BS EN ISO 6873:2013

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Dentistry — Gypsum products (ISO 6873:2013)

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National foreword

This British Standard is the UK implementation of EN ISO 6873:2013. It supersedes BS EN ISO 6873:2000 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/106/2, Prosthodontic materials.

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

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

ISBN 978 0 580 74586 7

ICS 11.060.10

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 April 2013.

Amendments issued since publication

Date	Text affected

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 6873

April 2013

ICS 11.060.10

Supersedes EN ISO 6873:2000

English Version

Dentistry - Gypsum products (ISO 6873:2013)

Médecine bucco-dentaire - Produits à base de gypse (ISO 6873:2013)

Zahnheilkunde - Gipse (ISO 6873:2013)

This European Standard was approved by CEN on 21 March 2013.

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EUROPÄISCHES KOMITEE FÜR NORMUNG

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Ref. No. EN ISO 6873:2013: E

Foreword

This document (EN ISO 6873:2013) has been prepared by Technical Committee ISO/TC 106 "Dentistry" in collaboration with Technical Committee CEN/TC 55 “Dentistry” the secretariat of which is held by DIN.

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of an identical text or by endorsement, at the latest by October 2013, and conflicting national standards shall be withdrawn at the latest by October 2013.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 6873:2000.

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Endorsement notice

The text of ISO 6873:2013 has been approved by CEN as EN ISO 6873:2013 without any modification.

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. 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.

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Specific qualitative and quantitative requirements for freedom from biological hazard are not included in this International Standard but it is recommended that, in assessing possible biological hazards, reference should be made to ISO 10993-1 and ISO 7405.

ISO 6873 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthodontic materials*.

This third edition cancels and replaces the second edition (ISO 6873:1998) of which Clause 4 and subclauses 5.4 and 8.2 have been technically revised. An alternative design for the extensometer used to measure setting expansion is included.

Introduction

This revision was necessary because gypsum products have been marketed since the last edition of ISO 6873 was published, which have properties (required for newly introduced dental technology) for which the requirements set in that edition were not appropriate. In this edition the classification has been altered to take this into account and in so doing, requirements have been set appropriately. In addition there was concern that Type 4 dental stone used for CAD/CAM models should not produce significant setting expansion at times beyond the 2 h period at which setting expansion was measured and a requirement had been set. In this edition the setting expansion for Type 4 dental stone is measured at 24 h as well.

INTERNATIONAL STANDARD **ISO 6873:2013(E)**

Dentistry — Gypsum products

1 Scope

This International Standard gives a classification of, and specifies requirements for, gypsum products used for dental purposes such as making oral impressions, moulds, casts, dies or model bases, and mounting models. It specifies the test methods to be employed to determine compliance with these requirements. It also includes requirements for the labelling of packaging and for adequate instructions to accompany each package.

This International Standard does not apply to dental bone graft substitutes composed of calcium sulfate hemihydrate (or gypsum).

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 1302, *Geometrical Product Specifications (GPS) — Indication of surface texture in technical product documentation*

ISO 1942, *Dentistry — Vocabulary*

ISO 3696:1987, *Water for analytical laboratory use — Specification and test methods*

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 and the following apply.

3.1
gypsum product
dental product composed essentially of a hemihydrate of calcium sulfate and any necessary modifiers

Note 1 to entry: Colouring matter and flavouring, if present, are regarded as necessary modifiers.

4 Classification

The five types of gypsum product used in dentistry are classified in accordance with this International Standard as follows:

a) **Type 1:** Dental plaster for impressions;

b) **Type 2:** Dental plaster for mounting (Class 1) and for models (Class 2);

c) **Type 3:** Dental stone for models;

d) **Type 4:** Dental stone (high strength, low expansion) for dies, model bases and CAD/CAM dies;

e) **Type 5:** Dental stone (high strength, high expansion) for dies when this degree of expansion is necessary for shrinkage compensation of some materials used in dental restoration.

5 Requirements

5.1 Quality

When tested according to 7.1, the powder shall be uniform and free from foreign matter and lumps. When mixed according to the manufacturer's instructions the product shall produce a homogeneous mix.

5.2 Fluidity at pouring time (Type 1 materials only)

When tested according to 7.2 at a pouring time of 1,25 min, the fluidity of type 1 materials shall be equal to or greater than 70 mm.

