INTERNATIONAL STANDARD

ISO 1564

Second edition
1995-11-01

Dental aqueous impression materials based on agar

Produits dentaires hydrauliques pour empreintes à base d'agar-agar

Reference number
ISO 1564:1995(E)

Contents

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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.

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.

International Standard ISO 1564 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthodontic materials*.

This second edition cancels and replaces the first edition (ISO 1564:1976) to which the following changes were made:

— The materials are now classified according to consistencies and purposes.

— The requirement for odour and flavour has been deleted due to lack of an appropriate test. However, it is recognized that the impression material, when handled in accordance with the manufacturer's instructions should have no unpleasant odour or flavour attributable to spoilage or contamination.

— A requirement and an accompanying test for tear resistance replaces the test for compressive strength because the tear test has been judged to be more significant to clinical performance of the agar materials, especially in relation to impressions for fixed prosthodontics.

— Requirements and tests for consistency and extrusion temperatures have been added.

— Designs for the apparatus used in the detail reproduction, compatibility with gypsum, recovery from deformation (permanent deformation), and strain-in-compression tests have been improved in the interest of obtaining more objective test results and to make the tests easier to conduct.

— A requirement relative to antimicrobial characteristics has been added.

— A requirement for manufacturers to identify gypsum products which have been found to be compatible with their impression materials has been added.

— The previous edition specified that most of the pass/fail determinations made for the materials being tested were to be based on averaged values calculated for two or more specimens. Pass/fail determinations made in accordance with this edition are based on the concept that results for each specimen should be compared with the specified performance limit in a separate pass/fail exercise.

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Dental aqueous impression materials based on agar

1 Scope

This International Standard specifies requirements for essential physical properties and other characteristics of impression materials having reversible agar hydrocolloid as a gel-forming ingredient, along with tests specified for determining compliance with those requirements. It also specifies requirements with respect to the manufacturer's instructions, and the essentials for packaging, labelling and marking.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 6873:1983, *Dental gypsum products.*

ISO/TR 7405:1984, *Biological evaluation of dental materials.*

3 Definitions

For the purposes of this International Standard, the following definitions apply.

3.1 gelation temperature: Temperature at which the agar impression material develops the elastic properties which will permit removal of an impression from undercuts in the mouth with only minimal distortion.

3.2 immediate container: Container which is in direct contact with the impression material.

3.3 storing: Conditioning of the material, immediately after liquefication, needed to reduce the temperature as required prior to its use in syringing, or prior to tempering.

3.4 tempering: Conditioning of the material, after the storing treatment, needed to reduce the temperature of the material as required prior to its insertion into the mouth.

4 Classification by type

Type 1 — High consistency: For making impressions of complete or partial dental arches, with or without the use of syringe-extruded increments of type 2 or type 3 materials.

Type 2 — Medium consistency: For making impressions of complete and partial dental arches, with or without the use of syringe-extruded increments, and also for use as a syringe-extruded material.

Type 3 — Low consistency: For syringe use only.

5 Requirements for characteristics and physical properties

The requirements are given in table 1.

5.1 Biocompatibility

Specific qualitative and quantitative requirements for freedom from biological hazards are not included in this International Standard, but it is recommended that reference be made to ISO/TR 7405 when assessing possible biological or toxicological hazards associated with infection or irritation of normal oral mucosa, or with the concentration of potentially toxic elements or components.

Table 1 — Required property value limits

Type	8.4 Extrusion temperature °C		8.5 Gelation temperature °C		8.6 Detail reproduction	8.7 Compatibility with gypsum	8.8 Recovery from deformation %	8.9 Strain in compression %		8.10 Resistance to tearing N/mm
	min.	max.[1)]	min.	max.			min.	min.	max.	min.
Type 1	—	—	37	45	0,02	0,05	96.5	4	15	0,75 [2)]
Type 2	45	52	37	45	0,02	0,05	96.5	4	15	0,75 [2)]
Type 3	45	52	37	45	0,02	0,05	96.5	4	15	0,5 [2)]

1) Maximum temperature the syringed material will transmit to the teeth as stated by the manufacturer [see clause 9 f)] and the maximum temperature that will be registered as the material is extruded to cover the thermometer bulb during the test.

