FINAL DRAFT
International Standard

ISO/FDIS 4823

Dentistry — Elastomeric impression and bite registration materials

Médecine bucco-dentaire — Produits pour empreintes et matériaux pour enregistrement des rapports intermaxillaires à base d'élastomères

ISO/TC **106**/SC **2**

Secretariat: **ANSI**

Voting begins on:
2025-03-25

Voting terminates on:
2025-05-20

ISO/CEN PARALLEL PROCESSING

Reference number
ISO/FDIS 4823:2025(en)

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Published in Switzerland

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthodontic materials,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This sixth edition cancels and replaces the fifth edition (ISO 4823:2021), which has been technically revised.

The main changes are as follows:

— packaging and instructions for use requirements have been updated;

— editorial corrections have been made.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Dentistry — Elastomeric impression and bite registration materials

1 Scope

This document specifies the requirements and their test methods for elastomeric impression and bite registration materials.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 48-4, *Rubber, vulcanized or thermoplastic — Determination of hardness — Part 4: Indentation hardness by durometer method (Shore hardness)*

ISO 1942, *Dentistry — Vocabulary*

ISO 6873, *Dentistry — Gypsum products*

3 Terms and definitions

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

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

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

3.2
elastic recovery
ability of an elastomer to return to its original shape when a compression load is removed

3.3
extrusion mixing
method by which two or more material components are extruded simultaneously from their separate primary containers through a mixing nozzle from which the material 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
hardness
resistance to indentation

Note 1 to entry: In this document, this term refers to shore hardness according to ISO 48-4, Type A.

[SOURCE: ISO 1382:2020, 3.247, modified — Note 1 to entry was added.]

3.6
minimum time in the oral cavity
minimum time necessary for the material to remain in the oral cavity to prevent significant deformation

3.7
mixing time
time, measured from first contact between different components of a material being mixed, until a homogeneous mixture of the components is achieved

Note 1 to entry: The time of first contact between extrusion-mixed material components is defined as the time when the material components enter the mixing nozzle.

3.8
outer package
wrapping or carton used to cover one or more primary containers in preparation for retail marketing

Note 1 to entry: Legislation or specific standards can apply.

3.9
primary packaging
container designed to come into direct contact with the product

[SOURCE: ISO 21067-1:2016, 2.2.3, modified — Term “packaging” replaced with “container” in the definition.]

3.10
strain in compression
flexibility/stiffness property ranges of the materials that determines whether the set materials, when formed as impressions, can be removed from the mouth without injury to the impressed oral tissues and have adequate stiffness in the more flexible portions of impressions to resist deformation when model-forming products are poured against them

3.11
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 prevents 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 document are classified according to the following consistencies, which are determined immediately after mixing is complete according to the manufacturer’s instructions (see 8.2):

— Type 0: putty consistency;

— Type 1: heavy-bodied consistency;

— Type 2: medium-bodied consistency;

— Type 3: light-bodied consistency;

— Type B: bite registration materials.

5 Requirements

5.1 Component colours (not applicable for transparent materials)

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.

5.2 Mixing time (hand-spatulated or hand-kneaded mixes)

When the material components are combined according to the manufacturer's instructions and the results of the mixing are evaluated according to 7.1, the average time required to achieve a homogeneous mixture (essentially streak-free) shall not exceed the time stated by the manufacturer.

5.3 Consistency

When tested according to 7.2, the test disc diameter shall be in the range given in Table 1 for the consistency assigned to the material by the manufacturer.

5.4 Working time

When tested according to 7.3, the working time shall not be less than that stated in the manufacturer's instructions.

5.5 Detail reproduction

When tested according to 7.4, the line width reproduced shall not exceed the appropriate value given in Table 1.

5.6 Linear dimensional change

When tested according to 7.5, the linear dimensional change shall not exceed the appropriate value given in Table 1.

5.7 Compatibility with gypsum

The impression material shall leave a smooth surface on the gypsum model material. It shall also separate cleanly from the gypsum model material poured against it. When tested according to 7.6, the line width reproduced shall not exceed the appropriate value given in Table 1.

5.8 Elastic recovery

When tested according to 7.7, the elastic recovery shall be greater than or equal to the value given in Table 1.

5.9 Strain in compression

When tested according to 7.8, the strain in compression shall be in the appropriate range given in Table 1.

5.10 Minimum time in the oral cavity for bite registration materials

When tested according to 7.9, the minimum time in the oral cavity shall be smaller than or equal to the value given by the manufacturer in the instructions for use.

5.11 Compression set of bite registration materials

When tested according to 7.9, the compression set after load removal shall be less or equal to the value given in Table 1.

5.12 Hardness of bite registration materials

When tested according to 7.10, the hardness of the material shall be greater than or equal to the value given in Table 1.

