INTERNATIONAL STANDARD

ISO 4823

Second edition
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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.

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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.

From the graph, obtain the time at which the thickness of impression material becomes twice the thickness obtained 15 s after the end of mixing (i.e. the first disc).

7.4.4 Expression of results

Calculate the mean of three such determinations, rounded to the nearest 15 s and record as the total working time. Discard any individual value deviating by more than ± 25 % from the mean and repeat the determination.

If, however, more than one combination of load and disc satisfies the test requirements, record the combination providing the longest total working time.

7.5 Strain in compression

7.5.1 Apparatus

7.5.1.1 Test instrument (for example as in figure 4) capable of applying the required load axially to the specimen and fitted with a **dial gauge** with a maximum contact force of (0,59 ± 0,1) N calibrated in millimetres and accurate to 0,01 mm.

7.5.1.2 Slit mould (for example as in figure 5) providing a specimen of (12,5 ± 0,05) mm in diameter and (20 ± 0,2) mm in height. The mould may be made of stainless steel or brass, at the discretion of the test laboratory.

7.5.1.3 Two flat plates, made of glass or stainless steel, approximately 50 mm × 50 mm and 3 mm thick.

7.5.1.4 Polyethylene sheets approximately 50 mm by 50 mm for covering flat plates.

7.5.1.5 Small clamp, suitable for clamping the plates on the ends of the mould.

7.5.1.6 Two water baths capable of being stirred and maintained at (35 ± 1) °C and (23 ± 1) °C respectively.

7.5.2 Preparation of test specimen

Place the fixation ring on one of the flat plates and fill it slightly more than one-half full with material, mixed according to the manufacturer's instructions. Press the slit mould into the fixation ring until the bottom of the mould touches the plate and material extrudes above the top of the mould. Then press the second plate down over the mould to force away the excess material and to form the top surface of the specimen.

Thirty seconds after the end of mixing, place the mould and its accompanying plates, fixed by the clamp, in the water bath at (35 ± 1) °C. At the stated setting time, remove the assembly from the first water bath.

Separate the specimen and transfer it to the second water bath at (23 ± 1) °C for 15 s. Place the specimen on the table of the test instrument.

Discard the specimen if it shows evidence of voids. If necessary prepare new specimens.

7.5.3 Procedure

Carry out the test in accordance with the time schedule detailed below where t is the manufacturer's stated setting time.

$t + 120$ s :	Apply the first load of 125 g to the specimen by lowering the rod.
$t + 150$ s :	Fix the rod with the clamping device. Gently lower the spindle of the dial gauge to contact the rod.
	Read the dial gauge and report the value to the nearest 0,01 mm as h_1.
	Fix the spindle of the dial gauge in an upward position.
$t + 180$ s :	Release the clamping device and increase the load up to 1 250 g within 10 s.
$t + 210$ s :	Fix the load with the clamping device. Gently lower the spindle of the dial gauge, read and report the value to the nearest 0,01 mm as h_2.

Carry out three such determinations.

7.5.4 Expression of results

Calculate the strain in compression, E, expressed as a percentage, using the formula:

$$E = 100\left(\frac{h_1 - h_2}{20}\right)$$

where

20 is the actual height of the mould, in millimetres;

h_1 is the height, in millimetres, of the specimen after application of the first load;

h_2 is the height, in millimetres, of the specimen after application of the increased load.

Report the result as the average of the three determinations to the nearest 0,1 %.

7.6 Recovery from deformation

7.6.1 Apparatus

7.6.1.1 Any instrument such as that illustrated in figure 6 capable of straining the specimen rapidly and accurately may be used. The **dial gauge** used to measure the height of the specimen may either be mounted on a separate device, or an integral part of the compression test instrument. It shall be accurate to 0,01 mm and shall exert a force of (0,59 ± 0,1) N equivalent to (60 ± 10) g.

7.6.1.2 Specimen forming and conditioning apparatus (see 7.5.1).

7.6.2 Preparation of test specimen

Prepare the specimen according to 7.5.2.

7.6.3 Procedure

Carry out the test in accordance with the time schedule detailed below, where t is the manufacturer's stated setting time.

