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ISO RECOMMENDATION

R 1564

AGAR IMPRESSION MATERIAL

1st EDITION

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BRIEF HISTORY

The ISO Recommendation R 1564, *Agar impression material,* was drawn up by Technical Committee ISO/TC 106, *Dentistry,* the Secretariat of which is held by the British Standards Institution (BSI).

Work on this question led to the adoption of Draft ISO Recommendation No. 1564, which was circulated to all the ISO Member Bodies for enquiry in December 1968. It was approved, subject to a few modifications of an editorial nature, by the following Member Bodies :

Australia	India	Spain
Belgium	Israel	Sweden
Brazil	Korea, Rep. of	U.A.R.
Canada	Netherlands	United Kingdom
Czechoslovakia	New Zealand	U.S.A.
Denmark	Peru	Yugoslavia
France	Poland	
Greece	South Africa, Rep. of	

The following Member Body opposed the approval of the Draft :

Switzerland

This Draft ISO Recommendation was then submitted by correspondence to the ISO Council, which decided to accept it as an ISO RECOMMENDATION.

ISO Recommendation | R 1564 | June 1970

AGAR IMPRESSION MATERIAL

INTRODUCTION

This ISO Recommendation is technically identical with F.D.I.* Specification No. 8, the only difference being in the wording and layout to bring the text into standard ISO form. Further studies are being undertaken to provide, if necessary, for a future revision of this ISO Recommendation in the light of technological advances supported by well-documented data.

NOTE. – Throughout this ISO Recommendation the figures for SI units are approximate conversions of the technical metric units using the conversion factors 1 N = 0.102 kgf and 1 MN/m^2 = 10.2 kgf/cm^2.

1. SCOPE

This ISO Recommendation gives the requirements for agar impression material, together with the test methods to be employed to determine compliance with these requirements.

2. FIELD OF APPLICATION

This ISO Recommendation is applicable to dental impression material in gel form containing a reversible agar hydrocolloid as the gel-forming ingredient.

3. REQUIREMENTS

3.1 General requirements

The material should be uniform and free from foreign matter. When used in accordance with the manufacturer's instructions accompanying the package (see clause 3.3), the material should form a smooth plastic mass suitable for taking impressions in the mouth.

3.2 Special requirements

3.2.1 *Odour and flavour.* The material when used in accordance with the manufacturer's instructions should not have an unpleasant odour or flavour.

3.2.2 *Freedom from toxicity.* The material should not contain poisonous ingredients in sufficient concentration to be harmful to human beings when used as directed in the manufacturer's instructions or in the event of accidental ingestion of 10 ml (see clause 7.3).

3.2.3 *Irritation.* The material used in accordance with the manufacturer's instructions should not normally cause visible evidence of irritation of the normal oral mucosa, when softened by boiling in water (100 °C), tempered at 40 to 50 °C and used for making impressions.

* Fédération Dentaire Internationale.

3.2.4 *Extrusion.* The material when prepared according to the manufacturer's instructions should be capable of extrusion through a hollow needle or tube having an inside diameter not exceeding 0.6 mm.

3.2.5 *Compatibility with gypsum.* The impression material should impart a smooth surface to, and separate cleanly from, a gypsum cast made from unmodified alpha calcium sulphate hemihydrate. The cast poured against the agar impression in accordance with clause 6.2.2.5 should, for the full width of the specimen, reproduce the line 0.075 mm wide, on the test block illustrated in Figure 1.

3.2.6 *Consistency.* The material should remain sufficiently plastic, when heated in boiling water for 8 minutes in a metal mixing syringe or 10 minutes in the original container, and tempered according to the manufacturer's instructions, to permit its easy removal from the syringe or container, and its adaptation to the impression tray.

3.2.7 *Temperature at gel formation.* The temperature at which the plastic mass sets to a gel on cooling should be not less than 37 °C nor more than 45 °C.

3.2.8 *Uniformity.* After boiling and tempering and during setting of the material, the ingredients should not segregate. The material prepared should be homogeneous, have a smooth surface and be free of lumps or granules.