2) These minimum values apply unless a manufacturer claims a higher value, in which case the test result shall not be less than that stated by the manufacturer.

5.2 Homogeneity (Sol state)

When evaluated in accordance with 8.1 and 8.3, the materials shall be free of foreign matter, lumps and granules, and shall exhibit no separation of ingredients that can be observed during extrusion of the materials from their containers or syringes.

5.3 Consistency: types 1 and 2 (Sol state)

When tested in accordance with 8.2, the prepared material shall be capable of being extruded from its immediate container into the specified tray within 30 s.

5.4 Extrudability: types 2 and 3 (Sol state)

When tested in accordance with 8.2, the prepared material shall be of a consistency that will permit the entire increment prepared for syringing to be extruded within 30 s.

6 Sampling

The sample shall be at least 1 500 g of the impression material taken from a single manufacturing batch, along with any devices or accessories specified in the manufacturer's instructions for use with the material. The method of procurement shall be subject to agreements between interested parties.

7 Test methods: basic conditions and procedures

7.1 Specimen preparation

7.1.1 Unless otherwise specified, the materials used for the test specimens shall be prepared and manipulated using the equipment recommended in the manufacturer's instructions (see clause 9).

7.1.2 The materials used for making the test specimens shall be exposed to only one liquefication treatment and the storage time before specimens are made shall not exceed 1 h.

7.1.3 In instances where the amount of material furnished in a single immediate container, or as a type 3 stick, is less than that needed to form a specimen, it will be necessary to liquefy, store and temper the material in a large single container, such as a modified plastic syringe, which will accommodate the required amount with no risk of dilution.

7.1.4 Gypsum products required for making specimens according to this International Standard shall be evaluated for compliance with the initial setting time test specified in ISO 6873 before use in the tests. After the initial opening of their immediate containers and between openings required thereafter, the gypsum materials shall be stored such that they will not be exposed to moisture contamination.

7.2 Test conditions

All specimen preparation and physical property tests shall be conducted under uniform atmospheric conditions of (23 ± 2) °C and (50 ± 10) % relative humidity. Unless otherwise specified in this International Standard, all equipment and materials shall be brought to the uniform condition before beginning specimen preparation or testing.

7.3 Number of specimens to be tested for pass/fail determinations

Unless otherwise specified in this International Standard, the number of specimens required is as follows.

Test a series of five specimens initially. If four of the specimens comply with the specified requirement, the material passes. If only one or two specimens comply, the material fails. If only three specimens comply, test an additional series of five specimens. If eight of the ten specimens (80 %) tested in the two series comply, the material passes.

7.4 Expression of results

Unless otherwise specified in this International Standard, results for the tests shall be reported as follows.

Report the number of specimens tested, the number of specimens complying with the specified requirement and whether the material passes or fails.

8 Test procedures

8.1 Homogeneity: type 1 only

NOTE 1 The extrudability test (8.3) constitutes a homogenity evaluation for type 2 and 3 materials.

8.1.1 Apparatus

8.1.1.1 Two glass plates, approximately 200 mm × 200 mm × 6 mm, designated as plate 1 and plate 2.

8.1.1.2 Apparatus for heating the glass plates to a temperature of (35 ± 1) °C.

8.1.1.3 Means of applying a 2 kg load. The mass of plate 2 shall be included as part of this load.

8.1.2 Test procedure

Liquefy and store five tubes of the material. Test only an increment consisting of the first third of the material extruded from the tube. Remove the heated glass plates from the heating apparatus (8.1.1.2) and immediately deliver the increment to be tested onto the centre of plate 1. Observe whether there is any separation of ingredients during extrusion of the impression material. Upon completion of extrusion, place plate 2 directly onto the impression material and apply the additional mass (8.1.1.3). Then 2 min later, examine the specimen between the plates for the presence of lumps and granules. Test increments from all five tubes.

Record whether there was any evidence of lumps, granules, foreign matter or separation of ingredients.

8.1.3 Expression of results

See 7.3 and 7.4 concerning pass/fail determinations.

8.2 Consistency: types 1 and 2

8.2.1 Apparatus

8.2.1.1 Large tray made for use with the agar materials.

8.2.2 Test procedure

Liquefy the contents of five tubes of the material and store the tubes for 30 min. Within the following 30 min, extrude enough of the material from each tube to fill the large tray. Determine whether the material can be extruded from each tube within 30 s.

