BRITISH STANDARD

BS EN ISO
1564:1999

Dental aqueous impression materials based on agar

The European Standard EN ISO 1564:1998 has the status of a British Standard

ICS 11.060.10

National foreword

This British Standard is the English language version of EN ISO 1564:1998. It is identical with ISO 1564:1995. It supersedes BS EN 21564:1991 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/51, Prosthodontic materials, which has the responsibility to:

— aid enquirers to understand the text;

— present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;

— monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this committee can be obtained on request to its secretary.

Cross-references

Attention is drawn to the fact that CEN and CENELEC Standards normally include an annex which lists normative references to international publications with their corresponding European publications. The British Standards which implement international or European publications referred to in this document may be found in the BSI Standards Catalogue under the section entitled "International Standards Correspondence Index", or by using the "Find" facility of the BSI Standards Electronic Catalogue.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, the EN ISO title page, page 2, the ISO title page, pages ii to iv, pages 1 to 14 and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

This British Standard, having been prepared under the direction of the Health and Environment Sector Committee, was published under the authority of the Standards Committee and comes into effect on 15 February 1999

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EUROPEAN STANDARD
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EN ISO 1564

November 1998

ICS 11.060.10

Supersedes EN 21564:1990

Descriptors: See ISO document

English version

Dental aqueous impression materials based on agar

(ISO 1564:1995)

Produits dentaires hydrauliques pour empreintes à base d'agar-agar
(ISO 1564:1995)

Dentale Abformmassen auf Agarbasis
(ISO 1564:1995)

This European Standard was approved by CEN on 20 November 1998.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart 36, B-1050 Brussels

Ref. No. EN ISO 1564:1998 E

Foreword

The text of the International Standard from Technical Committee ISO/TC 106 "*Dentistry*" of the International Organization for Standardization (ISO) has been taken over as an European Standard by Technical Committee CEN/TC 55 "*Dentistry*", the secretariat of which is held by DIN.

This European Standard replaces EN 21564:1990.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 1999, and conflicting national standards shall be withdrawn at the latest by May 1999.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 1564:1995 has been approved by CEN as a European Standard without any modification.

NOTE Normative references to International Standards are listed in Annex ZA (normative).

EN ISO 1564:1998

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

Descriptors: Dentistry, dental materials, dental impressions, agar, classification, specifications, materials specifications, physical properties, mechanical properties, tests, physical tests, mechanical tests, test equipment, marking, labelling, packaging.

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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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.

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.[a]	min.	max.			min.	min.	max.	min.
Type 1	—	—	37	45	0,02	0,05	96.5	4	15	0,75[b]
Type 2	45	52	37	45	0,02	0,05	96.5	4	15	0,75[b]
Type 3	45	52	37	45	0,02	0,05	96.5	4	15	0,5[b]

[a] 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.
[b] 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.

5.1 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.

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 ringstand 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.

8.5.3 ***Expression of results***

See **7.3** and **7.4** concerning pass/fail determinations.

8.6 Detail reproduction

8.6.1 ***Apparatus***

8.6.1.1 *Ruled test block,* part A, and *accessories,* parts B and C, illustrated in Figure 2.

The ruled test block shall be cleaned ultrasonically and be brought to a temperature of (35 ± 1) °C before each use.

8.6.1.2 *Flat glass plate* sufficiently large to cover part B.

8.6.1.3 *Polyethylene sheets* to cover the glass plates.

8.6.1.4 *Instrument* capable of × 4 to × 12 magnification and low angle illuminations.

8.6.1.5 *Water bath* for cooling the specimen according to the manufacturer's instructions.

8.6.2 ***Test procedure***

Liquefy and store the amount of material needed for five specimens. Upon completion of the storage time, temper the materials in the containers in which they were liquified and stored.

NOTE 4 More than 10 ml of the type 3 materials must be tempered for this test. It will usually be necessary to temper these materials in a container large enough to accommodate this amount.

Place part B in the recess of part C and seat this assembly on part A. Upon completion of the tempering cycle, extrude the material to overfill part B slightly. Use the flat plate (**8.6.1.2**) to force the excess impression material from part B. Cool the assembly for the specified time, then separate the specimen in part B from the lined block assembly, flush it with distilled or deionized water and use a gentle air blast to remove excess moisture. Immediately thereafter, use the magnification instrument (**8.6.1.4**) to examine the extent to which the specimen has copied the lines on the test block.

NOTE 5 Depending upon the colour of the materials it may be necessary to use colour filtered illumination when viewing impression material and gypsum specimen surfaces, in order to make objective determinations as to whether the specimens comply with the requirements for detail reproduction and compatibility with gypsum.

Record which of the lines (a, b and c) between the cross-lines (d_1 and d_2) have been reproduced for the full length. If the first specimen appears to have failed, determine whether the apparent failure may be colour-related (see note 5). Then test the remaining four specimens.