3.2.9 *Permanent deformation.* The permanent deformation of the set material should be not more than 1.5 % after a 10 % strain is applied for 30 seconds, when tested in accordance with clause 6.2.5.

3.2.10 *Compressive strength.* The compressive strength should be not less than 0.2 MN/m^2 (2.5 kgf/cm^2) when tested in accordance with clause 6.2.6.

3.2.11 *Strain in compression.* The strain should be not less than 4.0 % nor more than 15.0 % between a stress of 0.01 MN/m^2 (0.1 kgf/cm^2) and a stress of 0.098 MN/m^2 (1.0 kgf/cm^2) when tested in accordance with clause 6.2.7.

3.3 Instructions for use

Adequate and accurate instructions for the manipulation of the contents should accompany each package. These instructions should contain at least the following details :

3.3.1 *Tray, syringe and needle.* The type of tray, syringe and needle recommended for use with the material.

3.3.2 *Softening and tempering conditions.* The time and temperature requirements for softening and tempering the material in the original container and in the syringe.

3.3.3 *Oral temperature.* The temperature at which the material should be inserted in the mouth.

3.3.4 *Cooling.* The technique recommended for chilling the impression in the mouth.

3.3.5 *Treatment.* The treatment of the impression during the interval between its withdrawal from the mouth and the preparation of the gypsum cast.

3.3.6 *Fungicide.* A statement that the material contains a fungicide that will effectively prevent mould growth.

4. SAMPLING

The method of procurement and the amount of impression material required for the tests should be the subject of agreement between the parties concerned.

5. PREPARATION OF TEST SPECIMENS

The specimens should be prepared in accordance with the manufacturer's instructions accompanying the package (see clause 3.3).

6. TEST METHODS

6.1 Visual inspection

Visual inspection should be used in determining compliance with requirements of clauses 3.1, 3.2.1, 3.2.3, 3.2.4, 3.2.5, 3.2.6, 3.2.8, 3.3, 6.2.1, 6.2.2 and 6.2.3 and section 7.

6.2 Physical tests

All physical tests should be made under uniform atmospheric conditions of 23 ± 2 °C and 50 ± 10 % relative humidity. Equipment and material should be conditioned in the testing room for not less than 10 hours prior to making the tests.

6.2.1 *Extrusion.* 3 ml of the softened material should be placed in a syringe and tempered in accordance with the manufacturer's instructions (see clause 3.3). The syringe should be of the type commonly used to inject the material into a preparation and should be fitted with a hollow needle or tube having an inside diameter of not more than 0.6 mm. The material should then be extruded from the syringe.

The force necessary for this extrusion should not exceed that which will readily allow accurate placement of the material into any required position.

6.2.2 *Compatibility with gypsum*

6.2.2.1 CHARACTERISTICS OF THE GYPSUM. The type of gypsum employed in the test for compatibility should be unmodified calcium sulphate hemihydrate to which has been added, if necessary, sufficient calcium sulphate dihydrate to adjust the time of setting to 10 ± 3 minutes under the conditions of setting described in clause 6.2.2.3. Moreover it should be such that when tested directly against the block shown in Figure 1 it will reproduce satisfactorily the 0.050 mm wide line.

6.2.2.2 PREPARATION OF THE GYPSUM SLURRY. Approximately 100 g of powder should be added gradually during 15 seconds to 30 ml of distilled water in a flexible mixing bowl. After allowing the powder to soak in the water for 15 seconds, the mix should be hand-spatulated for 1 minute with a flexible metal spatula 18 ± 1 mm wide.

6.2.2.3 DETERMINATION OF GYPSUM SETTING TIME. The slurry should be poured immediately into a cylindrical mould 25 mm in diameter and 25 mm in length. The time of setting should be determined with a Vicat needle of mass 300 ± 0.5 g and having a penetrating shaft 1 ± 0.05 mm in diameter and approximately 50 mm long.

The Vicat needle should be lowered vertically until the top of the specimen is touched and then released to allow the needle to sink into the mixture.