5.3 Setting time

When tested according to 7.3, the setting time of type 1 materials shall be in the range of 2,5 min to 5,0 min and the setting time of all material types shall be within 20 % of the value claimed by the manufacturer in 8.2.1 h) or 8.2.2 h), whichever is appropriate for the packaging in which the product is supplied. If the manufacturer claims a range of setting time, then the midpoint of this range is taken as the value claimed by the manufacturer.

5.4 Linear setting expansion

When tested according to 7.4, the linear setting expansion shall be within the range listed in Table 1.

Table 1 — Linear setting expansion and compressive strength

Type	Linear setting expansion %				Compressive strength MPa	
	2 h		24 h		1 h	
	min.	max.	min.	max.	min.	max.
1	0,00	0,15	-	-	4,0	8,0
2 (Class 1)	0,00	0,05	-	-	9,0	-
2 (Class 2)	0,06	0,30	-	-	9,0	-
3	0,00	0,20	-	-	20,0	-
4	0,00	0,15	0,00	0,18	35,0	-
5	0,16	0,30	-	-	35,0	-

5.5 Fracture (Type 1 materials only)

When tested according to 7.5, Type 1 impression plaster shall break with a clean fracture and be readily reassembled to form the shape and size of the original unbroken specimen.

5.6 Compressive strength

When tested according to 7.6, the compressive strength shall meet the requirement(s) of Table 1.

5.7 Reproduction of detail

Types 1 and 2: When tested according to 7.7, groove c in Figure 6 shall be reproduced.

Types 3, 4 and 5: When tested according to 7.7, groove a in Figure 6 shall be reproduced.

6 Testing — Generalities

6.1 Sampling

Select the material for testing from one lot that has been produced for retail and that is not beyond its expiry date [8.2.1 b) or 8.2.2 b), whichever is appropriate for the packaging in which the product is supplied]. Do not use powder from previously opened, broken or damaged containers.

6.2 Test conditions

Carry out all mixing and testing of the dental gypsum product at (23 ± 2) °C and (50 ± 10) % relative humidity. Ensure that all apparatus and instruments used in mixing and testing are clean, dry and free from particles of gypsum. Before testing begins, hold material and test apparatus at the test temperature for a period of time that is sufficient to equilibrate with this temperature.

NOTE A minimum storage period of 15 h is recommended.

6.3 Mixing method

Mix by one of the methods (hand or mechanical) specified by the manufacturer in the instructions (see 8.3), using water, which meets the requirements of ISO 3696, Grade 3.

7 Test methods

7.1 Visual inspection

Carry out visual inspection without magnification to determine compliance with the requirements given in 5.1, 5.5 and 5.7 (unless as stated otherwise, as in 7.7).

Determine compliance with the requirements given in Clause 8 for packaging, marking and information supplied by the manufacturer.

7.2 Fluidity at pouring time for Type 1 materials

7.2.1 Apparatus

7.2.1.1 Cylindrical mould, constructed from a corrosion-resistant, non-absorbent material, having a length of (50,0 ± 0,1) mm and an inside diameter of (35,0 ± 0,1) mm. Clean and dry.

7.2.1.2 Glass plate, flat and smooth, with sides of length at least 100 mm. Clean and dry.

7.2.1.3 Means of measuring lengths from 35 mm to 100 mm, for measuring the major and minor diameters of the slumped mix to the nearest millimetre.

7.2.2 Procedure

Rest the glass plate on a surface that is free of vibration. Place the mould upright on the centre of the plate.

Add (100,0 ± 0,1) g of the sample to the manufacturer's recommended quantity of water (ISO 3696, Grade 3) dispensed to an accuracy of 0,1 ml to a mixing bowl and mix as described in 6.3.

Completely fill the mould and level off the mixed material so that it is flush with the top of the mould. At 1,25 min after the start of mixing, lift the mould vertically from the plate at a rate of approximately 10 mm/s and allow the mix to slump or spread over the plate. One minute after the mould is lifted, measure the major and minor axes of the slumped material to the nearest millimetre. Record the average of these two diameters as the fluidity at the pouring time.

