an aluminium disk and centred under the S-I bulb, should be placed on a phonograph turntable, operated at 33 revolutions per minute. The specimen should be held by screws approximately 5 mm above the disk and 127 mm from the centre and should be maintained at a temperature between 60 and 65 °C. The plane of the top surface of the specimen should be 178 mm from the bottom of the S-I bulb.

After exposure for 24 hours, the specimen should be compared with an unexposed duplicate by visual inspection in daylight.

8. PACKAGING AND MARKING

8.1 Packaging

The material should be supplied in properly sealed containers made of materials which will not contaminate or permit contamination of the contents.

8.2 Marking

8.2.1 *Lot numbers.* Each container of material should be marked with a serial number or combination of letters and numbers which refer to the manufacturer's records for that particular lot or batch.

8.2.2 *Date of manufacture.* The date of manufacture (year and month) should be given on the container either as a separate item or as part of the lot number.

8.2.3 *Net mass and volume.* The minimum net mass of powder, in grammes, and the minimum net volume of liquid, in millilitres, should be given in legible type on the containers.

When the term "unit" is given as a designation, it should represent not less than 21 g of powder and a sufficient volume of liquid to combine with the powder, when mixed according to the manufacturer's instructions.

Dimensions in millimetres

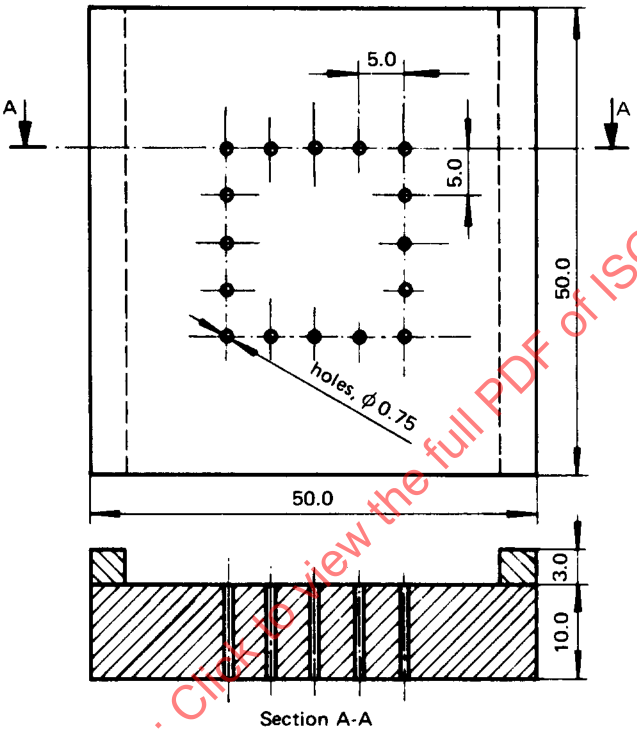

FIG. 1 – **Brass die for packing test**