Repeated trials should be made in different areas of the specimen at 1 minute intervals until the needle no longer penetrates to the bottom of the specimen.

The time of setting should be the number of minutes that elapse from the beginning of the addition of the powder to the water until the needle fails to penetrate to the bottom of the specimen.

6.2.2.4 PREPARATION OF AGAR SPECIMEN. A ring of the type recommended in clause 6.2.5.2 should be positioned on a stainless steel test block, similar to that shown in Figure 1, so that the intersection of the cross-line and the 0.025 mm wide line is in the centre of the ring.*

The ring should be slightly overfilled with the impression material. A flat plate should be placed on the top and the excess material should be squeezed out.

15 minutes later the ring with the impression material should be separated from the plate and the test block. The impression should be shaken by hand to remove the excess exudate.

* The stainless steel test block may be lightly dusted with talcum powder and the excess talcum powder blown off.

6.2.2.5 PREPARATION OF GYPSUM CAST. A gypsum slurry, prepared as described in clause 6.2.2.2 and under gentle vibration, should be poured against the agar impression, prepared as described in clause 6.2.2.4, within 2 minutes from the time the impression is separated from the test block.

The assembly should be placed in a conditioning chamber at 23 ± 2 °C and 100 % relative humidity for 30 minutes.

The gypsum cast should be removed and examined, without magnification, under low-angle illumination with a microscope lamp, for surface finish and for the quality of the impression of the 0.075 mm line.

The reproduction of the 0.075 mm line should be considered satisfactory if it is continuous for the full width of the ring.

6.2.3 *Consistency.* At a temperature of 43 to 50 °C the material should not run out of an inverted, perforated, metal tray, as is commonly used for hydrocolloid impression materials, during an interval of 15 seconds.

6.2.4 *Temperature of gel formation*

6.2.4.1 APPARATUS (see Fig. 2)

(*a*) *Metal tray,* whose approximate inside dimensions are 100 mm × 28 mm × 20 mm, drilled to accommodate a thermometer bulb.

(*b*) *Metal tube,* having an inside diameter of 10 mm and a wall thickness of approximately 1 mm.

6.2.4.2 PROCEDURE. Extrude into a small tray approximately 50 ml of the material, which has been softened and tempered in accordance with clause 3.3, at a temperature of 50 °C. The thermometer should be inserted into the material through the side hole of the tray.

During the cooling of the specimen from 50 °C, at the rate of 1.5 ± 0.5 °C per minute, insert the tube several times vertically into the material until the tube touches the floor of the tray, thus making a series of impressions.

The tube should be withdrawn immediately each time.

Near the gelation temperature, trials should be made every 0.5 °C.

The final trials should be made in that portion of the material lying near the thermometer bulb.

6.2.4.3 EXPRESSION OF RESULTS. The temperature of gel formation is the highest temperature at which the two concentric circles caused by the inside and outside surfaces of the indenting tube are clearly outlined and the material does not cling to the polished surface of the tube.

The mean of three test results should be reported to the nearest degree Celsius. When this average falls midway between two whole numbers the even number should be recorded.

6.2.5 *Permanent deformation caused by fixed strain*

6.2.5.1 APPARATUS. Use an instrument of the type shown in Figure 3. This instrument consists of :

(*a*) *a dial indicator* (B), graduated in 0.02 mm, mounted on a stable base and equipped with a screw (A), positioned in such a manner that sufficient force can be applied to the specimen to produce the required amount of strain, and a foot intended to exert the force on the specimen;

(*b*) *a lightweight plate,* to be placed on top of the specimen (C), another plate being inserted between the bottom of the specimen and the base of the instrument.

6.2.5.2 PREPARATION OF TEST SPECIMENS. The specimen should be made by placing a metal ring, 30 mm inside diameter and 16 mm high, on a flat glass or metal plate and filling the ring slightly more than one-half full with softened and tempered material. A metal mould in the form of a cylinder 12.7 mm inside diameter, 25.4 mm outside diameter and 19 mm high, should be placed immediately inside the ring and should be forced into the material until the mould touches the plate and the material has exuded onto the top of the mould.

