INTERNATIONAL STANDARD

ISO 4823

Third edition
2000-12-15

Dentistry — Elastomeric impression materials

Art dentaire — Produits pour empreintes, à base d'élastomères

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

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.

Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 4823 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthodontic materials*.

This third edition cancels and replaces the second edition (ISO 4823:1992), which has been revised to reflect the following technical differences:

— the 60 s limit on **Mixing time** (5.4, second edition) has been eliminated;

— the **Consistency test** requirement for **Type 1** and **Type 2** impression materials has been relaxed (see Table 1, both editions);

— a more realistic approach for making pass/fail determinations (8.4);

— apparatus and procedures specified for the **Working-time test** (9.3) and the **Elastic recovery tests** (9.7) provide for more objective test results than those specified in 7.4 and 7.6 of the second edition;

— Figure 2 illustrates how the instrument depicted in Figure 4 of the second edition can be modified to make it suitable for use in the **Consistency test** as well as for the **Strain-in-compression test**;

— Figure 15 illustrates how the **split mould** shown in Figure 5 of the second edition can be modified to provide for more uniformly shaped specimens.

Annex A of this International Standard is for information only.

Dentistry — Elastomeric impression materials

1 Scope

This International Standard specifies requirements and tests for evaluating elastomeric dental impression materials.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 1942, *Dental vocabulary.*

ISO 6873, *Dental gypsum products.*

3 Terms and definitions

For the purposes of this International Standard, the terms and definitions given in ISO 1942 and the following apply.

3.1
consistency
degree of firmness with which particles of a material, prepared for use, cohere so as to allow the material to flow, or resist flow, as required to achieve the purpose for which it is intended

3.2
elastic recovery test
compression set (deprecated)
permanent deformation (deprecated)
recovery from deformation (deprecated)
⟨elastic impression materials⟩ method of determining whether the materials possess the elastic properties required to recover adequately after deformation occurring when the materials, used for forming impressions, are removed from the mouth

3.3
extrusion mixing
method by which two or more material components are extruded from their separate immediate containers through a special mixing tip, from which the components emerge as a homogeneous mixture

3.4
hand mixing
method of mixing the components of a material by means of manual kneading or spatulation

3.5
immediate container
container which is in direct contact with a material or a component thereof

NOTE An immediate container may be an unlabelled container protected by a more durable labelled outer packaging component such as a can, carton or drum. If it is strong enough to protect its contents without outer packaging, an immediate container can also serve as a primary container on which labelling may be required.

3.6
mixing time
time, measured from first contact between different components of a material being mixed, required to achieve a homogeneous mixture when the components are mixed according to the manufacturer's instructions

NOTE The time of first contact between extrusion-mixed material components is defined as the time when the material components can be seen entering into the mixing nozzle.

3.7
outer package
wrapping or carton, which may be required by law or a standard to bear specified labelling, used to cover one or more immediate or primary containers in preparation for retail marketing

3.8
primary container
retail marketing packaging component, such as a bottle, carton, drum, jar, tube, etc., which may be required by law or a standard to bear specified labelling

NOTE A primary container may also be an immediate container.

3.9
strain-in-compression test
⟨elastic impression materials⟩ method of measuring the flexibility/stiffness property ranges of materials so as to determine whether the set materials, when formed as impressions, 1) can be removed from the mouth without injury to impressed oral tissues, and 2) will have adequate stiffness, in the more flexible portions of impressions, to resist deformation when model-forming products are poured against them

3.10
working time
period of time, beginning with the commencement of mixing and ending before the material being mixed has begun to exhibit elastic properties that will prevent the material from being manipulated as required to form an impression or a mould having the desired surface detail and dimensional characteristics

4 Classification

Materials covered by this International Standard are classified according to consistencies determined immediately after completion of mixing according to the manufacturer's instructions (10.3):

— Type 0: putty consistency

— Type 1: heavy-bodied consistency

— Type 2: medium-bodied consistency

— Type 3: light-bodied consistency

5 Biocompatibility advisory

Specific qualitative and quantitative requirements for freedom from biological hazards are not included in this International Standard. It is recommended that, in assessing possible biological or toxicological hazards, reference be made to ISO 7405 and ISO 10993-1 (see Bibliography).

6 Requirements for characteristics and properties

6.1 Component colours

Different components intended for use in the same mixture shall be supplied in contrasting colours to provide a means of determining when the components have been thoroughly mixed.

