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R 1563

ALGINATE IMPRESSION MATERIAL

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BRIEF HISTORY

The ISO Recommendation R 1563, *Alginate 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. 1563, 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 1563 | June 1970

ALGINATE IMPRESSION MATERIAL

INTRODUCTION

This ISO Recommendation is technically indentical with F.D.I.* Specification No. 9, 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 classification of and requirements for alginate 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 powder form containing an alginate as the gel-forming ingredient.

3. CLASSIFICATION

Alginate impression materials may be classified into the following types :

– **Type I** : Fast setting (see clause 4.2.6);

– **Type II** : Normal setting (see clause 4.2.6).

* Fédération Dentaire Internationale.

4. REQUIREMENTS

4.1 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 4.3), the material should form a smooth plastic mass suitable for taking impressions in the mouth.

4.2 Special requirements

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

4.2.2 *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 the accidental ingestion of 10 ml (see clause 8.3).

4.2.3 *Irritation*. The material used in accordance with the manufacturer's instructions should not normally cause visible evidence of irritation of the normal oral mucosa.

4.2.4 *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 alginate impression in accordance with clause 7.2.2.5 should for the full width of the specimen reproduce the line 0.075 mm wide on the test block illustrated in Figure 1.

4.2.5 *Mixing time*. The time of mixing, as stated in the manufacturer's directions, to obtain a smooth working consistency should be not more than 1 minute.

4.2.6 *Setting time*. The setting time when tested as in clause 7.2.3 should not be less than 60 seconds nor more than 120 seconds, for Type I – Fast setting – and should be not less than 120 seconds nor more than 4 minutes and 30 seconds for Type II – Normal setting.

4.2.7 *Working time*. The working time when tested as in clause 7.2.4 should be not less than 1 minute 15 seconds for Type I – Fast setting – and should be not less than 2 minutes for Type II – Normal setting.

4.2.8 *Uniformity*. The ingredients, after mixing, should not segregate. The mixed material should be homogeneous, have a smooth surface, and should be free from lumps and granules.

4.2.9 *Permanent deformation*. The permanent deformation should be not more than 3.0 % after 10.0 % strain is applied for 30 seconds when tested in accordance with clause 7.2.5.

4.2.10 *Compressive strength*. The compressive strength should be not less than 0.34 MN/m^2 (3.5 kgf/cm^2) when tested in accordance with clause 7.2.6.

4.2.11 *Strain in compression*. The strain should be not less than 10 % nor more than 20 % 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 7.2.7.

4.2.12 *Deterioration*. The compressive strength of the material when tested as in clause 7.2.6 after storage as described in clause 7.2.8 should be not less than 0.25 MN/m^2 (2.6 kgf/cm^2).

4.3 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 :

4.3.1 *Powder-water ratio*. The powder-water ratio in grammes of powder and millilitres of water.

4.3.2 *Mixing*. The time and method of mixing.

4.3.3 *Temperature*. The temperature of the water and the material.

4.3.4 *Set*. The time in the mouth for proper set.

4.3.5 *Special treatment*. Any special treatment of the impression, such as use of fixative solution, in the interval between withdrawal from the mouth and preparation of the gypsum cast.

5. SAMPLING

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

6. PREPARATION OF TEST SPECIMENS

Specimens of the mixed material should be prepared in accordance with the instructions which accompany the package (see clause 4.3).

7. TEST METHODS

7.1 Visual inspection

Visual inspection should be used in determining compliance with the requirements of clauses 4.1, 4.2.2, 4.2.3, 4.2.4, 4.2.5, 4.2.8 and 4.3, and section 8.

7.2 Physical tests

7.2.1 *General.* 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.

7.2.2 *Compatibility with gypsum*

7.2.2.1 CHARACTERISTICS OF THE GYPSUM. The type of gypsum employed in the test should be unmodified alpha 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 7.2.2.3. 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.

7.2.2.2 PREPARATION OF 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.

7.2.2.3 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 recorded as the number of minutes from the beginning of the addition of the powder to the water until the needle fails to penetrate to the bottom of the specimen.

7.2.2.4 PREPARATION OF ALGINATE SPECIMEN. A ring of the type recommended in clause 7.2.5.2 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 top and the excess material should be squeezed out.