A second flat glass or metal plate should be pressed on the top of the mould to remove the excess material.

30 minutes later, the specimen should be removed from the mould and placed in an atmosphere of 100 % relative humidity at 23 ± 2 °C for approximately 30 minutes.

During the test, the specimen should be protected by a loosely wrapped moistened cloth gauze to prevent excessive moisture losses.

6.2.5.3 PROCEDURE. One hour from the start of the mix, place a specimen, prepared as detailed in clause 6.2.5.2 in the testing instrument (see clause 6.2.5.1 and Figure 3).

A lightweight plate should be placed on the top of the specimen, and the foot of the dial indicator should contact the plate. The force exerted by the plate and indicator should be 0.49 ± 0.05 N (50 ± 5 gf).

The dial indicator should be read 30 seconds after its foot contacts the plate. This value should be reading *A*. The foot of the indicator should be lowered 1.9 mm by the screw, then left for 30 seconds, then released, and the specimen allowed to rest under no load*, for 30 seconds. Then the dial indicator should be lowered onto the plate for 30 seconds, and a second reading taken. This value should be reading *B*.

The difference between readings *A* and *B*, divided by the original length of the specimen and multiplied by 100, should be recorded as the percentage permanent deformation.

The average permanent deformation of three specimens should be recorded.

6.2.6 *Compressive strength*

6.2.6.1 APPARATUS. Any device for the testing of compressive strength, accurate to 0.5 N (50 gf).

6.2.6.2 PROCEDURE. One hour after a specimen is prepared as specified in clause 6.2.5.2 it should be placed in the testing machine, and tested for compressive strength.

A piece of heavy writing paper** should be placed under and over the specimen in the machine.

The specimen should be loaded continuously at a uniform rate of 100 ± 20 N (10 ± 2 kgf) per minute until fracture.

6.2.6.3 EXPRESSION OF RESULTS. The maximum load at fracture should be recorded to the nearest 0.5 N (50 gf).

The maximum load should be divided by the cross-sectional area of the mould and the average strength of three specimens, in MN/m^2 (or kgf/cm^2), recorded.

6.2.7 *Strain in compression*

6.2.7.1 APPARATUS. Any instrument having a dial indicator graduated in 0.02 mm, capable of producing the amount of compression required for the test in accordance with the procedure outlined below.

* Except that of the lightweight plate.

** Sometimes known as Bond paper.

6.2.7.2 PROCEDURE. One hour from the start of mixing, a specimen prepared as detailed in clause 6.2.5.2 should be placed in a suitable instrument (see Fig. 4) and should be subjected to a load calculated to produce a stress of 0.01 MN/m^2 (0.1 kgf/cm^2).

30 seconds later the dial indicator should be read. This value should be recorded as reading *A*.

60 seconds after application of a stress of 0.01 MN/m^2 (0.10 kgf/cm^2) an additional load calculated to produce a total stress on the specimen of 0.098 MN/m^2 (1.0 kgf/cm^2) should be gradually applied during an interval of 10 seconds. 30 seconds after initiation of the stress of 0.098 MN/m^2 (1.0 kgf/cm^2) a reading of the dial should be taken. This value should be reading *B*.

6.2.7.3 EXPRESSION OF RESULTS. The difference between readings *A* and *B*, divided by the original length of the specimen* and multiplied by 100, should be recorded as the percentage strain between the stresses of 0.01 and 0.098 MN/m^2 (0.10 and 1.0 kgf/cm^2).

The average strain of three specimens should be recorded.

7. PACKAGING AND MARKING

7.1 Packaging

The material should be supplied in properly sealed containers made of materials which will not contaminate or permit contamination of the contents. The containers should be suited to the purpose for which they are intended.

7.2 Instructions for use

Instructions for use should accompany each package.

7.3 Freedom from toxicity

A certificate, furnished by the manufacturer, stating that the material complies with the requirements of clause 3.2.2, should accompany each package.