8.6.3 ***Expression of results***

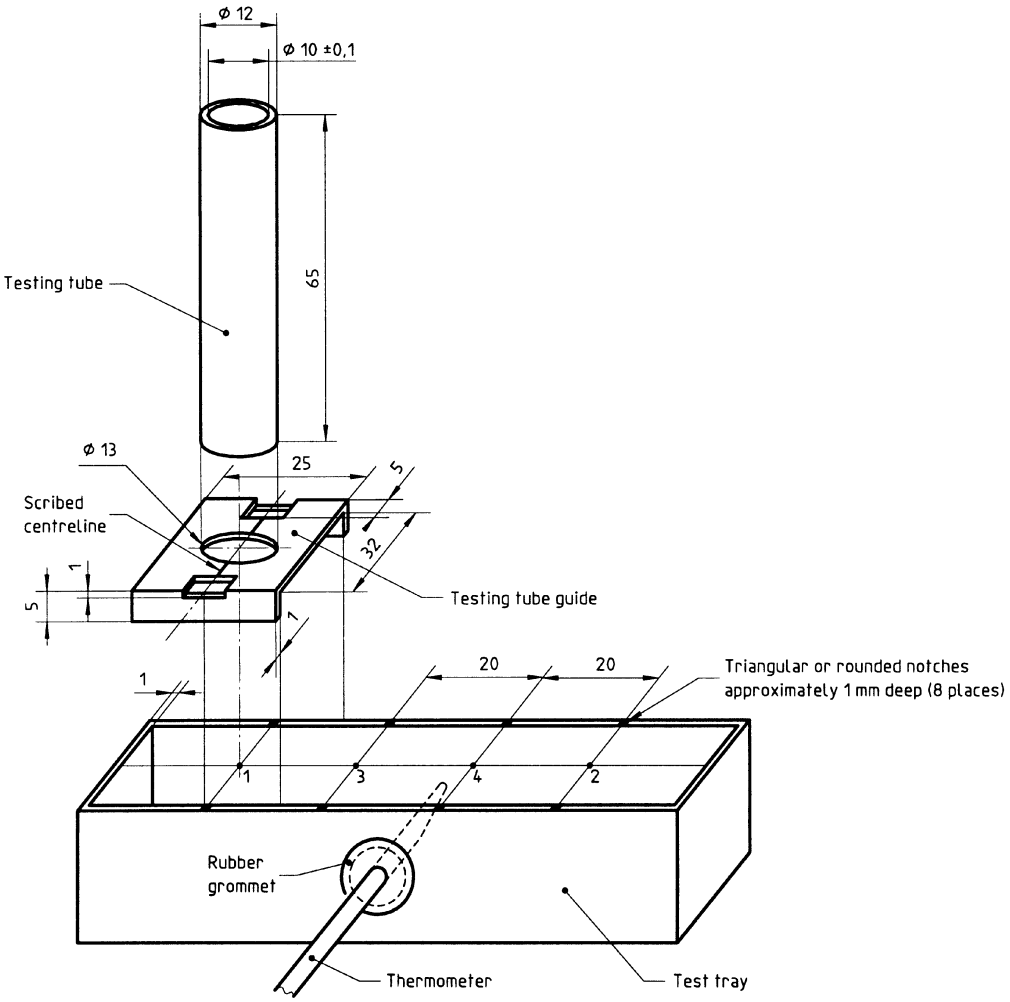
See **7.3** and **7.4** concerning pass/fail determinations.

8.7 Compatibility with gypsum

8.7.1 ***Equipment and materials***

8.7.1.1 Impression made of the lined block (in part B).

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

8.7.1.2 Slit mould, part D, illustrated in Figure 2, and a **worm gear clamp** or similar mechanism for use in closing the slit. Use of this part requires the mould to be clamped such that the slit will be closed during the formation of the specimen. Later, the clamping force is released to allow the slit to open for easy removal of the specimen. The metal used for the mould therefore needs a modulus of elasticity that will enable the slit to be closed and opened repeatedly without significant reduction in width of the slit.

8.7.1.3 Instrument capable of × 4 to × 12 magnification and low angle illumination.

8.7.1.4 Gypsum products [see subclause **7.1.4** and clause **9** o)].

8.7.1.5 Mould release agent, such as silicone grease, that will be non-reactive with part D and the gypsum products.

8.7.2 *Test procedure*

Treat the inner surface of part D with a thin film of the non-reactive release agent and use the worm gear clamp to close the slit in the mould.

Place the impression (**8.7.1.1**) in part B, lined surface down, into the seat in part D. Invert the assembly, and immediately prepare a gypsum mix. Introduce the mixed gypsum (**8.7.1.4**) via mechanical vibration, down into part D, along an internal surface so that it will first contact the ends of lines a, b and c, on one side of the impression. Then direct flow of the mix to follow the lines to their opposite ends. After the impression surface is covered, add enough of the mix to underfill the mould slightly.

