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Dentistry — Hydrocolloid impression materials

Médecine bucco-dentaire — Produits pour empreintes à base d'hydrocolloïdes

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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 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).

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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/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 second edition cancels and replaces the first edition (ISO 21563:2013), which has been technically revised.

The main changes compared to the previous edition are as follows:

— The detail reproduction before and after disinfection for alginate powder and paste/paste materials has been corrected to be 50 microns.

— The elastic recovery test has been modified to allow for the use of poly(methyl methacrylate) plates as an alternative to glass or metal.

— Figures A.2, A.3, A.4, and A.6 have been corrected.

— Multiple editorial changes have been made throughout the document.

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 — Hydrocolloid impression materials

1 Scope

This document specifies the requirements and test methods for hydrocolloid impression materials. This document helps to determine whether elastic aqueous agar and alginate hydrocolloid dental impression materials, as prepared for retail marketing, are of the quality needed for their intended purposes. It also specifies requirements for labelling and instructions for use. 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 1942, *Dentistry — Vocabulary*

ISO 6873, *Dentistry — Gypsum products*

ISO 3696, *Water for analytical laboratory use — Specification and test methods*

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 http://www.electropedia.org/

3.1
bonding
adherence of the *impression* (3.6) material components in a single impression after each of the interfacing materials has reached the level of effective setting required for successful removal from the mouth

3.2
bulk container
labelled packaging holding a greater amount of otherwise unpackaged granular, liquid, powder, or other loose substance than is usually needed for a single dental clinical or laboratory procedure

3.3
consumer packaging
retail packaging
sales packaging
packaging constituting, with its contents, a sales unit to the final user or consumer at the point of retail

[SOURCE: ISO 21067-1:2016, 2.2.7, modified — "retail packaging" and "sales packaging" have been changed from preferred terms to admitted terms.]

3.4
elastic recovery
elastic properties required to recover adequately from deformation

3.5
extrusion
process of obtaining a liquefied Type 3 or Type 3A agar *impression* (3.6) material from the containing cartridge or syringe

3.6
impression
negative copy of oral or craniofacial tissue surfaces obtained by placing a mouldable impression material into contact with the tissue surfaces, and allowing it to harden, or to become elastic, such that the entire impression material/tray assembly can be removed from the contact without significant harm to the tissues or to the assembly

Note 1 to entry: A properly formed impression is capable of having a relatively fluid model (cast) forming material poured against the intaglio surface so that, when the modelling material sets, a positive copy of the impressed surfaces is formed.

3.7
initial setting time
time, measured from commencement of mixing components of a material, or otherwise activating the chemistry involved, and ending at a time when results of a prescribed test show that the activated material has begun to set at a rate indicating that the effective setting time will be reached at some predictable time thereafter

Note 1 to entry: Initial setting times stated in the manufacturer's instructions are useful to test operators, users and standards developers because they can be helpful:

— in determining whether quality of a product has deteriorated before or after opening of the packaging; for example, if the initial setting time found by the test operator or user corresponds closely to that stated in the manufacturer's instructions, it can be assumed that the product is of a quality suitable for testing or use;

— in the development of standards for certain materials when there is a need for a standard to identify a reference point in time that can be used as a basis for specifying a later point in time at which a subsequently specified procedure can safely begin.

3.8
liquefaction
process of heating an agar *impression* (3.6) or duplicating material to change it from the elastic gel state to the mouldable or pourable sol state

3.9
non-reversible impression material
impression (3.6) material which, having been brought to the effective setting stage as required for removal from the mouth, cannot be returned to the mouldable state required for forming impressions

3.10
primary packaging
primary container
DEPRECATED: immediate container
packaging designed to come into direct contact with the product

[SOURCE: ISO 21067-1:2016, 2.2.3, modified — The admitted term "primary container" and the deprecated term "immediate container" have been added.]

3.11
reversible impression material
impression (3.6) material such as an agar hydrocolloid which, after having been brought to the gel state for marketing purposes, can be heated so as to bring it to the relatively fluid colloid or paste-like state required for making an impression

Note 1 to entry: Whereas in past years the “gel to sol” and “sol to gel” reversibility capacities of such impression materials have allowed them to be recycled for repeated uses, modern infection control practices now discourage user recycling of the reversible impression materials for repeated uses in the mouth.

3.12
secondary packaging
DEPRECATED: over packaging
packaging designed to contain one or more *primary packagings* (3.10) together with any protective materials and accessory devices that may have to be provided for use with the product

[SOURCE: ISO 21067-1:2016, 2.2.4, modified — The deprecated term "over packaging" has been added; "where required" has been replaced by "and accessory devices that may have to be provided for use with the product".]

