SLOVENSKI STANDARD
SIST EN 24823:2000

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Dental elastomeric impression materials (ISO 4823:1992)

Dental elastomeric impression materials (ISO 4823:1992)

Zahnärztliche elastomere Abformmassen (ISO 4823:1992)

Produits dentaires pour empreintes, a base d'élastomeres (ISO 4823:1992)

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Produits dentaires pour empreintes, à base d'élastomères (ISO 4823:1992)

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This European Standard was approved by CEN on 1993-12-20. 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.

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CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

Foreword

This European Standard has been taken over by Technical Committee CEN/TC 55 "Dentistry" from the work of ISO/TC 106 "Dentistry" of the International Standardization Organization (ISO).

The text was submitted to the Unique Acceptance Procedure (UAP) and approved as a European Standard.

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of an identical text or by endorsement, at the latest by June 1994, and conflicting national standards shall be withdrawn at the latest by June 1994.

In accordance with the CEN/CENELEC Internal Regulations, following countries are bound to implement this European Standard: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

Endorsement notice

The text of the international standard ISO 4823:1992 was approved by CEN as a European Standard without any modification.

INTERNATIONAL STANDARD

ISO 4823

Second edition
1992-03-15

Dental elastomeric impression materials

Produits dentaires pour empreintes, à base d'élastomères

Reference number
ISO 4823:1992(E)

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 4823 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Sub-Committee SC 2, *Prosthodontic materials*.

This second edition cancels and replaces the first edition (ISO 4823:1984), of which it constitutes a technical revision.

This revision of ISO 4823 differs from the first edition in the following respects:

a) The system of classification into categories, based upon two different physical properties, has been deleted by reason of simplification. The classification is now based on types only and completed with the introduction of type 0 — very high consistency.

b) The physical property "compression set" is changed to "recovery after deformation" with the consequence that the value is between 96,5 % and 100 %.

c) For the physical requirement "strain in compression" a lowest limit of 0,8 % is now permitted.

d) A special requirement for "gas evolution" is deleted, as it is inherent to the test about compatibility with gypsum when it is stated whether the lines are completely reproduced over the full length.

International Organization for Standardization
Case Postale 56 • CH-1211 Genève 20 • Switzerland

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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 hazard, reference should be made to the appropriate clauses of ISO/TR 7405:1984, *Biological evaluation of dental materials*, or any more recent edition.

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Dental elastomeric impression materials

1 Scope

This International Standard specifies requirements for elastomeric impression materials based, for example, on polysulfides, polysiloxane or other non-aqueous materials capable of reacting to form a rubber-like material suitable for taking impressions.

2 Normative reference

The following standard contains provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the edition indicated was 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 edition of the standard indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 6873:1983, *Dental gypsum products*.

3 Definitions

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

3.1 mixing time: That part of the total working time starting at the commencement of mixing required to obtain a homogeneous mix of the components of the material.

3.2 total working time: Period of time between the start of mixing and the commencement of the development of elasticity and the loss of plasticity.

3.3 setting time: Period of time between the start of mixing and the development of the elasticity necessary for removal of the impression with the least amount of distortion.

4 Classification

The impression materials described in this International Standard shall be classified into types according to their consistency (see 5.3), determined in accordance with 7.3 (after mixing but before setting).

Type 0: very high consistency — putty

Type 1: high consistency — heavy bodied

Type 2: medium consistency — medium bodied

Type 3: low consistency — light bodied

5 Requirements

5.1 Components

All components shall be supplied in contrasting colours to provide a means of indicating when a uniform streak-free mix is achieved.

Components, if supplied in a tube, shall not show gross separation and shall be capable of being extruded by hand pressure at normal room temperature (18 °C to 25 °C). When tubes are used they shall not rupture during extrusion of the components. The crimped end of the tube shall be sealed so that no leakage can occur.

Testing shall be carried out in accordance with 7.2.

5.2 Biocompatibility

See the Introduction for guidance on biocompatibility.

5.3 Consistency

Diameters of the consistency test discs shall comply with requirements shown in table 1.

Testing shall be carried out in accordance with 7.3.

5.4 Mixing time

The mixing time, within that stated by the manufacturer [see 8.2 e)], shall not exceed 60 s.

5.5 Mixed material

When mixed according to the manufacturer's instructions, streak-free mixes shall be obtained.

Testing shall be carried out in accordance with 7.2.

5.6 Total working time

The total working time shall not be less than that stated by the manufacturer and shall be at least 30 s longer than the time required to obtain a streak-free mix.

Testing shall be carried out in accordance with 7.4.

5.7 Setting time

The setting time stated by the manufacturer shall be the time in which the material develops the recovery from deformation as stated in 5.9.

Testing shall be carried out in accordance with 7.6.

5.8 Strain in compression

The strain in compression shall comply with the requirements in table 1 for each type of material.

Testing shall be carried out in accordance with 7.5.

5.9 Recovery from deformation

The recovery from deformation shall be between 96,5 % and 100 %.

Testing shall be carried out in accordance with 7.6.

5.10 Linear dimensional change

The linear dimensional change after 24 h shall be within the range of 0 to 1,5 %.

Testing shall be carried out in accordance with 7.7.

5.11 Detail reproduction

The material shall reproduce a line according to at least the minimum requirements given in table 1.

Testing shall be carried out in accordance with 7.8.

5.12 Compatibility with gypsum

The material shall impart a smooth surface to, and shall separate cleanly from, the cast poured against the material.