Then, 45 min after the initial setting time determined for the gypsum product, release the worm gear clamp (**8.7.1.2**) and remove the poured cast from part D. Use the magnification instrument (**8.7.1.3**) to examine the gypsum cast under low angle illumination. Record which lines (a, b and c) have been reproduced in the gypsum for the full distance between the cross-lines d_1 and d_2. If the first specimen appears to have failed, determine whether the apparent failure may be colour-related (see note 5). Then make four additional gypsum specimens each poured against a new impression.

8.7.3 *Expression of results*

See **7.3** and **7.4** concerning pass/fail determinations.

8.8 Recovery from deformation

8.8.1 *Apparatus*

8.8.1.1 *Split cylindrical mould B* with *fixation ring A,* illustrated in Figure 3, at a temperature of (35 ± 1) °C.

8.8.1.2 *Two flat glass plates* approximately 50 mm × 50 mm × 6 mm.

NOTE 6 Metal back-up plates may be used between the glass plates and the C-clamp parts to minimize scratching and avoid breakage of the glass plates.

8.8.1.3 *C-clamp* with a maximum opening of at least 40 mm and a minimum throat depth of 40 mm.

8.8.1.4 *Water bath* capable of maintaining the tempering condition specified by the manufacturer.

8.8.1.5 *Water bath* capable of maintaining the cooling temperature specified by the manufacturer.

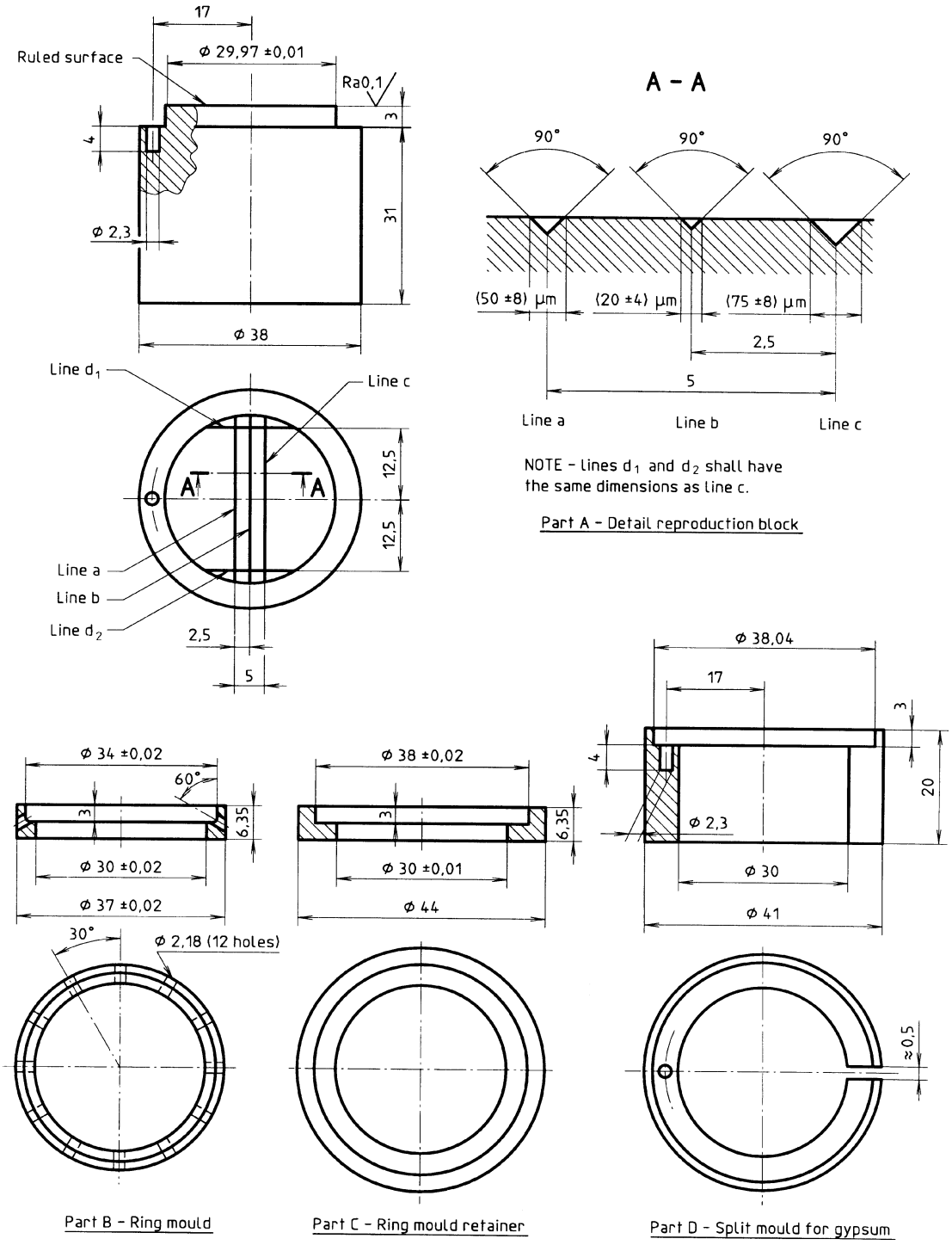
8.8.1.6 *Small glass plate* approximately 15 mm × 15 mm × 2 mm.