3.13
storing
process of holding increments of liquefied reversible agar hydrocolloid *impression* (3.6) material at a reduced temperature pending time they will be injected or tempered for impression making purposes

3.14
strain-in-compression
flexibility/stiffness property ranges of materials so as to determine whether the set materials, when formed as *impressions* (3.6), 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

3.15
tempering
process of holding a heavy or medium bodied agar *impression* (3.6) material in a slightly higher than mouth temperature water bath, after the material has been placed into an impression tray, so as to further reduce the sol state temperature as necessary for safe and effective seating in the mouth

3.16
unit packet
packaging containing only the amount of product usually needed for a single dental clinical or laboratory application

4 Classification of agar hydrocolloid impression materials

The agar impression materials are classified according to the consistencies they exhibit while they are ready for impressing against the oral or craniofacial tissue surfaces, and when tested according to 5.2.

— Type 1 heavy bodied, for making impressions of complete or partial dental arches, with or without the use of companion increments of lighter bodied Type 2 or Type 3 agar impression materials.

— Type 2 medium bodied, for making impressions of complete and partial dental arches, with or without the use of companion syringe-extruded increments of Type 3 agar materials.

— Type 3 light bodied, for syringe use with either the Type 1 or Type 2 agar materials.

— Type 3A light bodied, material formulated for syringe use in a reversible/non-reversible impression material system, and that has been claimed to be capable of bonding to a companion alginate impression material that will make up the greater part of an agar/alginate impression material system.

5 Requirements — Characteristics and properties

5.1 General

The requirements applicable to only one category of hydrocolloid impression materials (agar or alginate) are stated in 5.2 to 5.6. The requirements applicable to both categories are displayed in Table 1.

5.2 **Consistency** (agar impression materials of all Types, in the sol state only)

After being exposed to the storing temperature treatment recommended in the manufacturer's instructions, the material shall have a consistency that will allow the entire content of the tube or syringes to be extruded within 30 s. No specimens need to be made but material shall be tested to see if all can be extruded within 30s.

5.3 **Working time** (alginate materials only)

When tested in accordance with 7.2, the thickness of the layer of material remaining between the tip of the test penetrator and the test base plate shall not exceed 0,25 mm.

5.4 **Initial setting time** (alginate materials only)

When tested in accordance with 7.3, the initial setting time shall be within 20 % of that stated in the manufacturer's instructions [8.2.4 h)].

5.5 **Linear dimensional change** (Type 3A agar materials only)

When tested in accordance with 7.9, the dimensional change shall not exceed 1,0 %.

5.6 **Tensile bond strength** (Type 3A agar materials only)

When tested in accordance with 7.10, the minimum tensile bond strength shall not be less than 50 kPa.

Table 1 — Other requirements for properties — Agar and alginate materials

Test subclause number	Test procedure	Agar materials		Alginate powder and paste/paste materials
		Type 1 and Type 2	Type 3 and Type 3A	
7.4	**Detail reproduction before and after disinfection** Line width reproduced (µm)	20	20	50
7.5	**Compatibility with gypsum** Line width reproduced (µm)	50	50	50
7.6	**Elastic recovery** % (min.)	96,5	96,5	95,0
7.7	**Strain-in-compression** % Range: min. to max.	4,0 to 15,0	4,0 to 15,0	5,0 to 20,0
7.8	**Tear strength** N/mm (min.)	0,75	0,50	0,38

6 Pre-test planning approaches

6.1 General

The information included 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.

6.2 Sampling

Observe the following when procuring samples of materials for testing.

a) Procure only samples that have been packaged for retail 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 8.1c)].

c) Procure samples in minimal amounts shown below when conducting certification testing that will require production of the several specimens needed for complete evaluation of the material.

   — For agar materials, Type 1 and Type 2 — at least 30 large tubes or the equivalent.

   — For agar materials, Type 3 and Type 3A – at least 150 sticks, cartridges or capsules.

   — For alginate impression materials – at least 900 g.

   — For alginate paste/paste materials – 5 l.

   — Gypsum materials for the compatibility with gypsum test — at least 1 000 g.

NOTE The sample sizes specified in this subclause have been justified by taking into account the probable amount to be consumed in testing for compliance with all stated requirements, and also the additional amounts often needed for pre-test specimen preparation and testing practice.

6.3 Pre-test product examinations

6.3.1 General

These evaluations are helpful in determining whether the sample procured (6.2) is fit for objective testing.