7.2.3 Evaluation

Carry out the test twice. If both average values meet the requirement given in 5.2, then the product meets the requirement for fluidity. If neither meets this requirement, then the product fails. If one average value meets the requirement given in 5.2, and the other fails, carry out three more tests. If all three of these average values meet the requirement given in 5.2, the product meets the requirement for fluidity. Otherwise it fails.

7.3 Setting time

7.3.1 Apparatus

7.3.1.1 Needle penetrometer, an example of which is shown in Figure 1, meeting the following requirements:

a) Penetrometer needle (1), 50 mm long, of circular cross-section, with a diameter of (1,00 ± 0,05) mm and a squared end.

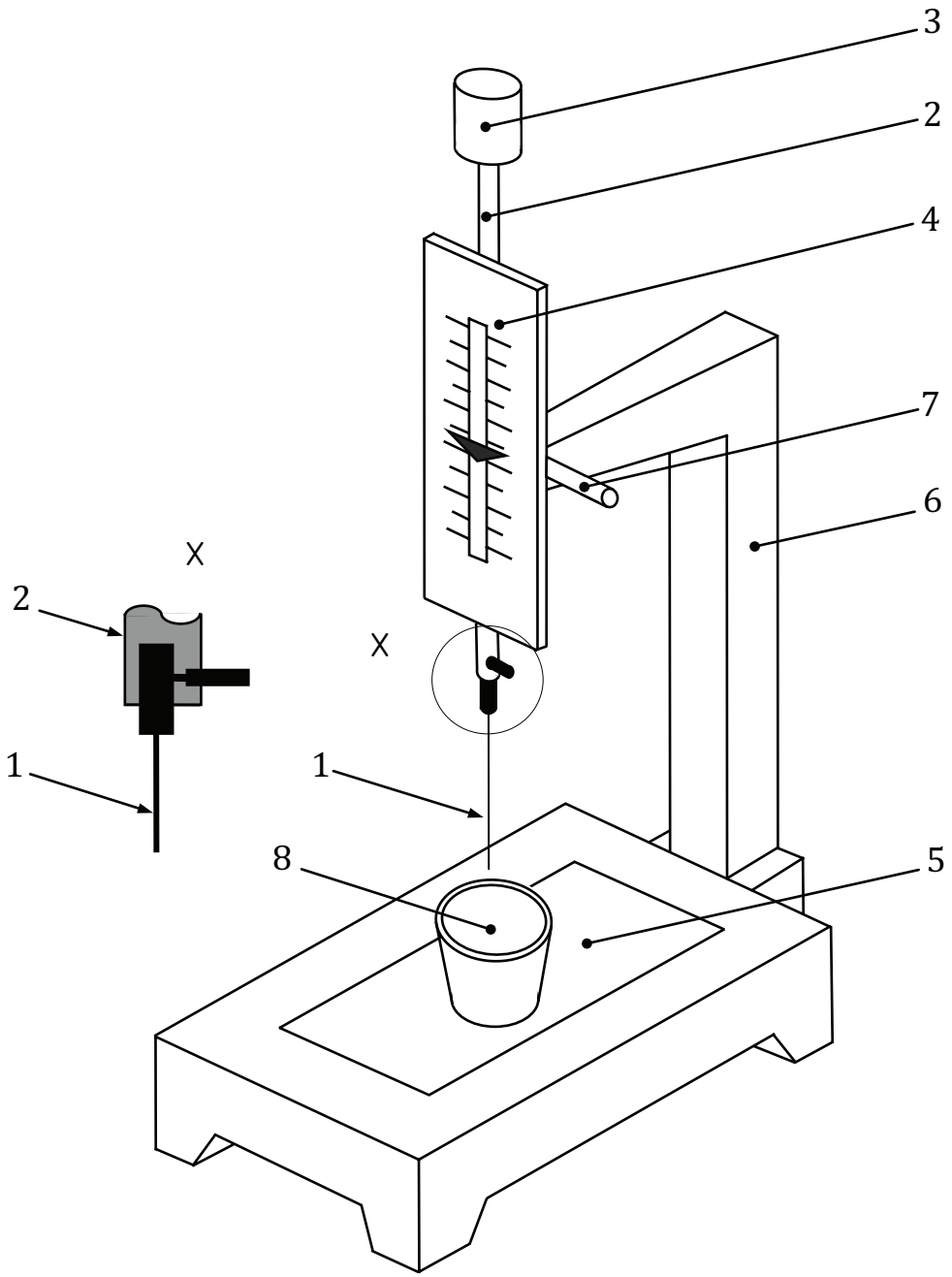
b) Rod (2), of approximate dimensions 270 mm long and 10 mm in diameter.

c) Additional (compensating) weight (3).

d) The total mass of all the parts that move with the rod shall be (300 ± 1) g.

e) Scale (4), graduated in millimetres.

f) Base-plate (5) of plate glass, measuring about 100 mm × 100 mm.