$t + 45$ s : Gently lower the spindle of the dial gauge to contact the plate upon the specimen for the first reading.

$t + 55$ s : Read the dial indication and record the value as reading h_1 to the nearest 0,01 mm. Fix the spindle in an upward position.

$t + 60$ s : Strain the specimen by (30 ± 0,5) % equivalent to (6 ± 0,1) mm within 1 s. Maintain the strain for (5 ± 0,5) s.

$t + 170$ s : Gently lower the spindle of the dial gauge to contact the plate upon the specimen for the second reading.

$t + 180$ s : Read the dial indication and record the value as reading h_2 to the nearest 0,01 mm.

7.6.4 Expression of results

Calculate the recovery from deformation, K, expressed as a percentage, using the formula:

$$K = 100\left(1 - \frac{h_1 - h_2}{20}\right)$$

where

20 is the actual height of the mould, in millimetres;

h_1 is the height, in millimetres, of the specimen before deformation;

h_2 is the height, in millimetres, of the specimen after recovery.

Report the result as the average of three determinations to the nearest 0,05 %.

7.7 Linear dimensional change

7.7.1 Apparatus

7.7.1.1 Ruled test block, ring mould and riser (figure 7).

7.7.1.2 Flat plate of glass or stainless steel (7.5.1.3).

7.7.1.3 Polyethylene sheet (7.5.1.4).

7.7.1.4 Instrument or other means of applying a load.

7.7.1.5 Travelling microscope, accurate to 0,01 mm.

7.7.1.6 Water bath capable of being stirred and maintained at (35 ± 1) °C.

7.7.1.7 Flat glass plate with talcum powder for storage of the specimen.

7.7.2 Preparation of test specimen

Lubricate the ring mould with a thin film of mould release agent such as high vacuum silicone grease. Clean the ruled test block with a solvent before use but do not lubricate.

Place the ring mould upon the test block. Mix the impression material to be tested, according to the manufacturer's instructions and by observing the requirements of 7.1, and place it in the mould by means of a spatula 15 s after the end of mixing. Immediately afterwards, cover the mould with the flat plate and apply sufficient load to extrude excess material and bring the plate into contact with the mould.

Immediately after that, transfer the assembly to the water bath maintained at (35 ± 1) °C. Three minutes after the setting time, remove the plate and separate the ring mould and test block in such a way as to minimize distortion of the test specimen.

7.7.3 Procedure

Immediately after the separation of the ring mould and test block, press the impression out of the mould with the aid of the riser, which, during this operation, has been kept in contact with the side of the impression opposite the lined surface. Dust the side opposite the lined surface with talcum powder and transfer the specimen, with the lined surface

uppermost, to the flat plate also dusted with talcum powder. Store the specimen for 24 h at (23 ± 2) °C and a relative humidity of (50 ± 10) %.

7.7.4 Observations

Measure the distance between the cross lines d-d (nominal value 25 mm) on the test block with the travelling microscope and record it to the nearest 0,01 mm as reading L_1.

Make the measurements in an identical manner with the aid of the edges of the cross line, for example from the left edge of one line to the left edge of the same line (a, b or c), using low-angle illumination.

Make the first reading, L_1, on the test block and the second reading, L_2, on the impression specimen 24 h after its separation from the block and storage.

7.7.5 Expression of results

Calculate the dimensional change, ΔL, as a percentage, using the formula:

$$\Delta L = 100\left(\frac{L_2 - L_1}{L_1}\right)$$

where

L_1 is the first reading, in millimetres, of the distance between both lines d on the test block;

L_2 is the second reading of that distance on the impression specimen.

Report the result as the average of three determinations to the nearest 0,05 %.

7.8 Detail reproduction

7.8.1 Apparatus

7.8.1.1 Specimen forming and conditioning components (7.5.1.3 and figure 7). Material types may be at the discretion of the test laboratory.

7.8.1.2 Ruled test block and ring mould (figure 7). This shall be of extruded austenitic stainless steel or austenitic steel for castings. The impression material mould shall be of austenitic stainless free-cutting steel. All other parts shall be of brass.