6.3.2 Examinations for compliance with labelling requirements

Examine the consumer packaging components for labelling compliance with the provision of 8.1 before any attempt to open a packaging component has defaced or obliterated any labelling entry information needed for storage or use of the product. Record the name, type, lot number and "use by" date as may be applicable for each primary container of the material to be tested.

6.3.3 Examinations for effectiveness of the packaging

Before opening any primary container, examine it for possibilities that the quality of the content may have been compromised since its manufacture; for example, evidence such as:

— loose tube caps or canister lids, or leakage;

— container rupture or punctures;

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

Immediately after opening an alginate container, examine the content for lumps or granules that may be due to faulty or compromised packaging.

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

6.3.4 Examinations for compliance with requirements for instructions for use

Before opening any primary container:

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

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

Immediately after the first opening of a primary container for powder alginate, examine the content for any instruction sheet that may have been placed inside the container.

6.4 Essential pre-test preparatory practices

6.4.1 Laboratory conditions

Unless otherwise specified in this document, conduct all specimen preparation and testing under 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.

6.4.2 Apparatus function verification steps

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

b) Perform whatever calibration steps necessary to ensure that the items comply with specifications stated for them in this document, or in ISO 6873.

c) Clear all instrumentation or equipment surfaces that will come in contact with the specimen material of any contaminants that might influence the test result.

6.4.3 Test material handling and use

6.4.3.1 Identification of separately packaged samples

When the sample procured for testing (6.2) includes two or more separate packages, assign an identifying numeric or alphabetical/numeric symbol to each separate primary container for the purpose of maintaining a record of the particular container from which the materials used to form a particular specimen was taken.

6.4.3.2 Storage and manipulation

Unless otherwise specified in this document, store, prepare and manipulate the materials used for forming the test specimens employing the equipment and procedures recommended in the manufacturer's instructions (8.2). When mixing the alginate materials, record the time required for each specimen preparation mix.

6.4.3.3 Mixing water for the alginate and gypsum products

The quality and temperature of the water used for making the specimens shall be as specified below:

— water quality: Grade 3 in accordance with ISO 3696, obtainable by distillation, deionization or reverse osmosis;

— water temperature: as recommended by the manufacturer [8.2.4 c)].

6.4.3.4 Amount of material to be prepared for each specimen

a) For agar hydrocolloid material mould assemblies

Type 1 and Type 2 agar materials – one tube for each specimen.

Type 3 and Type 3A agar materials, when used to make part of a specimen, such as for detail reproduction, gypsum compatibility, dimensional change or tensile bond strength test — one stick or one cartridge.

For Type 3 and 3A agar materials when used to make up the entire volume of the elastic recovery, strain-in-compression or tear strength specimen — a volume greater than that contained in one syringe will usually be needed.

b) For alginate materials

Powder or paste materials supplied in bulk containers — a mixture having a volume of about 40 ml (enough for making a medium-sized impression).

Powder materials supplied in unit packets — whatever volume results from mixing the powder provided in one packet with the recommended volume of water.

6.4.4 Simulated oral time/temperature treatment of specimens formed in completely closed moulds

After the specimen forming material has been completely enclosed in the specimen forming assembly, the entire assembly shall be conditioned for the time and at the temperature [8.2.2 c)] simulating that to which the material should be exposed after the impression has been seated in the mouth; for example:

— an assembly containing alginate alone, or containing agar/alginate combinations, shall be immersed in a cooling water bath set at (35 ± 2) °C and shall remain so immersed for the time recommended in the instructions for the impression material/tray assembly to remain seated in the mouth;

— assemblies containing agar material alone shall be immersed in the cooling a water bath for the time and at the cooling water temperature recommended in the instructions for obtaining the desired degree of gelation of the material after it has been seated in the mouth.

6.4.5 Order of conducting tests

When testing the alginate impression materials, always conduct the working time test (7.2) and the initial setting time test (7.3) first in order because, when the results obtained in these tests differ significantly from manufacturer claims [8.2.4 g)] and [8.2.4 h)], it is likely that the quality of the sample procured for testing has somehow been compromised and that the manufacturer should be contacted relative to the difference noted.

6.4.6 Test schedules timing

Time the schedules for specimen preparation and testing using a timing device such as a stopwatch accurate within 1 s over a period of 30 s.

6.4.7 Pass/fail determinations

The minimum number of specimens to be tested for pass/fail determinations shall be either three or five, as indicated in the first specimen preparation subclause for each related test in Clause 7.

a) 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 comply, 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.

b) 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 less than three specimens comply, the material fails. If only three specimens comply, make a series of five additional specimens. If four of the second series of specimens comply, the material passes; otherwise the material fails.