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

7.2.2.5 PREPARATION OF GYPSUM CAST. A gypsum slurry prepared as described in clause 7.2.2.2 and under gentle vibration should be poured against the alginate impression, prepared as described in clause 7.2.2.4, within 2 minutes from the time the impression is separated from the test block.

The whole 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.

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

7.2.3 *Setting time*. A cylindrical metal ring, 30 mm inside diameter and 16 mm high, should be placed on a flat plate and overfilled with the mixed impression material. The excess impression material should then be struck off level with the top of the ring with the spatula used in mixing. Immediately thereafter the flat end of a polished rod of poly(methyl methacrylate), 6 mm in diameter and 100 mm long, should be placed in contact with the exposed surface of the impression material and immediately withdrawn. This contact should be repeated at 10 second intervals until the end of the rod cleanly separates from the impression material. The time of setting should be the number of minutes and seconds elapsed from the commencement of mixing until the time when the impression material does not adhere to the end of the rod. The average of two tests should be reported to the nearest 10 seconds.

7.2.4 *Working time*. A penetrometer using a cylindrical point 4 mm in diameter with a load of 0.49 N (50 gf) and having an indicator sensitive to 0.002 mm should be used for this test. A smooth flat plate should be placed under the point and a fiducial reading made. A ring 16 mm high and of approximately 30 mm inside diameter should be placed upon the flat plate, beneath the point, and filled with material mixed in accordance with the manufacturer's instructions. The top surface should be levelled and at 1 minute 15 seconds from the start of the mix for Type I – Fast setting – or 2 minutes from the start of the mix for Type II – Normal setting – the point should be placed in contact with the top surface of the material and released. The indicator reading should be made 10 seconds after release. The difference between the two readings should be not more than 0.25 mm. All readings should be made to the nearest 0.02 mm.

7.2.5 *Permanent deformation caused by fixed strain*

7.2.5.1 APPARATUS. Use an instrument of the type shown in Figure 2. 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 the top of the specimen (C), another plate being inserted between the bottom of the specimen and the base of the instrument.

7.2.5.2 PREPARATION OF TEST SPECIMEN. Test specimens should be made by placing a 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 alginate material mixed according to the manufacturer's instructions. A cylindrical metal mould, 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.

2 minutes from the commencement of mixing, the mould and its accompanying plates should be placed in a water bath maintained at 37 ± 1 °C. 5 minutes and 30 seconds from the commencement of mixing, the mould and plates should be removed from the water bath. Prior to and during the test the specimen should be protected by a loosely wrapped moistened cloth gauze to prevent excessive moisture losses. The test should be carried out at 23 ± 2 °C.

7.2.5.3 PROCEDURE. 6 minutes from the commencement of mixing, a specimen prepared as specified in clause 7.2.5.2 should be placed in the testing instrument (see Fig. 2). 6 minutes after the commencement of mixing, the lightweight plate should be placed on top of the specimen and the foot of the dial indicator should contact this 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 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.

* Except that of the lightweight plate.

7.2.6 *Compressive strength*

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

7.2.6.2 PROCEDURE. 8 minutes from the commencement of mixing, a specimen prepared as specified in clause 7.2.5.2 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.

7.2.6.3 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.

7.2.7 *Strain in compression*

7.2.7.1 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.

7.2.7.2 PROCEDURE. 10 minutes from the start of mixing, a specimen prepared as detailed in clause 7.2.5.2 should be placed in a suitable instrument (see Fig. 3) 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, graduated in 0.02 mm, should be read. This value should be recorded as reading *A*.

60 seconds after application of a stress of 0.01 MN/m^2 (0.1 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*.

7.2.7.3 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.

7.2.8 *Deterioration.* Sufficient material to make three specimens in accordance with clause 7.2.5.2 should be stored in their original packages for one week at 60 ± 1 °C and 100 % relative humidity. At the end of the storage period three specimens should be made and tested in accordance with clause 7.2.6. The average compressive strength of three specimens should be recorded.

8. PACKAGING AND MARKING

8.1 Packaging

The material should be supplied in sealed airtight containers which should neither contaminate nor permit contamination of the contents.

8.2 Instructions for use

Instructions for use should accompany each package. (See clause 4.3.)

* Sometimes known as Bond paper.

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

8.3 Freedom from toxicity

A certificate, furnished by the manufacturer, stating that the material complies with the requirements of clause 4.2.2, should accompany each package.