7.8.1.3 Lens and light for approximately × 6 magnification at low-angle illumination.

7.8.2 Preparation of test specimen

Prepare the test specimen as described in 7.7.2.

7.8.3 Procedure

Three minutes after the setting time remove the specimen and visually inspect the lines formed from the ruled test block using low-angle illumination and approximately × 6 magnification.

Select the appropriate line for the type of material (see table 1). Observe that portion of the longitudinal line extending between the two transverse lines d of the ruled test block in figure 7.

7.8.4 Expression of results

Make three determinations and report whether the lines are unbroken between the cross lines d.

7.9 Compatibility with gypsum

7.9.1 Apparatus and materials

7.9.1.1 Test specimen according to 7.7.2.

7.9.1.2 Slit mould with the internal surface lubricated with a non-reactive grease (figure 7).

7.9.1.3 A commercially available **gypsum product** (50 g minimum) complying with type 4 in ISO 6873:1983 with a setting time of ± 20 % of the time stated by the manufacturer.

NOTES

1 The gypsum product may be coloured with a suitable dye for better definition.

2 To check that the gypsum product has not deteriorated, it is recommended that the setting time is determined in accordance with ISO 6873:1983, clause 7.4.

7.9.1.4 Lens and light for approximately × 6 magnification at low-angle illumination.

7.9.2 Procedure

After separating the test specimen from the ruled test block, place the ring mould which retains the specimen into the slit mould with the lined surface down.

Invert the assembly and place the bottom of the ring mould to rest on a flat surface. At the earliest time recommended by the manufacturer, vibrate gypsum product slurry onto the surface of the impression and completely fill the slit mould over a period of 5 s. Allow the gypsum mix to harden for the time recommended by the manufacturer plus 10 min ± 1 min.

7.9.3 Observation

Separate the gypsum cast from the specimen made of impression material and examine under low-angle illumination using approximately × 6 magnification.

7.9.4 Expression of results

Carry out three determinations and report whether the lines are complete for the length d-d.

8 Manufacturer's information

Adequate and accurate instructions for use and information characterizing the product shall accompany each unit package. They shall include the information in 8.1 to 8.3.

8.1 Information on material and storage

a) Type of material in same wording used in describing classification in clause 4.

b) Chemical nature of elastomeric system, for example silicone, polysulfide or polyether.

c) Recommended storage conditions, for example temperature, humidity, etc.

8.2 Instructions for use

a) Trade- or brand-name of the product.

b) Precautions for handling the components, if necessary.

c) Proportions of the components required, if needed, by mass and volume.

d) Mixing apparatus and/or technique to be used.

e) Mixing time, if relevant.

f) The minimum time the impression should remain in the mouth, stated to the nearest 15 s.

g) A statement whether or not the impression can be disinfected and, if so, the preferred method, including agents and/or solutions.

h) A statement whether or not electroplating is recommended and, if recommended, the type of bath to be used.

i) Minimum and maximum recommended time for pouring the cast.

8.3 Statement of properties

a) Type, stated in the same wording used in describing classification in clause 4.

b) Total working time, stated to the nearest 15 s.

c) Setting time stated to the nearest 15 s.

d) Maximum strain in compression expressed as a percentage.

e) Recovery from deformation expressed as a percentage.

f) Linear dimensional change expressed as a percentage.

9 Packaging

Elastomeric dental impression materials shall be packed in bulk packages or unit packs which neither contaminate not permit contamination of the contents. The structure of the containers and capping mechanism shall be such that no leakage or inadvertent extrusion can occur.

10 Marking

10.1 Labelling and marking of outer wrapping

The outer wrapping shall be marked with the following information:

a) Trade- or brand-name of the product.

b) Manufacturer's name and address and/or agent in the country of sale.

c) Type, in wording used in describing classification in clause 4.

d) Chemical nature of elastomeric system.

e) Recommended storage conditions.

f) "Use before" or expiry date beyond which the material may not exhibit its best properties.

g) The mass or number of dose units.

h) Special indications or warnings, if relevant.

i) Manufacturer's batch reference.

10.2 Labelling and marking of immediate container

The immediate container shall be marked with the information required in 10.1 a), b), c), d) and i).