The cast shall reproduce for each type of material the line according to the requirements of table 1. The reproduction shall be considered to be satisfactory if the respective line (a, b or c) is continuous between the d-lines (see figure 7).

Testing shall be carried out in accordance with 7.9.

Table 1 — Physical requirements

Type	Consistency, disc diameter mm	Strain in compression %	Detail reproduction, line width mm	Compatibility with gypsum, line width mm
0	35 max.[1)]	0,8 to 20	0,075	0,075
1	32 max.	0,8 to 20	0,050	0,050
2	31 to 39	2 to 20	0,020	0,020
3	36 min.	2 to 20	0,020	0,020

1) Mixed in the hands.

6 Sampling

The test samples shall consist of a retail package or packages of materials from the same batch.

7 Test methods

7.1 General

Unless otherwise specified, all tests shall be conducted in an environment having a temperature of (23 ± 2) °C and a relative humidity of (50 ± 10) %. All materials and test equipment shall be brought to temperature equilibrium in this environment before testing.

7.2 Visual inspection

Compliance with the requirements laid down in 5.1, 5.5, 5.11, 5.12, and clauses 8 and 10 shall be checked visually, if appropriate with magnification.

7.3 Consistency

7.3.1 Apparatus

7.3.1.1 Load of (1 500 ± 2) g mass, mounted in a loading device, such as that shown in figure 1 or 3, in such a manner as to allow essentially frictionless movement in a vertical direction.

7.3.1.2 Two glass plates approximately 60 mm by 60 mm each with a mass of (20 ± 2) g.

7.3.1.3 Delivery device of a suitable design and material, for example glass or polytetrafluoroethylene (PTFE) tube, having an internal diameter of approximately 10 mm and designed to deliver (0,5 ± 0,02) ml by means of a plunger.

7.3.1.4 Discs or sheet of polyethylene or other suitable material 10 mm in diameter and approximately 0,035 mm thick for covering the plunger head each time it is used.

7.3.2 Procedure

Dispense 0,5 ml of the paste, mixed according to the manufacturer's instructions and with the shortest mixing time stated, by means of the delivery device onto the centre of one of the glass plates. (The polyethylene disc will be delivered with the paste.) Centre and gently lower the second glass plate over the first and place the 1 500 g load on top 30 s after the end of the mixing.

During the test procedure, ensure that the glass plates are maintained parallel to each other and that no rotational movement takes place.

After 5 s remove the load. After allowing the material to set, measure the diameter of the disc to the nearest 0,5 mm across two diameters at right angles to each other.

7.3.3 Expression of results

Carry out the procedure three times and record the average of the six determinations to the nearest millimetre.

7.4 Total working time

7.4.1 Apparatus

7.4.1.1 Tray, as shown in figure 2, having a flat and smooth internal surface. Six compartments may be added if desired.

7.4.1.2 Twelve circular solvent-resistant plastic discs at least 5 mm thick, each disc having flat surfaces parallel within 0,01 mm. Six of these discs shall be (16 ± 0,2) mm and the other six shall be (10 ± 0,1) mm in diameter.

7.4.1.3 Loading device, as shown in figure 3, that allows essentially frictionless movement in the vertical direction.

Two movable columns are required, one with a mass of 30 g and another with a mass of 125 g. The columns shall end in a platen with a diameter 1 mm smaller than the discs used and parallel to the base of the instrument. Provision shall be made for the attachment of weights to increase the mass of the movable column to 500 g and 2 000 g.

7.4.1.4 Dial gauge, accurate to 0,01 mm, mounted perpendicularly on a stable base. The force exerted by the gauge shall be (0,59 ± 0,1) N equivalent to (60 ± 10) g.

7.4.2 Selection of mass-disc combination

An appropriate mass (30 g, 125 g, 500 g or 2 000 g) shall be selected so that the impression material layer under the first disc of 16 mm diameter has a thickness between 0,13 mm and 0,33 mm. When the thickness is found to exceed 0,33 mm with the 2 000 g mass, the 16 mm discs shall be replaced by those of 10 mm.

If it is impossible to obtain a thickness within the prescribed range using any described combination, the actual layer thickness shall be accepted, for example, less than 0,33 mm with the 2 000 g mass and 10 mm discs.

7.4.3 Procedure

Position six discs of the same diameter at regular intervals on the mould assembly and place this beneath the dial gauge so that the spindle contacts the upper surface of the first disc. Read the dial gauge to the nearest 0,01 mm and record the value as A_1, A_2, A_3, A_4, A_5 and A_6. Remove the discs for use later in the same order and positions.

Mix about 20 g of material according to the manufacturer's instructions. If a range of mixing times is given, use the shortest time recommended. Fill the mould assembly with mixed material and roughly level it with a spatula. Position the first disc on the surface of the mixed material and place the mould assembly on the base of the loading device.

Apply the appropriate load to the first disc 15 s after the end of mixing and maintain the load for 10 s.

Place the other discs on the material, while the first disc is loaded. Load the second disc, again for 10 s, 30 s after the end of mixing. Load the remaining four discs each for 10 s at intervals and make measurements before and after the time at which the layer is expected to become twice the thickness of the layer under the first disc.

After this loading sequence, transfer the whole assembly to the dial gauge. When the impression material shows evidence of setting, take readings with the spindle of the dial gauge in contact with each disc in turn and record these values to the nearest 0,01 mm as B_1, B_2, B_3, B_4, B_5 and B_6. Record the difference between the respective B and A readings, as the thickness of the impression material beneath each disc.

Plot the values, $B - A$, against time on graph paper and draw the best curve through or near the points.