



American National Standard/
American Dental Association
Standard No. 128

Hydrocolloid Impression Materials

Identical adoption of ISO 21563:2013, *Dentistry-Hydrocolloid Impression Materials*

ADA American
Dental
Association®
Council on
Scientific Affairs

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AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION STANDARD NO. 128 FOR HYDROCOLLOID IMPRESSION MATERIALS

The Council on Scientific Affairs of the American Dental Association has approved revised American Dental Association Standard No. 128 for Hydrocolloid Impression Materials. This and other standards for dental materials, instruments and equipment are being formulated by working groups of the ADA Standards Committee on Dental Products. The Committee has representation from all interests in the United States in the standardization of materials, instruments and equipment in dentistry. The Council has adopted the standards, showing professional recognition of their usefulness in dentistry, and has forwarded them to the American National Standards Institute with a recommendation that the standards be approved as American National Standards. The American National Standards Institute granted approval of revised ADA Standard No. 128 as an American National Standard on January 29, 2015.

The ADA Standards Committee on Dental Products thanks the members of Working Group 2.10 and the organizations with which they were affiliated at the time the standard was developed:

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FOREWORD

(This Foreword does not form a part of ANSI/ADA Standard No. 128 for Hydrocolloid Impression Materials).

ANSI/ADA Standard No. 128 is an identical adoption of ISO 21563:2013, Dentistry – Hydrocolloid impression materials. ADA SCDP Working Group No. 2.10 on Impression Materials examined the International Standard and found it acceptable for identical adoption as ANSI/ADA Standard No. 128.

ANSI/ADA Standard No. 128:2015 cancels and replaces ADA Standard No. 18 for Dental Alginate Impression Material and ANSI/ADA Standard No. 82 for Combined Reversible/Irreversible Hydrocolloid Impression Materials.

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INTRODUCTION

Parties seeking clarification of any provisions of this document, or desiring to recommend improvements for the next edition, are encouraged to do so by contacting the ADA Standards Committee on Dental Products, American Dental Association, 211 East Chicago Ave., Chicago, IL 60611 or standards@ada.org.

AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION STANDARD NO. 128 FOR HYDROCOLLOID IMPRESSION MATERIALS

1 SCOPE

This standard 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 standard 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 ANSI/ADA Standard No. 41^[1], ISO 7405^[2] and ISO 10993^[3]

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 — Specifications and test methods*

(Copies of ISO Standards for dentistry may be obtained from the American Dental Association, Department of Standards Administration, 211 E. Chicago Ave., Chicago, IL, or <http://catalog.ada.org>. Other ISO Standards may be obtained from the American National Standards Institute, 25 West 43 St., New York, NY 10036; or www.ansi.org).

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 retail³

3.5

elastic recovery test

method of determining whether an elastic impression material will possess the elastic properties required to recover optimally from deformation occurring during removal of impressions from contact with the impressed oral or craniofacial tissues

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 moldable 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: 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 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 moldable 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 moldable state required for forming impressions

3.11

primary packaging

primary container

immediate container (deprecated)

packaging designed to be in direct contact with the product³

NOTE Adapted from ISO 21067:2007^[4], Packaging vocabulary

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: 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 product³

NOTE Adapted from ISO 21067:2007, Packaging vocabulary

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 test

standardized test method for determining whether elastic impression materials, when formed as impressions, will have the

- flexibility required to permit removal of the impressions from the mouth without significant injury to the impressed oral tissues and,
- the stiffness to resist the deforming forces possibly occurring during the pouring of a model forming gypsum into the impressions, or to make the material more effective for transferring implant components and securing them in desired positions in an impression

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 5.2

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

The requirements applicable to only one category of hydrocolloid impression materials (agar or alginate) are stated immediately below in subclause 5.1 through 5.6. 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 manufacturers 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	20
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.	4.0-15.0	4.0-15.0	5.0-20.0
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.

- Procure only samples that have been packaged for retail marketing and that have labelling **use by** dates that have not expired
- Wherever possible select only those samples that have the same lot (batch) number [see 8.1c)]
- 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 or capsules
 - For alginate impression materials – at least 900 g
 - For alginate paste/paste materials – 5 liters
 - Gypsum materials for the compatibility with gypsum test - at least 1000 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 Clause 8.1 before any attempt to open a packaging component has defaced or obliterated any labelling entry information needed for storage