8.8.1.7 *Instrument* such as the type illustrated in Figure 4, for deforming the specimens and measuring the recovery from deformation. The dial indicator shall be accurate to 0,01 mm and shall have a capacity for contributing, along with the mass of the small glass plate (**8.8.1.6**), to the application of an initial force of (0,59 ± 0,1) N.

8.8.2 *Specimen preparation*

Place the fixation ring (A in Figure 3) on top of one of the larger glass plates (**8.8.1.2**). After the liquefied impression material has been stored and tempered for the recommended times, fill the fixation ring (**8.8.1.1**) slightly more than half full and, immediately thereafter, press the split mould (B in Figure 3) halves down through the impression material until their bases contact the glass plate (**8.8.1.2**) so as to extrude the impression material above the top of the mould. Then place the second larger glass plate (**8.8.1.2**) over the impression material and force it against the top of the mould by means of the C-clamp (**8.8.1.3**). Immediately thereafter, place the specimen-forming assembly in the cooling water bath (**8.8.1.5**), in simulation of cooling the impression in the mouth, for the recommended time. Upon completion of the cooling cycle, separate the specimen from the assembly and place it in the testing instrument (**8.8.1.7**). Centre the small glass plate (**8.8.1.6**) on top of the specimen.

Dimensions in millimetres
Surface roughness in micrometres



Materials:

Part A: Cast or wrought austenitic stainless steel
Parts B and C: Plastics, brass or stainless steel
Part D: Brass

Figure 2 — Apparatus for detail reproduction and compatibility with gypsum test

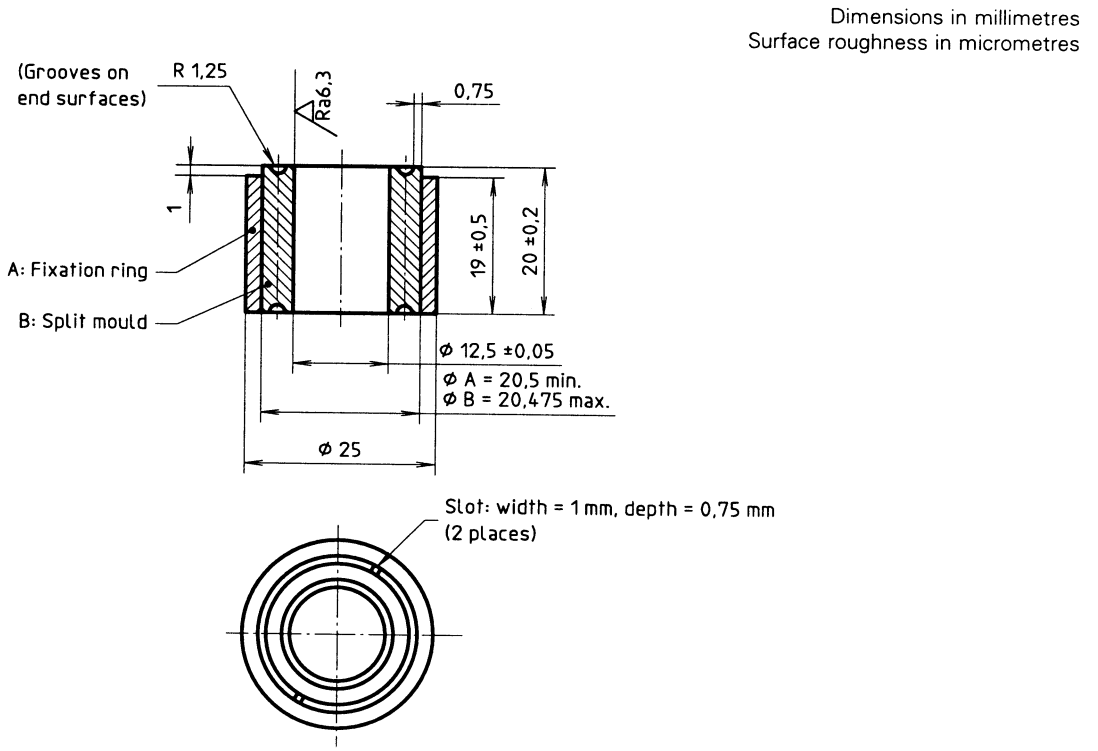


Figure 3 — Split mould for forming specimens for testing properties in compression

