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Dentistry — Elastomeric impression materials

Médecine bucco-dentaire — Matériaux à empreintes, 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 on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information.

The committee responsible for this document is ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthodontic materials*.

This fourth edition cancels and replaces the third edition (ISO 4823:2000), which has been technically revised with the following changes:

— modification of the sequence of requirements having the requirements for packaging and labelling listed before the requirements for characteristics and properties;

— the restriction that the working time shall be at least 30 s longer than the mixing time was eliminated; this was considered necessary in view of the fact that several products have shorter working time;

— working time test procedure using the dead weight method (Sink-in method) for Type 0 materials which had been exempt from this requirement in the third edition was introduced (see 7.3.2);

— the current displacement Rheometer procedure stated in ISO 4823:2000 will continue to be used for testing Type 1, 2, and 3 materials without modifications;

— concerning the order in which some clauses are presented, whereas in later years, most dental product standards have been structured to have the requirements and test methods clauses appear before the requirements for labelling and instructions for use clauses, this International Standard gives first ordering to the labelling and instructions for use requirements. This change was thought to be necessary because experience informs us that test operators will be better equipped to obtain success in testing if they first take into account the information available in the labelling and in the instructions for use;

— Clause 6 has been added for reasons explained in its first paragraph;

— concerning the Annexes

  — Annex A was created due to the ISO Central Secretariat suggestion that all figures, grouped together instead of being presented individually on related pages of the text, are to be presented in a normative Annex and numbered according to existing rules. This is to make it easier for the figures to be located by users of the document;

— Annex B provides for standardized hand mixing methods to be used by test operators so that specimen preparation mixing of the test specimens will be uniform and consistently fairer to the various products;

— Annex C identifies sources for the working-time test apparatus and the linear variable displacement transducer (LVTD).

Dentistry — Elastomeric impression materials

1 Scope

This International Standard specifies the requirements and tests that the state-of-the art body of knowledge suggests for helping determine whether the elastomeric impression materials, as prepared for retail marketing, are of the quality needed for their intended purposes.

NOTE This International Standard does not address possible biological hazards associated with the materials. Therefore, interested parties are encouraged to explore ISO 7405 and ISO 10993 for assessment of such hazards.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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.

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
DEPRECATED: compression set
DEPRECATED: permanent deformation
DEPRECATED: recovery from deformation
⟨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 simultaneously from their separate primary containers through a special mixing tip 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
primary packaging
container designed to come into direct contact with the product

[SOURCE: ISO 21067:2007, 2.2.2, modified — “packaging” replaced by “container” in the definition.]

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 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.

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

3.8
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, can be removed from the mouth without injury to impressed oral tissues and will have adequate stiffness in the more flexible portions of impressions to resist deformation when model-forming products are poured against them

3.9
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 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.

5 Requirements for packaging, labelling, and information in manufacturer's instructions

5.1 Packaging requirements

No packaging requirements are specified in this International Standard, but it is important for manufacturers to take into account that the packaging should be such that it will 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.

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 may 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.

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.

5.3 Requirements for information in 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

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 may be 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 and Annex B);

f) working time;

g) minimum time the impression should remain in the mouth before removal;

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, 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

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 impression 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.

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	
	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 % min.	Strain-in-compression %	
	min	max					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 A.12.

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 taken into account 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 of the 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).

NOTE 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:

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

— **Use by** date for the product;

— 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:

— loose tube caps or canister lids or leakage;

— container rupture or punctures;

— 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 International Standard, 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.

6.3.2 Apparatus function verification steps

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 will come in contact with the specimen material of any contaminants that might influence the test result.

c) Perform whatever calibration steps necessary to ensure that the items comply with specifications stated for them in this International Standards or in the normative supporting reference ISO 6873.

6.3.3 Volume of materials to be mixed for each specimen

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

6.3.4 Order for conducting examinations and tests

a) Irrespective of the number of tests required, always conduct the examinations first and then conduct the mixing time test, the component colour evaluation, and the working time test, in that order.

b) When there is a need to conduct all of the other tests, conduct all of the tests in the order they are described in Clause 7, unless there is some compelling reason not to do so.

6.3.5 Standardized approaches to proportioning, mixing, and handling of hand mixed materials to be tested

See Annex B.

6.3.6 Timing for the specimen preparation and test procedures

A timing device such as a stop watch accurate to 1 s over a 30 s period shall be used for timing each requiring specimen preparation and test step.

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

(For the detail reproduction, linear dimensional change, elastic recovery, and strain-in-compression test specimens)