Key

1	Needle	5	Base plate
2	Rod	6	Stand
3	Additional (compensating) weight	7	Scale adjustment locking screw
4	Scale	8	Mould

Figure 1 — Example of needle penetrometer

7.3.1.2 Ring mould, constructed from a corrosion-resistant, non-absorbent material. There are two alternatives.

7.3.1.2.1 Large conical mould, with an inside diameter of 70 mm at the top and 60 mm at the base, and a height of 40 mm.

7.3.1.2.2 Small cylindrical mould, with an inside diameter of 20 mm and height of 30 mm.

NOTE For effective utilization of resources, the smaller mould can be used in the place of the traditional larger mould. The user will be aware that the decreased area allows fewer indentation sites [according to 7.3.2] and that greater attention must be given to the time (relative to the anticipated setting time) of the first indentation.

7.3.1.3 Mould release agent, such as silicone spray or silicone grease.

7.3.2 Procedure

Coat the inside of the ring mould with a thin layer of mould release agent. Place the ring mould on the base-plate, positioned to one side of the needle.

Mix the gypsum according to 6.3, using a mass of powder with the appropriate volume of water (ISO 3696, Grade 3) that will produce a workable mix sufficient to fill the mould. Both powder and liquid should be dispensed to an accuracy of 0,5 %.

NOTE 1 If the larger mould is used, add 400 g of the investment powder to the manufacturer's recommended quantity of water in a mixing bowl. If the smaller mould is used, add 100 g of the investment powder to the manufacturer's recommended quantity water in a mixing bowl.

The timer used during mixing is to continue running after mixing is completed and is the reference for subsequent times.

Overfill the mould with the mix and then level the specimen surface to be flush with the top of the mould. Raise the needle and move the mould to a position under the needle that is not less than 4 mm from the mould wall. Lower the needle until it makes contact with the surface of the mix. Adjust the scale of the penetrometer to read zero on its indicator and lock the scale in this position with the scale adjustment locking screw. Hold the needle in contact with the surface of the specimen.

NOTE 2 For this design, the adjustable scale is attached to the rod and, once locked, moves (relative to the fixed indicator) when the rod is raised or lowered. The zero locking position should allow an upward movement to allow the needle to be withdrawn from the specimen and cleaned between readings, and a downward movement for penetration into the specimen when readings are taken.

NOTE 3 An alternative design is possible and permitted if it produces the same relative movement between scale and indicator to record the movement of the needle.

Beginning at a time between 1 min to 2 min prior to the anticipated setting time, which is the setting time or mid-point of the setting time range given by the manufacturer in accordance with 8.2.1 h) [or 8.2.2 h), as appropriate for the packaging in which the product is supplied], release the rod gently and record the release time as the first reading. Allow the needle to penetrate the specimen.

NOTE 4 For the smaller mould a maximum of 8 indentations is possible, for which the time between the first and last readings is 1,75 min. The investigator should consider if this time span is adequate for the product under test even when the minimum recommended starting time is used (i.e. 1 min before the anticipated setting time). If this is in doubt, the larger mould is recommended.

NOTE 5 It is not necessary to wait for the needle to penetrate any further than 3 mm. Once this depth is reached, the needle can be withdrawn in preparation to take the second reading.

Take the second and subsequent readings at (15 ± 1) s intervals as follows:

a) Raise the rod to withdraw the needle from the specimen. Move the mould to allow the next penetration to be in a new area, which is at least 4 mm from the mould wall and from any other penetration mark.

b) Wipe the needle clean and then bring its tip into contact with the specimen surface.

c) At the appropriate time, release the rod and record the release time (as the second reading, or after that any subsequent reading). Allow the needle to penetrate the material for a time that will let steps 7.3.2 a) and b) for the next measurement to be completed in the 15 s period between measurements.