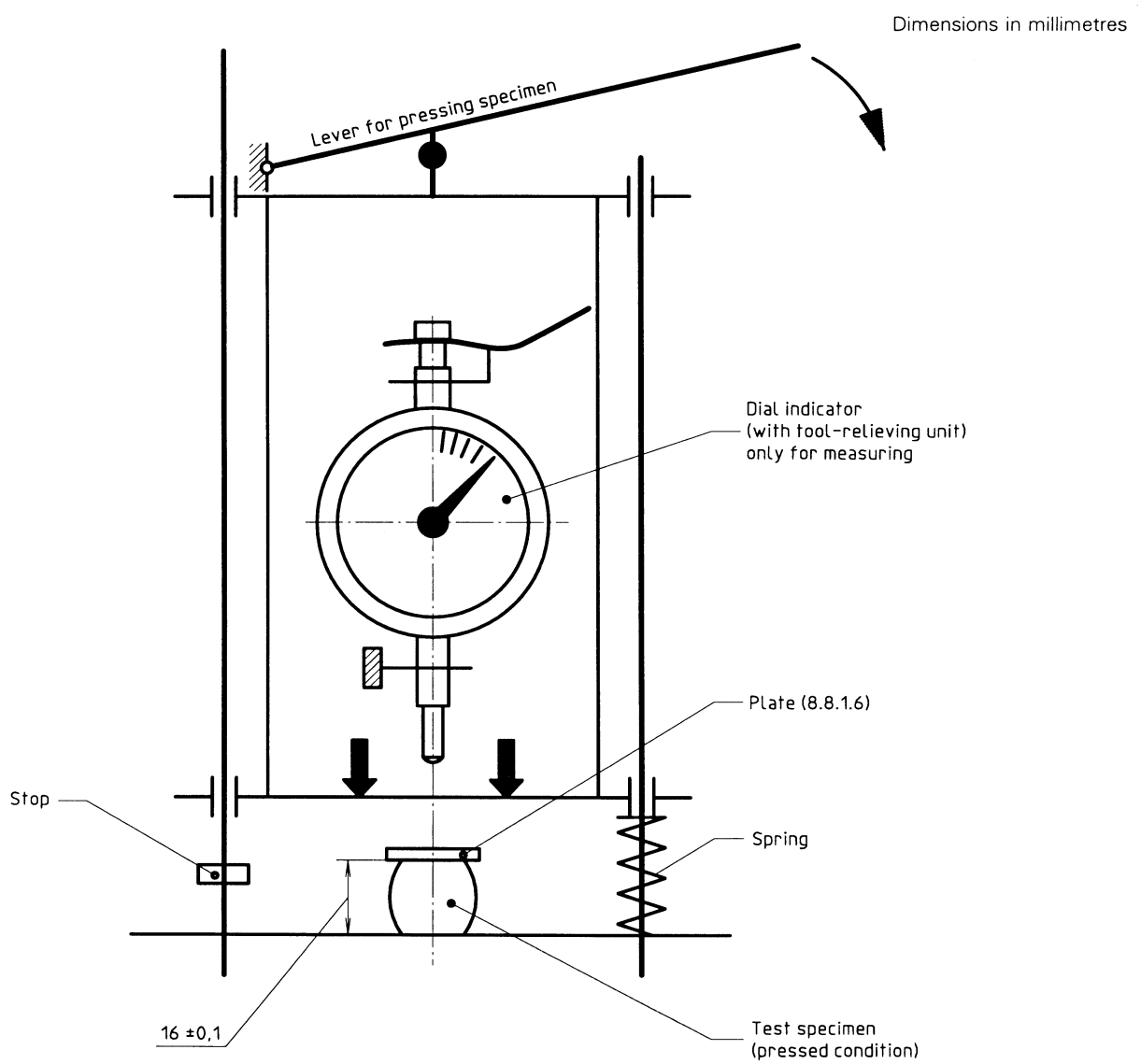


Figure 4 — Apparatus for determining recovery from deformation

8.8.3 ***Test procedure***

Conduct the test in accordance with the following time schedule, where t is the time the specimen was removed from the cooling water bath (**8.8.1.5**).

a) t + 45 s: gently lower the dial indicator spindle until its foot contacts the glass plate on top of the specimen.

b) t + 55 s: read the dial indicator, lift the spindle foot from contact with the plate and record the dial indicator reading as h_1.

c) t + 60 s: deform the specimen by compressing it to a height of (16 ± 0,1) mm, equivalent to (20 ± 0,5) % of its original length, within 1 s. Then immediately remove the compressive force, except for the glass plate.

d) t + 90 s: gently return the dial indicator foot to contact with the glass plate on top of the specimen.

e) t + 100 s: read the dial indicator and record the value as h_2.

NOTE 7 To avoid recording values for defective specimens, section each failing specimen axially into eight approximately equal-sized segments and examine each segment for defects such as air inclusion. Discard values found for defective specimens.

8.8.4 ***Expression of results***

Calculate the recovery from deformation, K, expressed as a percentage, using the formula:

$$K = 100\left(1 - \frac{h_1 - h_2}{20}\right)$$

where

20 is the height of the mould, in millimetres;

h_1 is the measurement, in millimetres, made in accordance with **8.8.3** b) before deformation of the specimen;

h_2 is the measurement, in millimetres, made in accordance with **8.8.3** e) after recovery of the specimen.

