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Dentistry — Polymer-based die materials

Art dentaire — Produits à base de polymère pour matrices

Reference number
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Foreword

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ISO 14233 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthodontic materials*.

Introduction

Polymer-based die materials are not covered by ISO 6873[1], which describes only gypsum-based die materials. Hence the need for this International Standard, whose requirements have been designed to delineate satisfactory polymer-based die materials and exclude unsatisfactory ones. It is anticipated that both manufacturer and user can apply this International Standard as a basis for producing or obtaining satisfactory products and results.

Dentistry — Polymer-based die materials

1 Scope

This International Standard gives compositional, performance, user-information, packaging and marking, and testing requirements for polymer-based die materials used in dentistry. It is applicable to die materials having a polymeric matrix as their principal constituent. Polymer-based die materials are used in the dental laboratory mainly to produce casts from dental impressions for the manufacture of fixed or removable restorations.

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 4823, *Dentistry — Elastomeric impression materials*

ISO 6507-1, *Metallic materials — Vickers hardness test — Part 1: Test method*

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

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
polymer-based die material
material which is primarily an epoxy resin, polyurethane or an acrylate resin and (especially epoxy resins and polyurethane) which contains metallic, metaloxides and/or inorganic fillers

4 Requirements

4.1 Components

The components of the polymer-based die material shall be free of extraneous matter and shall show no sign of deterioration. When treated according to the manufacturer's instructions, the material shall form a solid suitable for the intended purpose.

Testing shall be carried out in accordance with 6.2.

4.2 Working time

The working time in minutes of the polymer-based die material shall be not less than that stated by the manufacturer. At the manufacturer's stated working time, the requirement of 4.4 shall be met.

Testing shall be carried out in accordance with 6.3.

4.3 Setting time

At the manufacturer's stated setting time the Vickers hardness of the polymer-based die material shall be not less than 6 HV 0,2.

Testing shall be carried out in accordance with 6.4.

4.4 Detail reproduction

The polymer-based die material shall reproduce a line 20 µm wide.

Testing shall be carried out in accordance with 6.3.

4.5 Linear dimensional change

The linear dimensional change of the polymer-based die material after 24 h shall be less than 1,0 %.

Testing shall be carried out in accordance with 6.3.

4.6 Vickers hardness

The Vickers hardness of the polymer-based die material determined 24 h after the preparation of the specimens shall be not less than that stated by the manufacturer.

Testing shall be carried out in accordance with 6.5.

5 Sampling

The test sample shall consist of one or more retail packages from the same batch and contain sufficient (approximately 50 ml) material to carry out the specified tests plus any necessary repetition of the tests.

6 Test methods

6.1 General

6.1.1 Test conditions

Prepare and test the specimens at (23 ± 2) °C and at a relative humidity of not less than 30 %.

6.1.2 Preparation of test specimens

Mix and process the polymer-based die material in accordance with the manufacturer's instructions.

6.2 Visual inspection

Use visual inspection to determine compliance with 4.1 and Clauses 7 and 8.