8.2.3 Expression of results

See 7.3 and 7.4 concerning pass/fail determinations.

8.3 Extrudability: types 2 and 3

8.3.1 Apparatus

8.3.1.1 Syringe and needle recommended by the manufacturer for extruding the material.

8.3.1.2 Equipment for liquefying, storing and conditioning of the impression material.

8.3.2 Test procedure

For the purpose of this test, liquefy and store the amount of material required for five separate syringe applications. Begin testing after 30 min at the storage temperature. Extrude all of the material from the syringe. Complete extrusions from the five syringes within 30 min. Determine whether the contents of each syringe can be extruded within 30 s.

8.3.3 Expression of results

See 7.3 and 7.4 concerning pass/fail determinations.

8.4 Extrusion temperature: types 2 and 3

8.4.1 Apparatus

8.4.1.1 Calibrated thermometer accurate to 0,1 °C. The thermometer shall be conditioned to (35 ± 1) °C for use in this test.

NOTE 2 Thermometers or other temperature-measuring instruments such as ASTM Model 14C (38 °C to 82 °C, 0,1 °C graduations, 375 mm long) may be used for this test.

Calibrated thermocouples and thermistor instruments may also be used.

8.4.1.2 Apparatus for holding the thermometer horizontal and such that it can be rotated easily with the fingers, or apparatus for securing thermocouple beads or thermistor probes in a fixed position.

NOTE 3 Wooden or plastics V-troughs or laboratory ring-stand thermometer holder systems are suitable for this purpose.

8.4.1.3 Oven for conditioning the thermometer/holder assembly to (35 ± 1) °C.

8.4.1.4 Syringe as recommended by the manufacturer for use with the material.

8.4.2 Test procedure

Liquefy and store the amount of material required for five syringe applications. After 30 min at the storage temperature, remove the thermometer holder (8.4.1.2) assembly from the oven (8.4.1.3) and extrude approximately one-third of the conditioned syringe contents onto the thermometer bulb (8.4.1.1) in simulation of the way the material would be applied to an individual tooth in the mouth. Rotate the thermometer during extrusion so as to apply a uniform thickness around the bulb. While extruding the material, note maximum temperatures reached. One minute after beginning the extrusion, note the temperature of the material again. Record the maximum and minimum temperatures. Test five specimens initially.

8.4.3 Expression of results

See 7.3 and 7.4 concerning pass/fail determinations.

8.5 Gelation temperature

8.5.1 Apparatus

8.5.1.1 Metal tray equipped with the thermometer (8.4.1.1), **testing tube** and **testing tube guide** with characteristics and dimensions shown in figure 1.

8.5.2 Test procedure

Prepare approximately 65 g of the material for each specimen. Temper and store enough of the types 1 and 2 materials in their original immediate containers in the amounts needed for five separate tests. Upon completion of the storage time, extrude enough of the conditioned material to fill the tray. Then insert the thermometer bulb through the grommet so as to centre the bulb in the tray. Position the tube guide in alignment with notches in the tray marking the No. 1 position.

For type 3 materials, use an adequately sized glass or plastics syringe to contain the amount of material required for the liquefaction and storage steps.