See **7.3** and **7.4** concerning pass/fail determinations.

8.9 Strain in compression

8.9.1 ***Test apparatus***

8.9.1.1 *Items* listed in **8.8.1.1** to **8.8.1.5**.

8.9.1.2 *Instrument*, such as the one illustrated in Figure 5, for applying the compression load and for measuring changes in specimen height. The dial indicator shall be accurate to 0,01 mm and shall have a capacity of applying a force of (0,59 ± 0,1) N.

8.9.2 ***Specimen preparation***

Employ the same procedure as in **8.8.2** except that the small glass plate is not placed on the specimen.

8.9.3 ***Test procedure***

Immediately after separation of the specimen from the assembly, position it for testing in the instrument (**8.9.1.2**).

Conduct the test in accordance with the following time schedule, where t is the time at which the specimen is removed from the cooling water bath (**8.8.1.5**).

a) t +60 s: subject the specimen to a load of (125 ± 10) g, thereby providing for a stress of approximately 0,01 N/mm^2. The load may consist of the force applied by the loading shaft alone or the required load may be obtained by allowing the dial indicator spindle foot to contact the loading shaft during the initial load application so that the required force will include the pressure applied by the dial indicator spindle plus the mass applied by the loading shaft. Careful calibration of the dial indicator is necessary if this combination of forces is used.

b) t + 90 s: lock the load in place so as to prevent further changes in stress on the specimen and note the dial gauge reading.

c) t + 95 s: unlock and return the 125 g load to the specimen and record the reading noted at t ± 90 s as h_1.

d) t + 20 s: increase the load to (1 250 ± 10) g gradually over a period of 10 s, thereby providing for a total stress of 0,1 N/mm^2.

e) t + 150 s: lock the load in place, read the dial indicator, and record the value as h^2.

Test five specimens initially.

NOTE 8 Examine any failing specimens according to the procedure indicated in note 7. Discard values found for defective specimens.

8.9.4 ***Expression of results***

Calculate the strain in compression, E, expressed as a percentage using the formula

$$E = 100\left(\frac{h_1 - h_2}{20}\right)$$

where

20 is the height of the mould, in millimetres;

h_1 is the measurement, in millimetres, made in accordance with **8.9.3** c) after application of the first load;

h_2 is the measurement, in millimetres, made in accordance with **8.9.3** e) after application of the increased load.

See **7.3** and **7.4** concerning pass/fail determinations.

8.10 Resistance to tearing

8.10.1 ***Apparatus***

8.10.1.1 *Equipment* for liquefying, storing and tempering the material (see **7.1.1**).

8.10.1.2 *Specimen-forming accessories* including

— a *mould* for producing specimens with the dimensions shown in Figure 6, where the specimen shall be (4 ± 0,1) mm thick and the radius of the apex of the specimen V-notch shall be 0,4 mm;

— *two glass slabs* (such as dental cement mixing slabs), each approximately 154 mm × 75 mm × 12 mm.

NOTE 9 The specimen-forming moulds can be made by first obtaining a machined pattern with the shape and dimensions illustrated in Figure 6. Dough or fluid resin materials can then be formed around the pattern to produce a mould. Recommended peripheral dimensions for the mould are length 118 mm, width 35 mm.

8.10.1.3 *Oven or bath* capable of conditioning the mould and glass slabs to a temperature of (35 + 1) °C.

8.10.1.4 *Water bath* capable of tempering the assembled specimen-forming accessories at the recommended temperature.