6.3 Working time, detail reproduction and linear dimensional change

6.3.1 Reagents and/or materials

6.3.1.1 Elastomeric impression material, compatible with the die material and conforming to ISO 4823.

6.3.2 Apparatus

6.3.2.1 Ruled test block, as shown in Figure 1.

6.3.2.2 Ring mould, as shown in Figure 2.

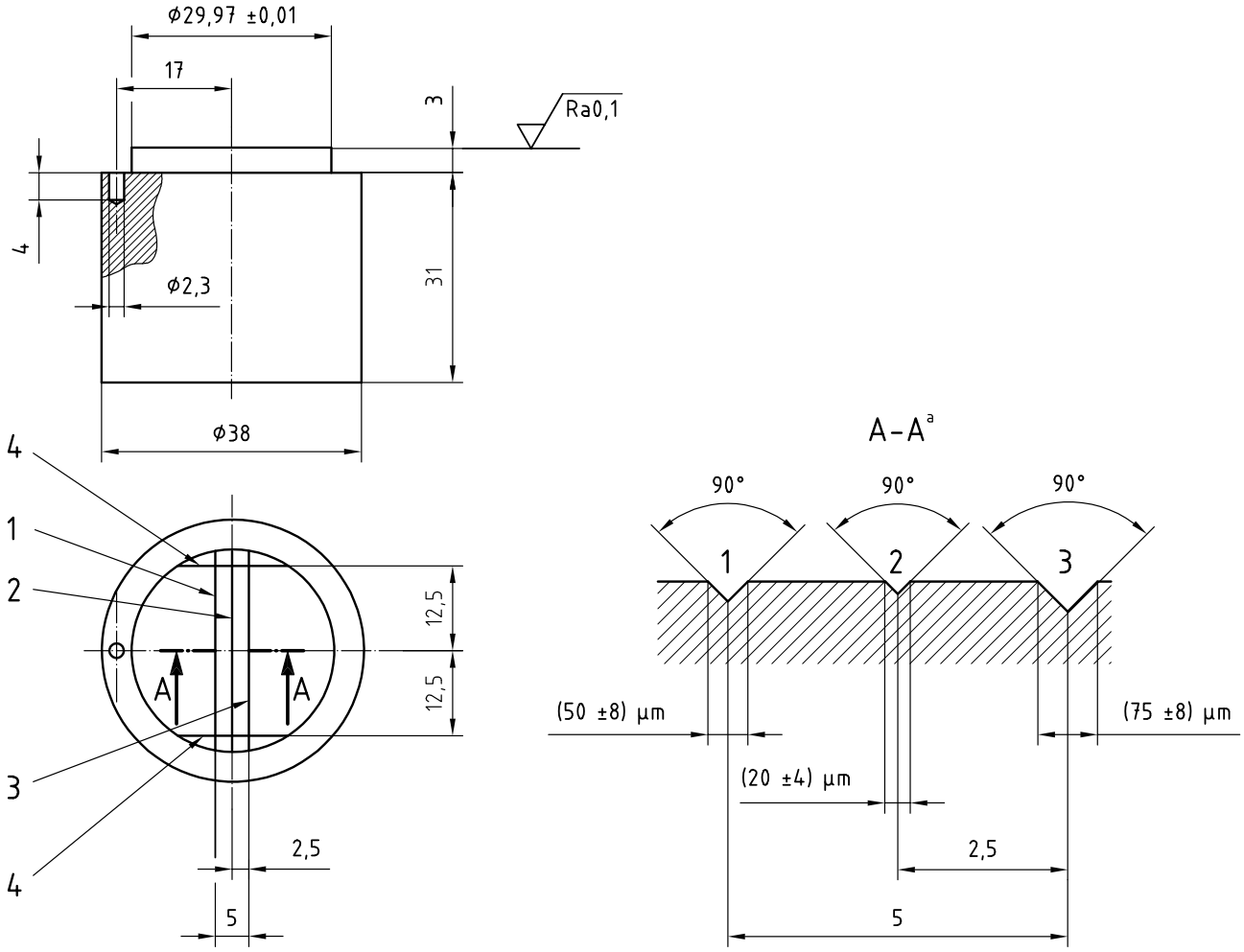
6.3.2.3 Split mould, as shown in Figure 3.

6.3.2.4 Glass plate, (50 ± 5) mm × (50 ± 5) mm × (4 ± 1) mm, dusted with talcum powder for storage of the impression.

6.3.2.5 Lens, for (6 ± 1) × magnification with light at low-angle illumination.

6.3.2.6 Measuring microscope, accurate to 0,01 mm.

Dimensions in millimetres
Tolerances: ± 0,1 mm, unless otherwise specified
Surface roughness (values in micrometres) of ruled surface 0,1; other surfaces 0,4.



Key

1 50 µm line;
2 20 µm line;
3 75 µm line;
4 75 µm transverse lines

[a] Enlarged view.

Figure 1 — Ruled test block — Side view, top view and sectional view A–A

Dimensions in millimetres
Tolerances: ± 0,1 mm, unless otherwise specified
Surface roughness (values in micrometres) 0,4.