NOTE 6 As for the first reading, when taking the second and subsequent readings it is not necessary to wait for the needle to penetrate any further than 3 mm. Once this depth is reached, the needle can be withdrawn in preparation for a subsequent reading.

d) Record the setting time as the total time from the start of mixing to the time when the needle first fails to penetrate the specimen to a depth of 2 mm.

7.3.3 Evaluation

7.3.3.1 Type 1 products

Carry out the test twice. If both measurements meet both requirements given in 5.3, then the product meets the requirement for setting time. If neither meets these requirements, then the product fails. If one measurement meets the requirements given in 5.3, and the other fails, carry out three more tests. If all three of these measurements meet the requirements given in 5.3, the product meets the requirement for setting time. Otherwise, it fails.

7.3.3.2 Type 2, 3, 4 and 5 products

Carry out the test twice. If both measurements meet the requirement given in 5.3, then the product meets the requirement for setting time. If neither meets the requirement, then the product fails. If one measurement meets the requirement given in 5.3, and the other fails, carry out three more tests. If all three of these measurements meet the requirement given in 5.3, the product meets the requirement for setting time. Otherwise, it fails.

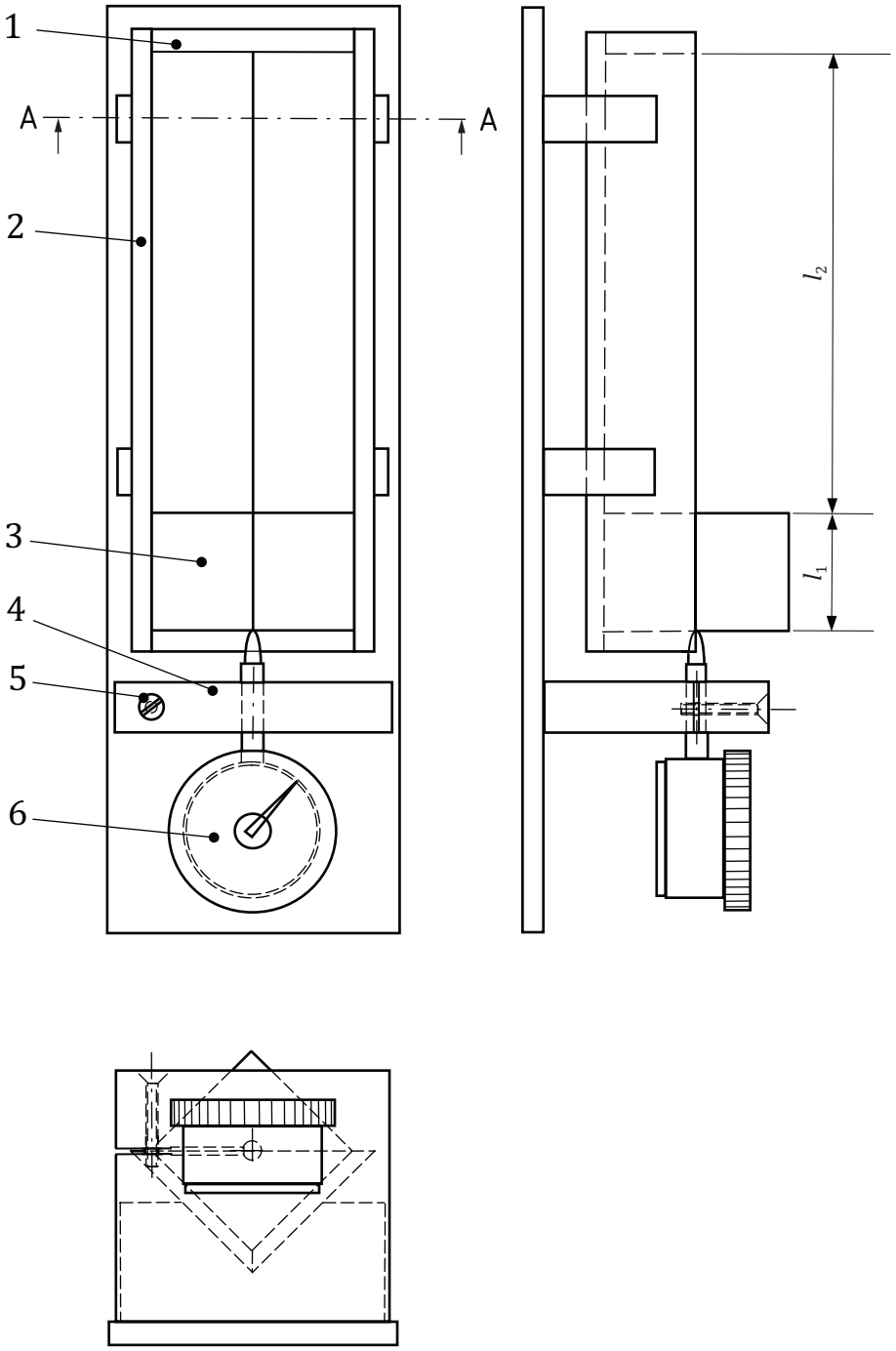
7.4 Linear setting expansion

7.4.1 Apparatus

7.4.1.1 Extensometer. There are two types. Either may be used.