8.4 Marking

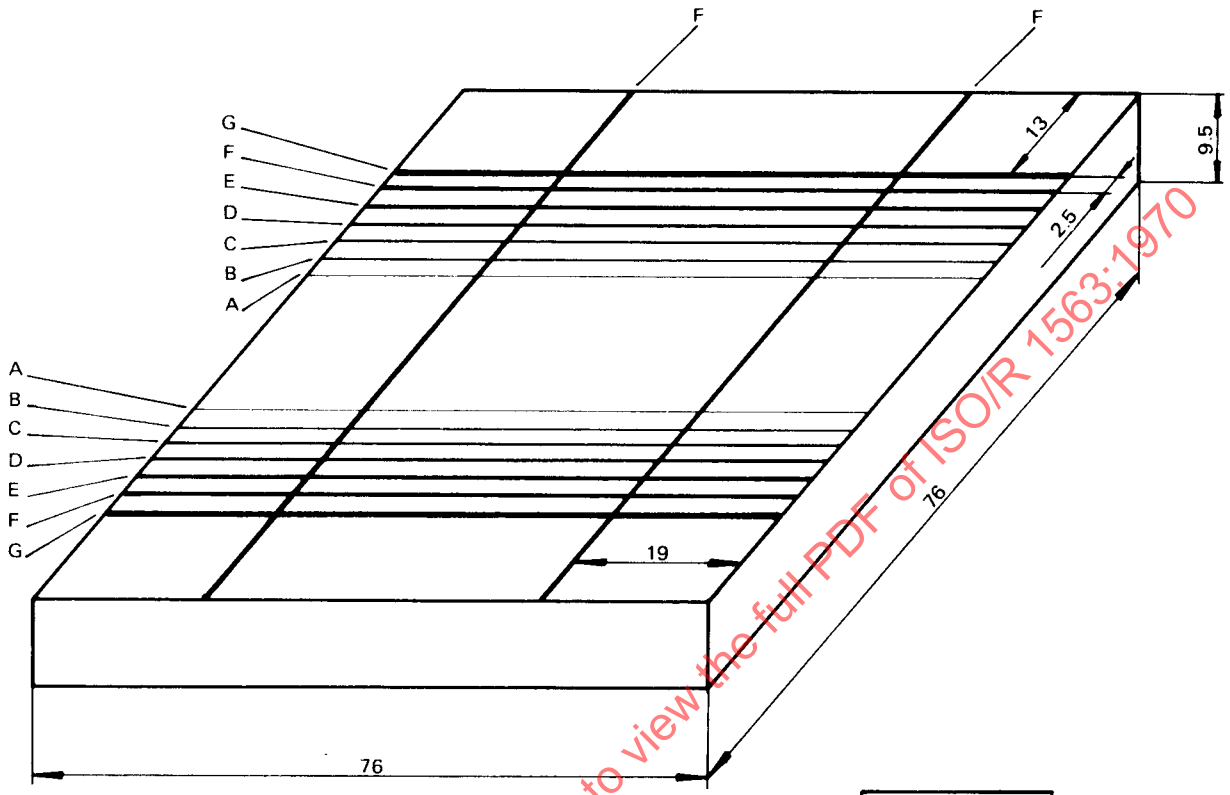
8.4.1 *Lot numbers.* Each container of material should be marked with a serial number or a combination of letters and numbers which refer to the manufacturer's records for the particular lot or batch.

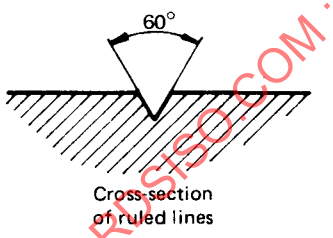
8.4.2 *Date of manufacture.* The date of manufacture (year and month) should be given on the container either as a separate item or as a part of the lot number.

8.4.3 *Volume after mixing.* The minimum volume, after mixing in accordance with the manufacturer's instructions (see clause 4.3) should be given in legible type on the bulk container to the nearest 10 ml, and on a container holding an individual impression "unit" to the nearest millilitre. When the term "unit" is used as a designation of the package, or if the material is supplied in individual "unit" packages, a "unit" should represent a volume of not less than 56 ml when mixed according to the manufacturer's instructions. The value should be reported as the average of tests on three individual impression "units" and should be recorded to the nearest millilitre.

8.4.4 *Type.* The type (see section 3) of alginate impression material should be indicated on all containers.

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**