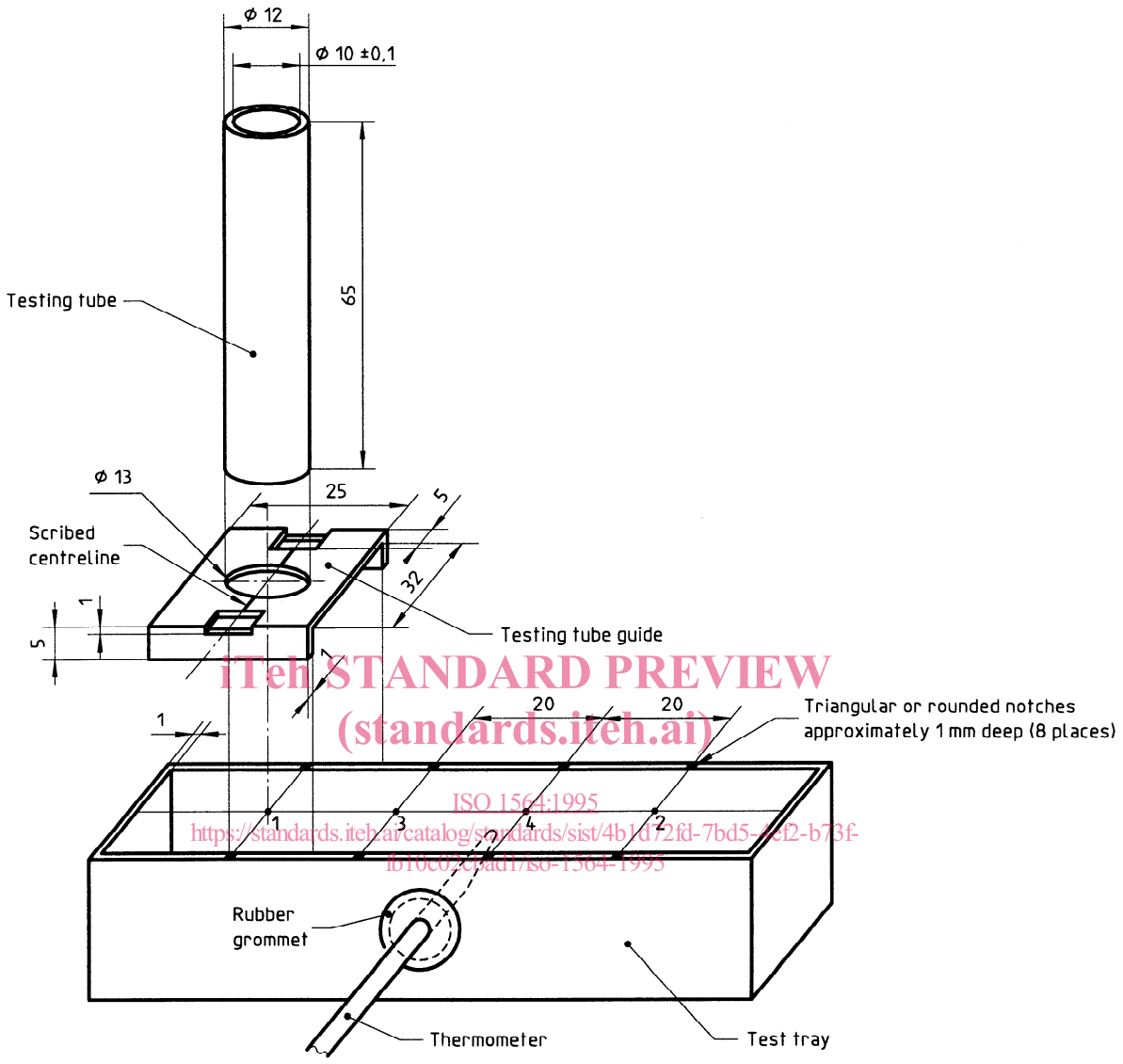
When the impression material in the tray reaches a temperature 2 °C above the gelation temperature stated by the manufacturer, conduct a trial test by thrusting the testing tube through the guide and into the material until the tube contacts the floor of the tray. Withdraw the testing tube immediately and wipe it clean, inside and out. Repeat the penetration procedure successively at positions 2, 3 and 4, at intervals indicated by each 0,5 °C drop in temperature.

The gelation temperature to be recorded is the highest temperature at which two concentric circles, caused by the inside and outside of the tube, are clearly outlined and when no material clings to the tube surfaces.

If a gelation temperature cannot be determined during the first trial test, conduct additional trial tests, each beginning at 1 °C less than the one preceding, until the gelation temperature can be determined when conducting the trial test procedure described above. The final trial test shall be considered a test for record purposes. Test four additional specimens for record purposes in accordance with the trial test procedure, except that the tube penetrations for these tests shall begin at 0,5 °C above the temperature determined during the final trial test.

Record the gelation temperature found for each specimen tested, either for trial or for record purposes, to the nearest 0,1 °C.

Dimensions in millimetres



Surface finish of testing tube surfaces: 0,5 µm max.

Materials:

Test tray and testing tube guide: stainless steel
Testing tube: brass or stainless steel.

Inside dimensions of test tray:

length = 100 mm
width = 28 mm
depth = 22 mm

Figure 1 — Apparatus for gelation temperature test