7.4.1.1.1 Triangular cross-section trough, as shown in Figure 2, 3 and 4, made from a non-corroding metallic material (such as aluminium, stainless steel or a brass alloy) and producing a specimen with a length of (100,0 ± 0,1) mm. The apparatus is fitted with a device which measures change in length to within 0,01 mm and exerts a measuring force which is no greater than 0,8 N. The internal cross-section of the trough is an isosceles triangle having an angle of 90° with internal side lengths of (30 ± 1) mm. One end of the trough is blocked with an immovable end-piece and the other with a movable end-piece having a mass of (200 ± 10) g.

On the inside of this trough a horizontal line is scribed so as to define a triangle with included sides of length (25 ± 1) mm.



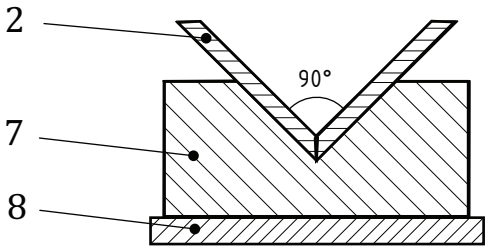
Key

1	Immovable end-piece	5	Dial gauge locking screw
2	Triangular cross-section trough	6	Dial gauge
3	Movable end-piece	l_1	Length dependent upon density of end-piece material
4	Gauge support	l_2	Measuring length of (100,0 ± 0,1) mm

A-A Position of the section through trough that is shown in Figure 3

NOTE For clarity, the line scribed on the sides and end-pieces to define the 25 mm fill line has been omitted.

Figure 2 — Example of extensometer for measuring setting expansion — Triangular cross-section trough



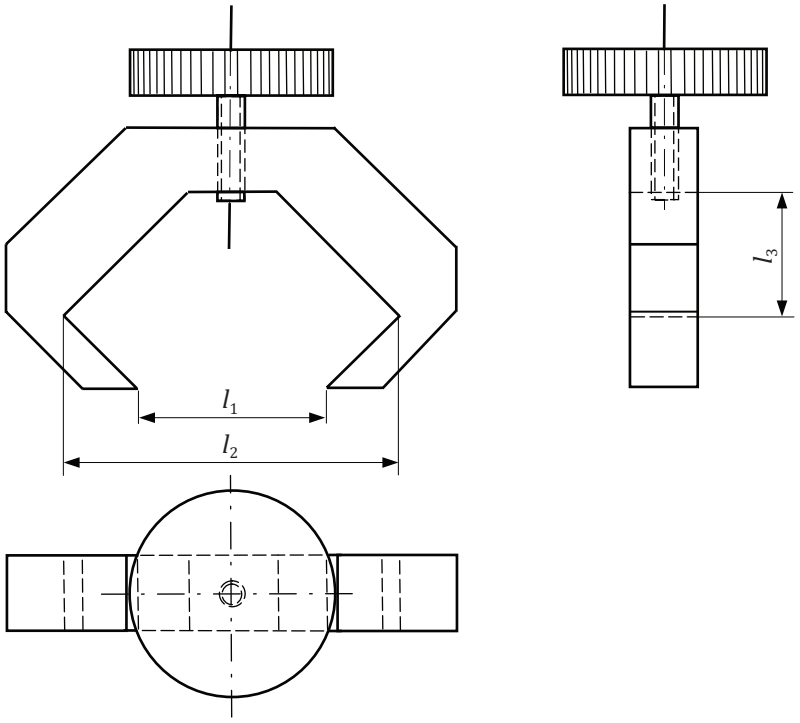
Key

2 Triangular cross-section trough

7 Trough support

8 Base-plate

Figure 3 — Section through A – A on the triangular cross-section trough extensometer