6.2 **Mixing time** (hand-spatulated or hand-kneaded mixes)

When the impression material components are combined according to the manufacturer's instructions given in 10.3 e) and the results of the mixing are evaluated according to 9.1, the average time required to achieve a homogeneous mixture (essentially streak free) shall not exceed the time stated by the manufacturer in 10.3 e).

6.3 Working time

When tested according to 9.3, the working time shall not be less than that stated in the manufacturer's instructions given in 10.3 f), and shall be at least 30 s longer than the time required to obtain a homogeneous mix (see 6.2 and 9.1).

6.4 Compatibility with gypsum

The impression material shall impart a smooth surface to, and separate cleanly from, the gypsum model material poured against it (see Table 1).

Table 1 — Additional characteristic and physical property requirements

Type	Test subclause No. and description							
	9.2		9.4	9.5	9.6	9.7	9.8	
	Consistency (Test disc diameter) mm		Detail reproduction (Line width reproduced) [a]	Linear dimensional change %	Compatibility with gypsum (Line width reproduced) [a]	Elastic recovery %	Strain-in-compression %	
	min.	max.	µm	max.	µm	min.	min.	max.
0	—	35	75	1,5	75	96,5	0,8	20
1	—	35	50	1,5	50	96,5	0,8	20
2	31	41	20	1,5	50	96,5	2,0	20
3	36	—	20	1,5	50	96,5	2,0	20

[a] The line reproduction shall be considered satisfactory if the required line a, b, or c is continuous between the lines d_1 and d_2. See test block in Figure 12.

NOTE Requirements for information to be included in the manufacturer's instructions for use, packaging and labelling are listed in clauses 10 and 11.

7 Sampling

Samples of materials to be tested shall be procured from a single manufacturing batch as packaged for retail marketing.

NOTE A volume of about 900 ml of the mixed material will usually be enough for conducting all the tests and for the considerable practice which may be necessary for the test operator to become proficient in specimen preparation and testing.

CAUTION — Before opening any packaging component, examine the labelling for compliance with 11.2 and for any precautions that should be observed in use and storage of the material. Before opening any immediate container examine the instructions for compliance with clause 10.

8 Test methods — General

8.1 Laboratory conditions

Unless otherwise specified in this International Standard, conduct all specimen preparation and testing under ambient laboratory conditions of (23 ± 2) °C and (50 ± 10) % relative humidity, and bring all equipment and materials used in the tests to the ambient temperature before use in specimen preparation and testing.

8.2 Apparatus function verification

Examine all accessories, instruments, and equipment before they are used to determine whether they are in acceptable working order. Perform whatever calibration steps are necessary to ensure that the items comply with specifications stated for them in this International Standard or in any normative document quoted therein.

8.3 Material manipulation and specimen preparation

Unless otherwise specified:

— use the equipment and procedures recommended in the manufacturer's instructions when preparing and manipulating the materials used for forming the test specimens. For materials requiring hand mixing, use only mass/mass proportioning of ingredients [10.3 c)];

— when the instructions specify manual kneading as a means of combining putty material components, cover the hands with gloves or polymer sheeting [10.3 d)] which will not react with the material to alter its behaviour;

— mix a volume of at least 15 ml for each specimen (the approximate amount required for a medium-sized complete arch impression);

— time the schedules for specimen preparation and testing using an instrument such as a stop-watch accurate to 1 s over a 30 s period.

8.4 Pass/fail determinations

The minimum number of specimens required for pass/fail determinations shall be either three or five, as indicated beside the related specimen preparation or test procedure headings. Unless otherwise specified, the following rules apply:

— for a three-specimen minimum, make a series of three specimens initially. If at least two of the three specimens comply with the related requirement, the material passes. If none complies, the material fails. If only one specimen complies, make three additional specimens. If all three of the additional specimens comply, the material passes; otherwise the material fails;

— for a five-specimen minimum, make and test a series of five specimens initially. If at least four of the five specimens comply with the related requirement, the material passes. If only one or two specimens comply, the material fails. If only three specimens comply, make a series of five additional specimens. If all five of the second series of specimens comply, the material passes; otherwise the material fails.

8.5 Expression of test results

Report the number of specimens tested, the number complying with the specified requirement and whether the material passes or fails.

9 Test methods — Specific

9.1 Mixing-time test

9.1.1 Apparatus

9.1.1.1 Recommended mixing apparatus [10.3 d)]

9.1.1.2 Timing device (8.3)

9.1.2 Specimen preparation and test procedure (five specimens)

Proportion and mix the required volume of material (8.3) for each specimen. Record the time required to obtain a homogeneous mixture for each specimen. Calculate the mean of the results for the five specimens.

