SLOVENSKI STANDARD
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Zobozdravstvo - Hidrokoloidni materiali za oblikovanje (odtise) (ISO/DIS 21563:2020)

Dentistry - Hydrocolloid impression materials (ISO/DIS 21563:2020)

Zahnheilkunde - Hydrokolloidabformmaterialien (ISO/DIS 21563:2020)

Médecine bucco-dentaire - Produits pour empreintes à base d'hydrocolloïdes (ISO/DIS 21563:2020)

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 21563 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthodontic materials*.

This second edition cancels and replaces the first edition, which has been technically revised. The following changes were made:

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

— The elastic recovery test was 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 were corrected and multiple editorial changes were made throughout the document.

Introduction

Parties seeking clarification of any provisions of this International Standard, or desiring to recommend improvements for the next edition, are encouraged to do so by contacting ISO/TC 106, Dentistry, whose address can be obtained through inquiry to the national standards body representing the interests of the inquiring parties.

Dentistry — Hydrocolloid impression materials

1 Scope

This document specifies the requirements and tests for helping determine whether the 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.

NOTE This document specifies no requirements or tests for freedom from unacceptable biological hazards. However, it is recommended that, to address possible biological hazards associated with the use of hydrocolloid impression materials, interested parties should refer to ISO 7405 and ISO 10993.

2 Normative references

The following referenced documents are indispensable for application 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.

3.1
bonding
adherence of the reversible and non-reversible impression material components constituting a single impression after each of the separate but interfacing materials has reached the level of elasticity and effective setting required for successful removal from the mouth

3.2
bulk container
labelled consumer packaging or primary packaging container 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
combined reversible/non-reversible impression material system
system of impression making in which a light bodied agar material is first syringed around selected teeth so that it can bond with the non-reversible alginate material that will be forced over it later during the formation of an impression

3.4
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 21067:2007, definition 2.2.5]

3.5
elastic recovery
elastic properties required to recover adequately from deformation

3.6
extrusion temperature
temperature at which a liquefied Type 3 or Type 3A agar impression material is extruded from the containing cartridge or syringe onto any oral cavity tissue

3.7
impression
negative copy of oral or craniofacial tissue surfaces obtained by impressing a mouldable impression material, usually contained in an impression tray, or injected 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.

3.8
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.

EXAMPLE It is reasonable to expect that the effective setting times for certain types of gypsum product mixtures will have been reached within 45 min after the initial setting times previously recorded for the mixes.

3.9
liquefaction
process of heating an agar impression or duplicating material to change it from the elastic gel state to the mouldable or pourable sol state

3.10
non-reversible impression material
any impression 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

3.11
primary packaging
primary container
immediate container (deprecated)
packaging designed to be in direct contact with the product

Note 1 to entry: Adapted from ISO 21067:2007, definition 2.2.2.

3.12
reversible impression material
impression 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 has 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.

3.13
secondary packaging
over packaging (deprecated)
packaging designed to contain one or more primary packagings together with any protective materials, accessory devices that may have to be provided for use with the product

Note 1 to entry: Adapted from ISO 21067:2007, definition 2.2.3.

3.14
storing
process of holding increments of liquefied reversible agar hydrocolloid impression material at a reduced temperature pending time they will be injected or tempered for impression making purposes

3.15
strain in compression
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

3.16
tempering
process of holding a heavy or medium bodied agar impression 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

3.17
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 5.1.

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

The requirements applicable to only one category of hydrocolloid impression materials (agar or alginate) are stated immediately below in 5.1 to 5.5. The requirements applicable to both categories are displayed in Table 1 which constitutes a part of Clause 5.

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

After being exposed to the recommended 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.

5.2 Working time (alginate materials only)

When tested in accordance with 7.1, 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.

5.3 Initial setting time (alginate materials only)

When tested in accordance with 7.2, the initial setting time shall be within 20 % of that stated in the manufacturer's instructions [8.2.3 h)]

5.4 Linear dimensional change (Type 3A agar materials only)

When tested in accordance with 7.8, the dimensional change shall not exceed 1,0 %

5.5 Tensile bond strength (Type 3A agar materials only)

When tested in accordance with 7.9, 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	
7.3	**Detail reproduction before and after disinfection** Line width reproduced (µm)	20	20	50
7.4	**Compatibility with gypsum** Line width reproduced (µm)	50	50	50
7.5	**Elastic recovery** % (min.)	96,5	96,5	95,0
7.6	**Strain-in-compression** % Range: min. to max.	4,0 to 15,0	4,0 to 15,0	5,0 to 20,0
7.7	**Tear strength** N/mm (min.)	0,75	0,50	0,38

6 Pre-test planning approaches

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.

6.1 Sampling

Observe the following guidelines 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.

6.2 Pre-test product examinations

These evaluations 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 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.

6.2.2 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.

6.2.3 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.

6.3 Essential pre-test preparatory practices

6.3.1 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.

6.3.2 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 the normative supporting reference 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.

6.3.3 Test material handling and use

6.3.3.1 Identification of separately packaged samples

When the sample procured for testing (6.1) 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.

6.3.3.2 Storage and manipulation

Unless otherwise specified in this International Standard, 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.

6.3.3.3 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 [8.2.3 c)].

6.3.3.4 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.

6.3.4 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 [8.2.1 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.

6.3.5 Order of conducting tests

When testing the alginate impression materials always conduct the working time test (7.1) and the initial setting time test (7.2) first in order because, when the results obtained in these tests differ significantly from manufacturer claims, [8.2.3g)] and [8.2.3 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.

6.3.6 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.

6.3.7 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.

6.3.8 Expression of test results

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

