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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

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Contents

Page

Foreword

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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 documents 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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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 fifth edition cancels and replaces the fourth edition (ISO 4823:2015), which has been technically revised and enhanced with regard to elastomeric bite registration materials. The following changes have been applied:

— the title and scope have been changed to reflect the inclusion of elastomeric bite registration materials;

— ISO 48-4:2018 has been added as a normative reference;

— a description of minimum time in the oral cavity for bite registration materials has been added;

— a description of hardness of bite registration materials has been added.

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.

NOTE This document does not address possible biological hazards associated with the materials. Assessment of these hazards is addressed in ISO 7405 and the ISO 10993 series.

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 databases for use in standardization at the following addresses:

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

— IEC Electropedia: available at http://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
elastic properties required to recover adequately after deformation

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, it is Shore hardness according to ISO 48-4:2018, Type A.

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

3.6
minimum time in the oral cavity
minimum time span the material stays in the oral cavity to sufficiently minimize deformation

3.7
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 1 to entry: 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.

3.8
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 — "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 determined immediately after completion of mixing according to the manufacturer's instructions (see 5.3):

— 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 Packaging requirements

No packaging requirements are specified in this document, but it is important for manufacturers to take into account that the packaging should be such that it does not contaminate or permit contamination of ingredients of the material components during recommended storage conditions. Structure of the primary packaging should also be such that no leakage or inadvertent extrusion of the contents can occur during storage and such that the containers will not rupture during use of the extrusion methods recommended by the manufacturer.

NOTE Additional information can be supplied at the discretion of the manufacturer or as required by regulation.

5.2 Labelling requirements

5.2.1 Outer packages (containing one or more primary containers)

Labelling of the outer packaging prepared for retail marketing containing one or more primary containers shall bear the following information:

a) recommended storage conditions for the unopened package;

b) brand name;

c) name and address of the manufacturer or the name of another company authorized by the manufacturer to market the material under a different brand name;

d) identification of the consistency of the material as putty, heavy-bodied, medium-bodied, or light-bodied (see Clause 4) (the type number can also be included);

e) manufacturer's batch reference(s);

f) USE BEFORE DATE, identified as such, beyond which the material may not exhibit its best properties; the date shall be expressed as a six-digit number, for example, 2014-09, where the first four digits indicate the year (2014) and the last two digits indicate the month (September);

g) minimum volume that would result from mixing the entire component contents included in the outer package.

NOTE Additional information can be supplied at the discretion of the manufacturer or as required by regulation.

5.2.2 Primary containers within outer packaging

Labels for primary containers shall bear the following information:

a) brand name;

b) name of the manufacturer or name of another company authorized to market the material under a different brand name;

c) component identification (not required when the components for extrusion mixing are supplied in separate but joined primary containers);

d) manufacturer’s batch references.

NOTE Additional information can be supplied at the discretion of the manufacturer or as required by regulation.

5.3 Requirements for information in the manufacturer's instructions

5.3.1 General

Each package in which the components of an impression material are prepared for retail marketing shall be accompanied by the instructions and other information needed to ensure optimum performance of the material in clinical practice.

NOTE Additional information to that specified in 5.3.2 and 5.3.3 can be supplied at the discretion of the manufacturer or as required by regulation.

5.3.2 Identifying information

The following identifying information is required:

a) trade name or brand name of the product;

b) chemical nature of the elastomeric system: for example, polyether, polysulfide, silicone (condensation type), or silicone (vinyl polysiloxane, addition type).