6.4.8 Expression of test results

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

7 Test methods

7.1 General

Test operators are advised to become familiar with the content of Clause 6 before beginning any specimen preparation. Figures illustrating instruments and accessories used in tests are in Annex A.

7.2 Working time test (alginate materials only)

7.2.1 Apparatus and materials (the array of devices or materials used or available for an undertaking)

a) **Rigid ring mould**, height (16,0 ± 0,1) mm, internal diameter (30,0 ± 0,2) mm.

b) **High vacuum grease**, such as silicone grease which will not be reactive with the ring mould or the material being tested.

c) **Flat glass plate**, approximately 50 mm × 50 mm and at least 3 mm thick.

d) **Working time test instrument** (Figure A.1). The combined mass of the penetrator shaft and penetrator tip shall be (50 ± 0,5) g.

7.2.2 Specimen preparation

7.2.2.1 General

Prepare a minimum of three specimens.

7.2.2.2 Advance preparation steps

a) Mark or modify the test instrument base [7.2.1 d)], the ring mould [7.2.1 a)], and the flat plate [7.2.1 c)] such that these parts can be related to each other in the same position for each test.

b) Coat surfaces of the ring mould with a thin film of the high vacuum grease [7.2.1 b)].

c) Centre and fix the ring mould onto the flat plate in position for the test.

d) Elevate and lock the penetrator shaft and the dial indicator spindle of the test instrument (Figure A.1) so as to allow the centre of the ring mould/flat plate assembly to be positioned directly below the penetrator tip.

e) Unlock the penetrator shaft so as to allow the tip to descend into contact with the centre of the glass base plate surface below the ring mould. Lower the dial indicator spindle contact point to rest on the top of the penetrator shaft and record the resulting dial indicator reading as the fiducial reading a.

f) Elevate and lock the penetrator shaft, and the dial indicator spindle, so that the penetrator tip is positioned far enough above the top of the ring mould to allow removal of the ring mould/flat plate assembly in preparation for filling the mould assembly with impression material.

7.2.2.3 Specimen formation and pre-test positioning

Immediately after completion of mixing the alginate, slightly overfill the ring mould and strike off the excess level with the top surfaces of the mould; centre the test specimen assembly beneath the penetrator tip. Then unlock the penetrator shaft and allow it to descend until the tip is barely in contact with the top surface of the material to be tested and lock the shaft with the tip in this position.

7.2.3 Test procedure

At 5 s before the end of the working time stated in the instructions, loosen the penetrator shaft locking screw so as to allow the penetrator tip to descend into the material under the combined weight of the shaft/tip complex [7.2.1 d)].

10 s thereafter, lower the dial indicator contact point to rest on the top of the penetrator shaft. Immediately thereafter record the resulting dial indicator reading as reading b. Then calculate the difference between readings a and b to the nearest 0,01 mm and record whether the thickness of the material remaining between the penetrator tip and the glass plate surface complies with the allowance stated in 5.4.

NOTE Since the material in the working time test assembly will not have reached the initial setting stage by the time descent of the penetrator has been completed, it will therefore be possible and time-saving to begin testing the same specimen for initial setting time according to 7.3.3 shortly thereafter.

7.2.4 Pass/fail determinations/and expression of results

See 6.4.7 and 6.4.8.

7.3 Initial setting time test (alginate impression materials only)

7.3.1 Apparatus

a) **Rigid ring mould** [7.2.1 a)], coated with the high vacuum grease [7.2.1 b)].

b) **Cylindrical polymethylmethacrylate test rod,** approximately 100 mm long and 6 mm in diameter, having both ends polished to a high lustre (scratch free as can be determined visually without magnification).

7.3.2 Specimen preparation

Prepare a minimum of three specimens.

As indicated in the NOTE under 7.2.3, the specimens prepared for the working time test can also be used for the initial setting time test. Otherwise complete the first three steps, a), b) and c) described in 7.2.2.2 for forming the specimens according to the introductory sentence of 7.2.2.3 and conduct the test as described in 7.3.3.

7.3.3 Test procedure

At 5 s after the working time stated in the instructions [8.2.4 g)], begin the test by placing an end of the test rod [7.3.1b)] into momentary contact with the unset specimen material. Clear any material left on the rod from the contact. Then repeat the contact/withdrawal rod clearing steps at 10 s intervals until the test rod separates cleanly from the material. Record the time of this occurrence as the initial setting time and compare it to the requirement stated in 5.5.