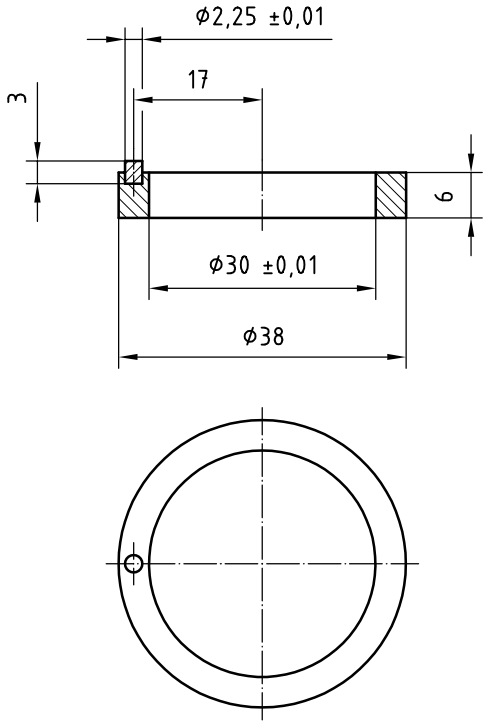


Figure 2 — Ring mould — Cross-section and top view

Dimensions in millimetres
Tolerances: ± 0,1 mm, unless otherwise specified
Surface roughness (values in micrometres) 0,4.

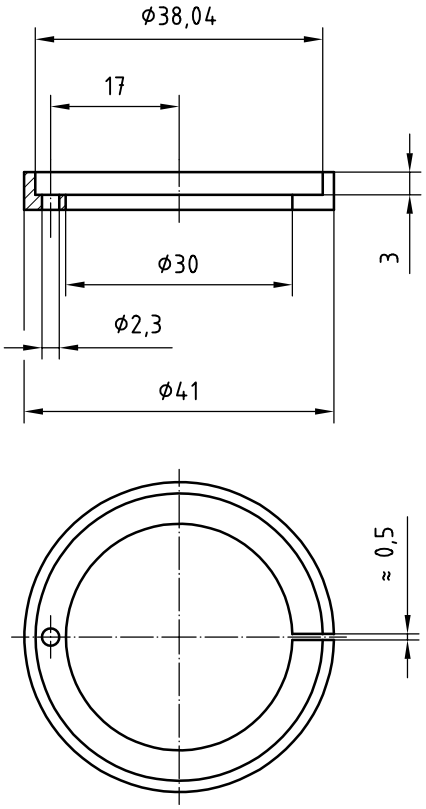


Figure 3 — Split mould — Cross-section and top view

6.3.3 Procedure

6.3.3.1 Clean the ruled test block (6.3.2.1) with a solvent before use but do not use a separating medium. Place the ring mould (6.3.2.2) on the ruled test block. Use the elastomeric impression material (6.3.1.1) according to the manufacturer's instructions. Immediately place the impression material into the mould within 15 s. Immediately cover the mould with the glass plate (6.3.2.4), applying sufficient load to extrude excess material, and bring the glass plate into contact with the ring mould. After twice the setting time of the elastomeric impression material, as stated by its manufacturer, remove the plate and separate the ring mould from the test block so that the impression stays in the ring mould. Use the lens for $(6 \pm 1) \times$ magnification with light at low-angle illumination (6.3.2.5) and inspect the lines 1, 2 and 3 on the impression for full continuous reproduction between the lines 4. If the lines are not fully continuous, repeat the impression. Prepare three satisfactory impressions.

6.3.3.2 Dust the unlined side of each impression with talcum powder. Transfer the ring mould with the impression to the glass plate, also dusted with talcum powder, with the lines facing up. Store the ring mould with the impression for 24 h in accordance with 6.1.1. Afterwards, measure the distance between the transverse lines 4 along lines 1, 2 and 3 on the impression with the measuring microscope (6.3.2.6) using low-angle illumination. Record the measurement to the nearest 0,01 mm as reading L_1.

Place the ring mould with the impression on a flat surface. Close the slit of the split mould (6.3.2.3) and place it on the ring mould. Mix the polymer-based die material according to the manufacturer's instructions. At the manufacturer's stated working time, fill the split mould with the mixed polymer-based die material. Store the assembly with the polymer-based die material specimens in accordance with 6.1.1. At the manufacturer's stated setting time, remove the polymer-based die material specimen from the impression and the split mould. Prepare a polymer-based die material specimen from each of the three satisfactory impressions.

6.3.3.3 Use the lens for $(6 \pm 1) \times$ magnification with light at low-angle illumination (6.3.2.5) and observe the reproduction of the 20 µm wide line of the ruled test block (Figure 1, Line 2). The portion of the 20 µm wide line between the two transverse lines 4 shall be reproduced continuously. Each polymer-based die material specimen shall be in accordance with 4.2 and 4.4. If one of the specimens fails to comply, repeat the whole test with three new specimens. All three new specimens shall be in accordance with 4.2 and 4.4.