NOTE Mixes made for this test may be used to provide increments of material needed for the consistency test (9.2)

9.1.3 Pass/fail determination and expression of results

Determine whether the mean result obtained in accordance with 9.1.2 complies with 6.2 and report the results.

9.2 Consistency test

9.2.1 Apparatus and materials

9.2.1.1 Two glass plates, one to serve as a base plate, and one to serve as a loading plate (Figure 2).

Dimensions for the loading plate shall be approximately 60 mm by 60 mm and at least 3 mm thick. Dimensions of the base plate may be greater.

9.2.1.2 Material delivery system, such as the one illustrated in Figure 1, for delivering a volume of (0,5 ± 0,02) ml of the material onto the base plate.

9.2.1.3 Polyethylene sheets, wrinkle-free, approximately 60 mm by 60 mm and 0,035 mm thick (one per specimen).

9.2.1.4 Polyethylene sheet discs, approximately 10 mm in diameter and 0,035 mm thick (two per specimen).

9.2.1.5 Elastomeric plug, for forming the floor of the test increment-containing cavity.

9.2.1.6 Test instrument for applying a force of (14,7 ± 0,1) N (Figure 2).

The mass of the glass loading plate shall be included as part of the test load.

NOTE The dial indicator illustrated as a part of the test instrument in Figure 2 plays no part in the consistency test.

9.2.1.7 **Linear measuring instrument**, accurate to 0,5 mm, for measuring diameters of the test specimen disc (9.2.3).

9.2.1.8 **Timing device** (8.3).

9.2.2 Advance preparation steps

Accomplish the following steps before beginning any of the test procedures:

— adjust the test instrument (9.2.1.6.) so that the contact surface of the loading shaft foot can descend within 5 mm of the top surface of the instrument base;

— cover the top surface of the base plate (9.2.1.1) with a polyethylene sheet (9.2.1.3). A thin film of silicon grease applied to the bottom of the loading plate will secure the polyethylene sheet covering in place, as required for the test;

— use the depth-gauge end of the plunger (Figure 1) to push the elastomeric plug (9.2.1.5) into the tapered end of the dispensing tube to the depth allowed by the stop;

— use the depth-gauge end of the plunger to seat two of the polyethylene sheet discs (9.2.1.4) to cover the cavity floor formed by the plug.

9.2.3 Specimen preparation and test procedure (3 specimens)

Accomplish the following steps within 25 s after the completion of mixing:

— slightly overfill the cavity in the dispensing tube (Figure 1) with the mixed material and strike off the excess to form the test increment;

— push the increment-extruding end of the plunger against the elastomeric plug to expel the test increment, along with one, or both, of the polyethylene discs, onto the centre of the base plate. Do not attempt to separate the discs from the test increment;

— centre the increment on the base of the test instrument (9.2.1.6) directly under the elevated loading-shaft foot;

— place and hold the glass loading plate centred and in contact with the shaft foot;

— allow the 14,7 N load to descend slowly onto the increment.

To obtain a more uniformly circular specimen disc, keep the glass plates as parallel as possible during loading and keep rotation of the plates to a minimum.

Allow the total load to rest on the specimen-forming assembly for 5 s. Lift the foot of the loading shaft from contact with the loading plate and allow the assembly to remain at room temperature for at least 15 min. Then separate the loading plate from the assembly so as to leave the specimen on the base plate. Use the measuring instrument (9.2.1.7) to make two diametral measurements of the specimen, one across the major diameter of the disc and one across the minor diameter. Report the average of the two measurements as the diameter to be considered when determining whether the specimen complies with the diameter requirement specified in Table 1.

9.2.4 Pass/fail determination and expression of results

See 8.4 and 8.5.

9.3 Working-time test

9.3.1 Apparatus and materials

9.3.1.1 **Working-time test instrument**, including the parts illustrated in Figure 3 through to Figure 10, as well as the three electronic components listed immediately below.

9.3.1.2 **Linear variable displacement transducer** (LVDT), having a linear working range > 12,5 mm. The transducer shall be passive, i.e. not spring-loaded.

9.3.1.3 **DC power supply**, (+ 15 V and – 15 V regulated), for modulating the LVDT signals.

9.3.1.4 **Chart recorder,** compatible with the LVDT and associated equipment.

9.3.1.5 **Mixing apparatus** [10.3 d)].

9.3.1.6 **Timing device** (8.3).