7.4 Marking

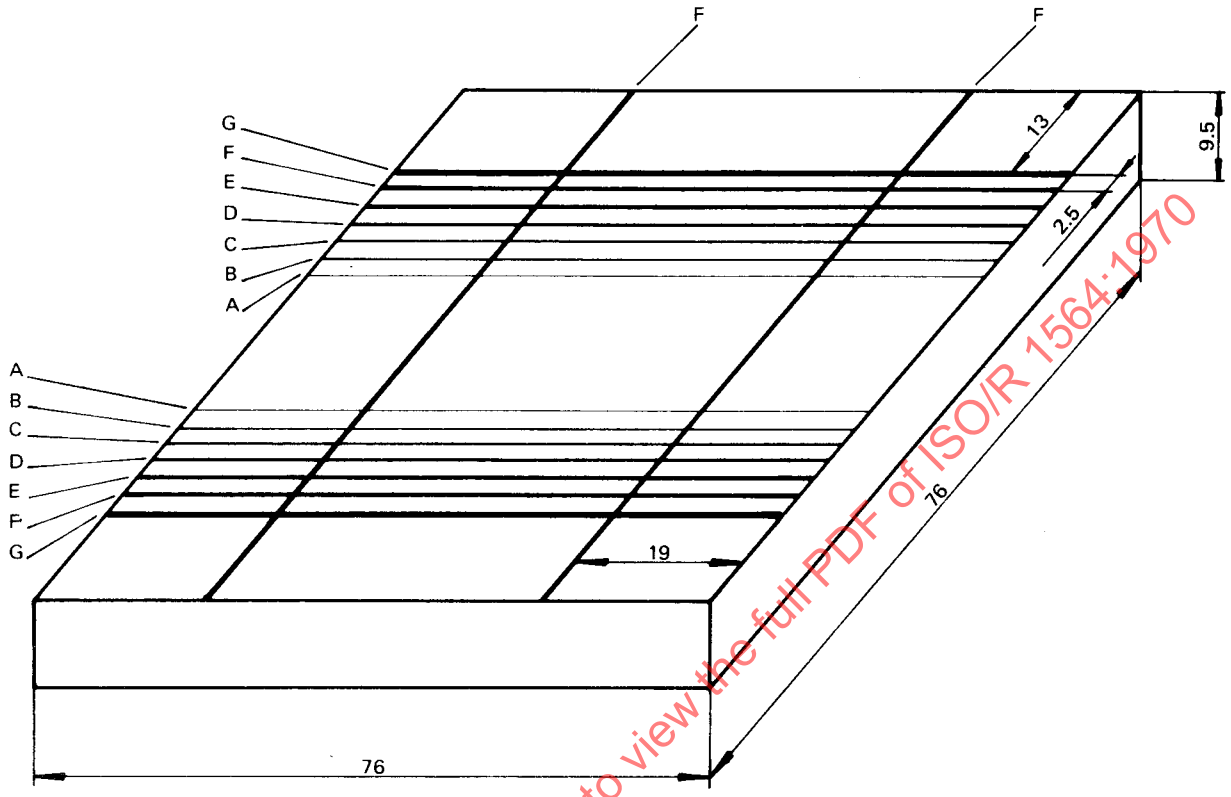
7.4.1 *Lot numbers.* Each container of material should be marked with a serial number or combination of letters and numbers which refer to the manufacturer's record for that particular lot or batch.

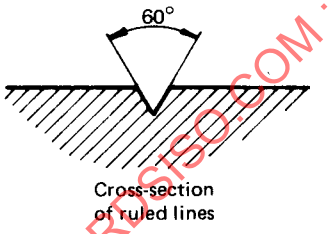
7.4.2 *Date of manufacture.* The date of manufacture (year and month) should be given on the container either as a separate item or as a part of the lot number.

7.4.3 *Net contents.* The minimum net contents expressed in millilitres or grammes should be given in legible type on the container.

* The original length of the specimen should be considered as the height of the mould used in forming it.

Dimensions in millimetres





Width of line (mm)	
A	0.025
B	0.050
C	0.075
D	0.100
E	0.150
F	0.200
G	0.300

FIG. 1 – **Block for detail reproduction**