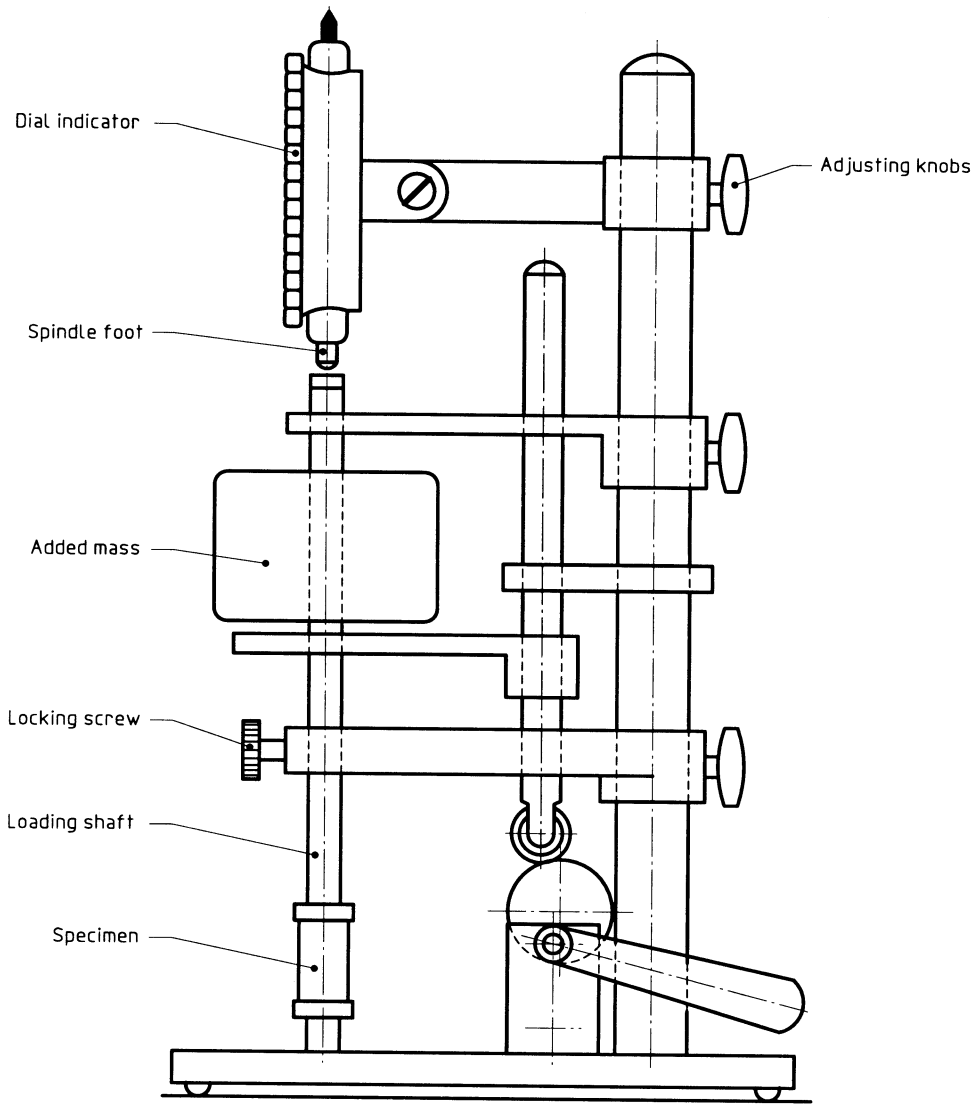


Figure 5 — Apparatus for determining strain in compression

8.10.1.5 *Water bath* capable of cooling the specimen-forming assembly to the recommended temperature.

8.10.1.6 *Calibrated caliper* accurate to 0,02 mm or a similarily suitable instrument, such as the one shown in Figure 5, for measurement the thickness of the specimen.

8.10.1.7 *Instrument* capable of applying a tensile force of at least 500 N.

NOTE 10 Either mechanically adjusted or pneumatic grips may be used for gripping specimens for this test. Experience seems to indicate that the optimum air line pressure for use with pneumatic grips is about 137 895 Pa.
Depending upon the type of gripping surfaces used, it may be necessary to cover faces of the grips with a 240 grit adhesive-backed abrasive paper in order to achieve effective gripping of the specimens.

8.10.2 ***Test procedure***

Condition the mould and glass slabs (**8.10.1.2**) to a temperature of (35 ± 1) °C. Then place the mould on one of the dry glass slabs and slightly overfill it with type 1 or 2 impression material tempered as recommended by the manufacturer. Immediately thereafter press the second glass slab onto the filled mould to expel the excess material. Then place the assembly in the cooling bath (**8.10.1.5**) for the maximum time recommended by the manufacturer. Follow the same procedure for the type 3 specimens, except that the material is injected into the mould at the storage temperature before tempering the material at the temperature recommended for the type 1 or 2 material with which they will be used.

Immediately after completion of the cooling cycle and separation of the assembly, measure the thickness of the specimen, at a point on the midline nearest the V-notch, to the nearest 0,1 mm.

Exercise considerable care to avoid compressing the specimen during the thickness measurement.

Immediately after measuring the specimen, position it in the testing instrument and then, within 45 s of removal from the cooling bath, apply a tensile force at a cross-head speed rate of 500 mm/min until rupture of the specimen occurs. Test five specimens initially. Discard any specimen having identifiable defects especially at the apex of the V-notch.

8.10.3 ***Expression of results***

Calculate the resistance to tearing as follows:

$$T_s = \frac{F}{d}$$

where

T_s is the tear resistance, in newtons per millimetre;

F is the force, in newtons;

d is the specimen thickness, in millimetres.

See **7.3** and **7.4** concerning pass/fail determinations.