9.3.2 Pretest instrumentation function verification and assembly

9.3.2.1 Check for friction

Before using the test instrument (9.3.1.1), use the following procedure to determine whether the friction between the bearing areas of glide track (Figure 5) and the sliding polymer blocks (Figure 7) is within acceptable limits (see also Figure 3):

— do not use lubricants in attempts to reduce friction;

— detach the LVDT core carrier rod (Figure 3) from the polymer block 4_L;

— clean and dry the bearing surfaces of the sliding blocks and glide track and examine them for defects that can be detected by touch (burrs, nicks, etc.). Eliminate any such defects;

— seat the sliding blocks in the glide track, and use the perforated test plate (Figure 8) and the plate aligning and locking pins, Parts 5_L and 5_R (Figure 3 and Figure 9) to relate the parts as for testing;

— elevate one end of the instrument so that the base is at an approximate 20° angle to horizontal;

— move by hand the sliding block/perforated test plate assembly in the glide track to the upper extreme position and release it immediately.

If the assembly moves freely to the lower extreme position under the pull of gravity, the friction is within acceptable limits.

Repeat the steps described above, with the opposite end of the instrument elevated, to determine whether freedom of movement in the opposite direction is also acceptable.

If the friction cannot be reduced to acceptable limits by removal of burrs, contaminates, etc., it may be necessary to resurface the bearing areas to eliminate binding interferences that may be contributing to the friction.

Upon achieving acceptable limits for friction, remove the test plate, reattach the core carrier rod to the sliding block 4_L in Figure 3 and proceed with assembly of the instrumentation.

9.3.2.2 Instrumentation assembly

Connect the LVDT (9.3.1.2) to the recorder (9.3.1.4) through the power supply (9.3.1.3). Then adjust the LVDT body position as required to establish a body/core relationship whereby a full-scale deflection of the recorder pen indicates a rheometer displacement of 3,5 mm. Confirm that the recorder pen reflects a linear function of the rheometer displacement.

9.3.3 **Test procedure** (five specimens)

When combining hand-mixed materials, start the timing device (9.3.1.6) at the commencement of mixing. For the extrusion mixed materials, delay starting the timing device until the material components can be seen entering into the mixing nozzle. After completion of mixing, accomplish the following steps within 55 s:

— deposit an increment of about 2 ml of the material centred on the slotted surface of the test specimen pedestal (Figure 3 and Figure 6);

— force the perforated test plate into the centre of the impression material increment until the undersides of both ends of the plate contact the upper surfaces of the sliding polymer blocks, 4_L and 4_R, and so that the mixed material extrudes through at least 28 of the perforations;

— align the locking pin holes in the perforated plate with the pin holes in the sliding blocks and insert the locking pins, 5_L and 5_R (Figure 3), to secure the parts in the relationship for testing;

— zero the chart recorder pen before activating the recorder chart drive as required to begin the test schedule described below.

For materials having a stated working time of 3 min or less [10.3 f)], begin testing at 60 s to 90 s after commencement of mixing. For materials having a greater stated working time, begin testing 2 min before the end of the stated working time. Apply finger pressure or another controlled force against the sliding block, 4_R, so as to displace the sliding block/perforated plate assembly 0,25 mm, as reflected by the chart recorder tracing. Remove the force immediately after completing this displacement and observe behaviour of the recorder pen.

Repeat the displacement procedure at 15 s intervals until the chart recorder pen tracing (Figure 11) first indicates that the specimen has begun to exhibit elastic properties that can adversely affect impression quality.

The chart recorder reading, at 15 s before the first recorded indication that the specimen has begun to exhibit elastic properties, shall be reported as the end of the effective working time.

9.3.4 Pass/fail determination and expression of results

See 8.4 and 8.5.

9.4 Detail reproduction test

9.4.1 Apparatus and materials

9.4.1.1 **Test block** (Figure 12) and **ring mould accessory** (Figure 13). Clean the test block ultrasonically before each use.

9.4.1.2 **Oven**, set at (35 ± 1) °C, for dry heat conditioning of the test block prior to use.

9.4.1.3 **Flat glass or metal plate**, approximately 50 mm by 50 mm and at least 3 mm thick.

9.4.1.4 **Polyethylene sheets**, approximately 50 mm by 50 mm and 0,035 mm thick (one per specimen).

9.4.1.5 **Water bath**, for maintaining a temperature of (35 ± 1) °C in simulation of a mouth temperature environment.

9.4.1.6 **Microscope**, equipped for ×4 to ×12 magnification and low angle illumination.

9.4.1.7 **Timing device** (8.3).