5.3.3 Specific instructions for use

Where applicable, the specific instructions for use shall include the following:

a) recommended storage conditions after the initial opening of the primary containers;

b) statements indicating that working time and other characteristics of the material can be affected significantly by the following factors, as applicable:

   — room temperature variations;

   — variations in the speed and friction involved in mixing;

   — hand/fingertip temperatures when kneading putty mixes;

   — moisture contamination or relative humidity;

   — contamination, either due to direct contact with latex dam or gloves used in clinical practice or due to the presence of such contaminants on teeth at the time they are impressed;

c) proportions for hand-spatulated mixes (mass to mass and volume to volume);

d) recommended mixing apparatus and procedures to include the generic identification of any hand coverings (gloves or polymer sheeting) that should be used to avoid contamination of the materials during hand manipulation;

e) mixing time required to obtain a homogeneous mixture of an amount of the material having a volume of 15 ml [see 5.3.3, d) and Annex B];

f) working time;

g) minimum time the material should remain in the mouth before removal.

The following items only apply to impression materials:

h) minimum or maximum time lapse, or both, permitted between removal of the impression from the mouth and pouring the gypsum product into the impression;

i) identification of at least two gypsum products, complying with requirements of ISO 6873:2013, which the impression material manufacturer has found to be compatible with the impression material being tested: one Type 3 product (dental stone, model) and either one Type 4 product or one Type 5 product (dental stone, high strength);

j) when the manufacturer's instructions state that an impression made of a material may be disinfected, the disinfecting procedure shall be described in detail and a reference indicating that the disinfection procedure will not alter the potential of the impression for optimum performance shall also be identified;

k) when a manufacturer claims that a material in itself is antimicrobial and will remain so without further treatment after the impression is removed from the mouth, the manufacturer shall identify the reference on which the claim is based.

5.4 Requirements for characteristics and properties

5.4.1 Component colours (hand-spatulated or hand-kneaded mixes)

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.

5.4.2 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.

5.4.3 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.

5.4.4 Working time

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

5.4.5 Detail reproduction

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

5.4.6 Linear dimensional change

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

5.4.7 Compatibility with gypsum

The impression material shall impart a smooth surface to and 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.

5.4.8 Elastic recovery

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

5.4.9 Strain in compression

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

5.4.10 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.

5.4.11 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.

5.4.12 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 no. 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

The information in this Clause is provided to help test operators avoid losses of time due to trial and error efforts occurring when such information is not considered before test procedures, such as those described in Clause 7, are begun.

6.1 Sampling

Observe the following guidelines when procuring samples of materials for testing.

a) Procure only samples that have been packaged for retail or franchise marketing and that have labelling **Use by** dates that have not expired.

b) Wherever possible, select only those samples that have the same lot (batch) number [see 5.2.1 e)].

c) Sample size required

— as much as 900 ml might be needed for conducting all required tests and for the considerable practice that might be necessary for the test operator to become proficient in specimen preparation and testing, and

— for the gypsum materials needed for the impression material compatibility with gypsum test, at least 1 000 g.

6.2 Pre-test product examinations

These examinations are helpful in determining whether the sample procured (6.1) is fit for objective testing.

6.2.1 Examinations for compliance with labelling requirements

Examine the consumer packaging components for compliance with the labelling requirements before any attempt to open a packaging component has defaced or obliterated any labelling entry information needed for storage or use of the product (for example, **Use by** date).

At this point, it is recommended that the following information about the product be recorded for future reference in a test record format, if possible:

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.

6.2.2 Examinations for effectiveness of the packaging

Before opening any primary packaging container, examine it for possibilities that the quality of the content might have been compromised since its manufacture. For example, evidence such as the following:

a) loose tube caps or canister lids or leakage;

b) container rupture or punctures;

c) shrinkage of the content of a container such as can be detected by sight, sound, or touch.

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

6.2.3 Examinations for compliance with requirements for instructions for use

a) Before discarding any secondary packaging:

— examine the labels to determine whether they include any of the instructions for use information specified in 5.3, and

— locate and retain any instruction sheet that might have been provided outside the primary container.

b) Examine the instructions for use for compliance with requirements stated in 5.3.3.

6.3 Essential pre-test preparatory practices

6.3.1 Laboratory conditions

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