9 Required instructions for use

The instructions for use shall bear the name of the manufacturer, the brand-name, and an identification of the type, expressed in the words used to describe the consistency for the particular type classified in clause **4**. As a minimum, the instructions shall include the following information as applicable:

a) a listing of the physical properties: recovery from deformation expressed as a percentage, resistance to tearing expressed in newtons per millimetre, and strain in compression expressed as a percentage;

b) the kind of tray recommended for use with the types 1 and 2 materials;

c) the equipment required for liquefying, storing and tempering the material, to include the kind of syringe and needle recommended for use with the types 2 and 3 materials;

d) the time required to liquefy the material at 100 °C, the minimum temperature required to liquefy the material and the maximum permissible temperature for the liquefication process;

e) the times and temperatures required for storing and tempering the material;

f) the maximum temperature to which a prepared tooth will be exposed upon contact with the syringed types 2 and 3 materials;

g) the maximum time allowed for the material to remain at the storage temperature before being used in the subsequent step;

h) the number of times the material may be reliquefied and stored after the initial liquefication process;

i) the procedures to follow in preventing the materials from becoming diluted during the liquefication and storage cycles;

j) information that the tempered material in the tray should remain in the tempering bath until immediately before the tray is introduced into the mouth;

k) the technique recommended for cooling the impression in the mouth, to include the lowest temperature recommended for the cooling water;

l) the method for determining when the impression can safely be removed from the mouth; for example, the time required for gelation of a large impression when cooled at a specified temperature;

m) any treatment the impression should receive before the gypsum cast is poured;

n) a statement that the impression should be poured within 15 min after removal from the mouth;

o) identification of at least one type 3 and one type 4 gypsum product certified to be in compliance with requirements of ISO 6873, and which has been found to be compatible with the agar impression material;

p) a statement advising that, to avoid the spread of infectious diseases, material once used for making an impression should not be recycled for further use;

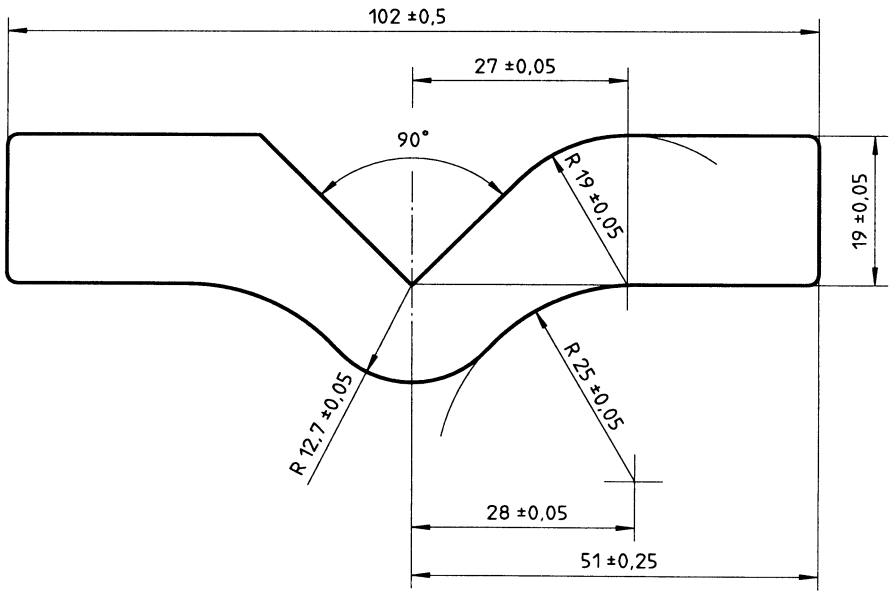


Figure 6 — Pattern for specimen for resistance to tearing test

q) a statement indicating whether an impression made of the material can be disinfected without altering its potential for optimum performance, and if so, the recommended method;

r) if a manufacturer claims a material, in itself, is antimicrobial and will remain so without further treatment after an impression is removed from the mouth, the manufacturer shall supply information justifying the claim.

10 Requirements for packaging and marking

10.1 Packaging

The packaging shall be such that it will neither contaminate nor permit contamination of the contents, nor permit inadvertent escape of any of the contents.

10.2 Labelling and marking

10.2.1 *Labelling and marking of outer wrappings or package surfaces*

The outer wrapping of the packages or package surface of the containers in which multiple units of the products are prepared for retail marketing shall be marked legibly with the following information:

a) manufacturer's name and address and brandname of the product;

b) type, expressed in the words used to describe the consistency classification in clause **4**;

c) for types 1 and 2 materials, the number of tubes contained and the net mass for each tube; for type 3 materials, the number of sticks and the net mass for the package;

d) lot or batch number;

e) recommended storage conditions, to include a recommended temperature range;

f) shelf life or expiry date, identified as such, applicable when the manufacturer's storage recommendations are observed.

10.2.2 Labelling and marking of immediate containers (excluding type 3 materials furnished in individual glass vials from which they are dispensed directly)

The immediate containers shall be marked with the following information:

a) manufacturer's name and address and brandname;

b) lot or batch number;

c) net mass of each tube for types 1 and 2, and for each container of type 3 sticks.

Annex ZA (normative)
Normative references to international publications with their relevant European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

Publication	Year	Title	EN	Year
ISO 6873	1983	Dentistry — Dental gypsum products	EN 26873	1991
ISO 7405	1997	Dentistry — Preclinical evaluation of biocompatability of medical devices used in dentistry — Test methods for dental materials	EN ISO 7405	1997

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