Table 1 — Characteristic and physical property requirements

Type	Test subclause number and description								
	7.2		7.4	7.5	7.6	7.7	7.8	7.9	7.10
	Consistency (test disc diameter) mm		**Detail reproduction** (line width reproduced) [a] µm	**Linear dimensional change** % max.	**Compatibility with gypsum** (line width reproduced) [a] µm	**Elastic recovery** %	**Strain in compression %**	**Compression set** mm	**Hardness** Shore A
	min.	max.				min.	min. | max.	max.	min.
0	–	35	75	1,5	75	96,5	0,8 | 20,0	–	–
1	–	35	50	1,5	50	96,5	0,8 | 20,0	–	–
2	31	41	20	1,5	50	96,5	2,0 | 20,0	–	–
3	36	–	20	1,5	50	96,5	2,0 | 20,0	–	–
B	–	–	–	1,5	–	–	– | –	0,1	50

[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 A.4.

6 Pre-test planning approaches

6.1 General

This clause is provided to help test operators avoid loss of time due to potential trial and error efforts occurring if such information were not considered before test procedures are begun.

6.2 Sampling

When procuring samples of materials for testing:

a) procure samples that have been packaged for retail or franchise marketing that have not passed the use-by date;

b) select samples that have the same lot (batch) number [see 8.1.g)] wherever possible;

c) ensure that the sample size is:

   1) up to 900 ml to conduct all required tests and for the considerable practice that is often necessary for the test operator to become proficient in specimen preparation and testing;

   2) for gypsum materials for the test on the compatibility of the impression material with gypsum, at least 1 kg.

6.3 Pre-test product examinations

6.3.1 General

The examinations outlined in 6.3 are helpful in determining whether the sample procured (6.2) is fit for objective testing.

6.3.2 Examinations for conformity with labelling requirements

Before opening any primary packaging container, examine it to check the quality of the content, in case it has been compromised since manufacture.

It is recommended to record the following information about the product in a test-record format:

a) brand name, type and class of the product, if applicable, along with an added numeric or alpha numeric symbol for the sample;

b) use-by date for the product;

c) lot number for each component.

6.3.3 Examinations for effectiveness of the packaging

Before opening any primary packaging container, examine it to check the quality of the content, in case it has been compromised since manufacture. Things to look for include:

a) leakage or loose tube caps or canister lids;

b) container rupture or punctures;

c) shrinkage of the content that can be detected by sight, sound or touch.

WARNING — Do not use any compromised materials for preparing specimens.

6.3.4 Examinations for compliance with requirements for instructions for use

Before discarding any secondary packaging:

a) examine the labels to determine whether they include any of the information on instructions for use specified in 8.2;

b) locate and retain any instruction sheet provided outside the primary container;

c) examine the instructions for use for conformity with requirements stated in 8.2.

6.4 Essential pre-test preparatory practices

6.4.1 Laboratory conditions

Unless otherwise specified in this document:

a) conduct all specimen preparation and testing under the ambient laboratory conditions of (23 ± 2) °C and (50 ± 10) % relative humidity;

b) bring all equipment and materials for the tests to the ambient temperature before beginning specimen preparation.

6.4.2 Apparatus function verification steps

Unless otherwise specified in this document:

a) examine all accessories, instruments and equipment for functional effectiveness before they are used in a test;

b) clear all instrumentation or equipment surfaces that come in contact with the specimen material of any contaminants;

c) perform whatever calibration steps necessary to ensure that the items conform to the specifications stated for them in this document or in ISO 6873.

6.4.3 Volume of materials to be mixed for each specimen

Unless otherwise specified in this document, the volume mixed for each specimen shall be (15 ± 0,5) ml.

6.4.4 Proportioning, mixing and handling of hand-mixed materials to be tested

Standardized approaches to proportioning, mixing and handling of hand mixed materials are listed in Annex B.

6.4.5 Timing for the specimen preparation and test procedures

A timing device such as a stop watch (permissible error of 1 s over a 30 s period) shall be used for timing each required specimen preparation and test step.

6.4.6 Simulated oral time/temperature treatment of specimens formed in completely closed mould assemblies

NOTE This applies to detail reproduction, linear dimensional change, elastic recovery and strain in compression test specimens.

Immediately after the specimen forming material has been completely enclosed in the specimen forming assembly, the entire assembly shall be conditioned at (35 ± 1) °C for the time period recommended by the manufacturer for leaving the material in the mouth.

6.5 Pass/fail determinations

The minimum number of specimens to be tested for pass/fail determinations shall be five.

If at least four of the five specimens meet the related requirement, the material passes. If only one or two specimens meet the requirement, the material fails. If only three specimens meet the requirement, make a series of five additional specimens. If four of the second series of specimens meet the requirement, the material passes. Otherwise, the material fails.

6.6 Expression of test results

Record the number of specimens tested and whether the material passes or fails.

7 Test methods

7.1 Mixing time

7.1.1 Apparatus

7.1.1.1 Recommended mixing apparatus [see 8.2.4 c)].

7.1.1.2 Timing device (see 6.4.5).

7.1.2 Specimen preparation and test procedure (five specimens)

Proportion and mix the required volume of material (see 6.3.3) 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 are suitable for providing increments of material for the consistency test (see 7.2).

7.1.3 Pass/fail determination and expression of results

Determine whether the mean result obtained in accordance with 7.1.2 conforms to 5.2 and report the results.