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Dentistry — Elastomeric impression and bite registration materials

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

FDIS stage

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: + 41 22 749 01 11
E-mail: copyright@iso.org
Website: www.iso.org

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Foreword

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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.htmlwww.iso.org/members.html.

Contents

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 48-4:2018, *Rubber, vulcanized or thermoplastic — Determination of hardness — Part 4: Indentation hardness by durometer method (Shore hardness)*

ISO 1942, *Dentistry — Vocabulary*

ISO 6873:2013, *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 ~~terminological~~terminology databases for use in standardization at the following addresses:

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

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

3.1 ~~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 ~~3.2~~
elastic recovery
ability of an elastomer to return to its original shape when a compression load is removed

3.3 ~~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 3.4
hand mixing
method of mixing the components of a material by means of manual kneading or spatulation

3.5 3.5
hardness
resistance to indentation

Note 1 to entry: In this document, this term refers to shore hardness according to ISO 48-4:2018, Type A.

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

3.6 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 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 into the mixing nozzle.

3.8 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 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 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 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):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 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 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 7.1,7.1, the average time required to achieve a homogeneous mixture (essentially streak-free) shall not exceed the time stated by the manufacturer.

5.3 5.3 Consistency

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

5.4 5.4 Working time

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

5.5 Detail reproduction

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

5.6 5.6 Linear dimensional change

When tested according to 7.5,7.5, the linear dimensional change shall not exceed the appropriate value given in Table 1.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 7.6,7.6, the line width reproduced shall not exceed the appropriate value given in Table 1.Table 1.

5.8 5.8 Elastic recovery

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

5.9 5.9 Strain in compression

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

5.10 Minimum time in the oral cavity for bite registration materials

When tested according to 7.9,7.9, 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 5.11 Compression set of bite registration materials

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

5.12 5.12 Hardness of bite registration materials

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

Table 1 — Characteristic and physical property requirements

Type	Test subclause number and description								
	7.27.2		7.47.4	7.57.5	7.67.6	7.77.7	7.87.8	7.97.9	7.107.10
	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	–	–