Measure the distance between the transverse lines 4 along lines 1, 2 and 3 on the polymer-based die material specimen (24 ± 1) h after preparation with the measuring microscope (6.3.2.6) using low-angle illumination. Record the measurement to the nearest 0,01 mm as reading L_2. Calculate the linear dimensional change ΔL as a percentage to the nearest 0,05 %, using the formula:

$$\Delta L = 100\ (L_2 - L_1) / L_1$$

where

L_1 is the first reading, in millimetres, of the distance between the transverse lines 4 on the impression;

L_2 is the second reading, in millimetres, of the distance between the transverse lines 4 on the specimen of the polymer-based die material, corresponding to reading L_1 of the same line.

Determine the mean of the linear dimensional change for each of the three specimens from the lines 1, 2 and 3. Each mean shall be in accordance with 4.5.

If one specimen fails to comply, repeat the test with three new polymer-based die material specimens. All three new specimens shall be in accordance with 4.5.

In addition, use the three specimens of polymer-based die materials to test the Vickers hardness in accordance with 6.4.2 and 6.5.2.

6.4 Setting time

6.4.1 Apparatus

Hardness testing instrument (see ISO 6507-1) for HV 0,2.

6.4.2 Procedure

Use the same three polymer-based die material specimens as specified in 6.3. At the manufacturer's stated setting time make five indentations with a loading time of 30 s on the surface of each specimen that has set against the impression of the ruled test block (see 6.3.2.1). For measuring the indentations, use low-angle illumination. Complete the test within one hour.

6.4.3 Treatment of results

Determine the mean hardness value for each of the three specimens. Each mean shall be in accordance with 4.3.

If one specimen fails to comply, repeat the test with three new polymer-based die material specimens. All three new specimens shall comply with the requirements of 4.3.

6.5 Vickers hardness

6.5.1 Apparatus

Hardness testing instrument (see ISO 6507-1) for HV 0,2, as in 6.4.1.

6.5.2 Procedure

Use the same three polymer-based die material specimens as specified in 6.3. At 24 h after the preparation of the polymer-based die material specimens, make five indentations with a loading time of 30 s on the surface of each specimen that has set against the impression of the ruled test block (see 6.3.2.1). For measuring the indentations, use low-angle illumination. Complete the test within one hour.

6.5.3 Treatment of results

Determine the mean hardness value for each of the three specimens. Each mean shall be in accordance with 4.6.

If one specimen fails to comply, repeat the test with three new polymer-based die material specimens. All three new specimens shall be in accordance with 4.6.

7 Manufacturer's instructions and user information

Instructions for use, together with the description of the product, shall be provided by the manufacturer with each set or package of polymer-based die material, together with at least the following information:

a) name and address of manufacturer and/or distributor;

b) trade name of the polymer-based die material;

c) method of polymerization;

d) range of application of the polymer-based die material;

e) type of impression material (according ISO 4823) with which the polymer-based die material is compatible;

f) principal components;

g) method of proportioning the components and mixing, and temperature, humidity and ambient light conditions during mixing, if relevant;

h) any special precautions regarding the manipulation;

i) procedure for the application;

j) working time in minutes;

k) setting time or polymerization procedure;

l) Vickers hardness HV 0,2 at 24 h after mixing;

m) recommended conditions for storage of components and shelf-life under those conditions.

8 Packaging and marking

8.1 Packaging

The polymer-based die material shall be supplied in packaging such that the contents are adequately protected [see 8.2.1 f) and 8.2.2 e)].

An outer pack may also be used to present the containers or a set as a single unit.

NOTE The containers are the immediate wrapping of the polymer-based die material.

8.2 Marking

8.2.1 Outer pack

Each outer pack shall be marked with at least the following information:

a) name and address of manufacturer and/or distributor;

b) trade name of the polymer-based die material;

c) method of polymerization;

d) net content of the components in grams or millilitres;

e) recommended storage conditions;

f) expiry date expressed as year and month in accordance with ISO 8601 when stored according to the recommended conditions;

g) batch identification.

8.2.2 Containers

Each container shall be marked with at least the following information:

a) name of the manufacturer and/or distributor;

b) trade name of the polymer-based die material;

c) net contents in grams or millilitres;

d) recommended storage conditions;

e) expiry date expressed as year and month in accordance with ISO 8601 when stored according to the recommended conditions;

f) batch identification.

Bibliography

[1] ISO 6873, *Dental gypsum products*

ICS 11.060.10

Price based on 10 pages