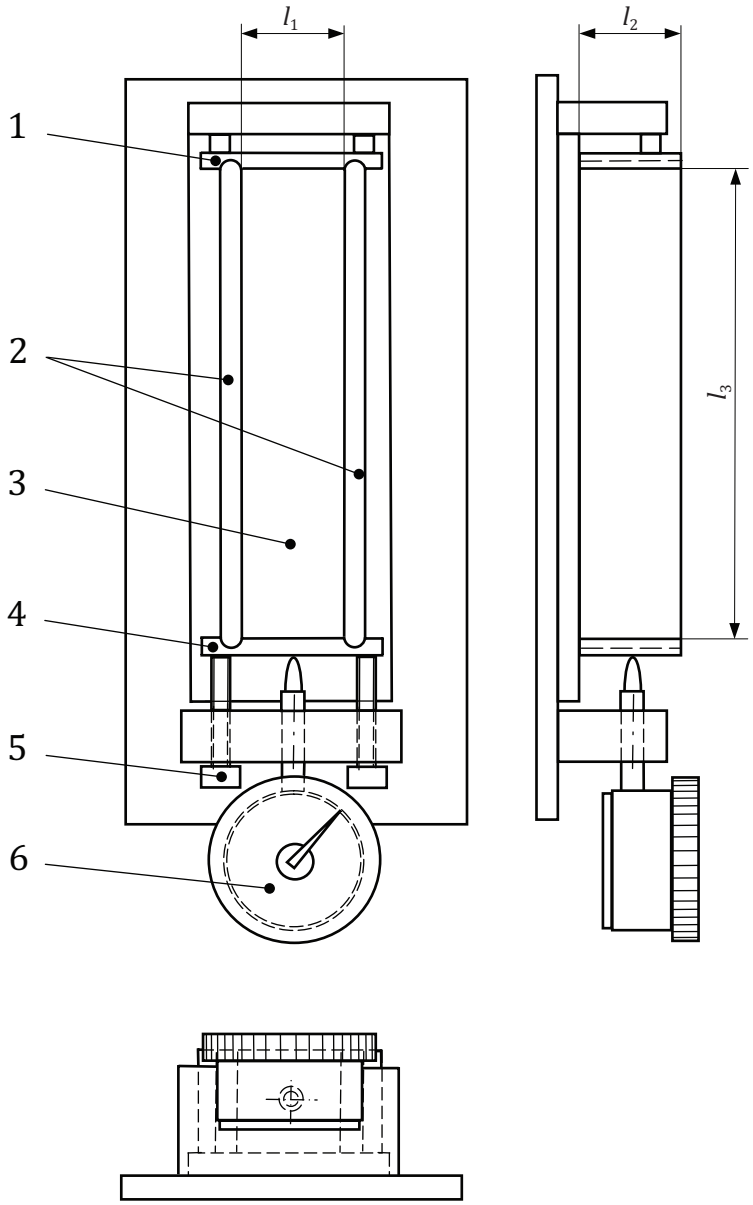
Key

l_1 Determined by dimensions of trough and trough support

l_2 Determined by dimensions of trough and trough support

l_3 Determined by dimensions of trough and movable end-piece

Figure 4 — Example of clamp for use with the triangular cross-section trough extensometer to hold the movable end-piece at its initial set position during the filling of the trough



Key

1	Fixed end-piece	6	Dial gauge
2	Trough walls	l_1	Trough width = (20,0 ± 0,1) mm
3	Trough base	l_2	Trough depth = (20,0 ± 0,1) mm
4	Movable end-piece	l_3	Measuring length = (100,0 ± 0,1) mm
5	Securing bolt		

Figure 5 — Example of extensometer for measuring setting expansion — Square cross-section trough

NOTE The securing bolts have been omitted from the side and end elevations to allow other features to be seen more clearly.

7.4.1.1.2 Square cross-section trough, as shown in Figure 5, made from a non-corroding metallic material (such as aluminium, stainless steel or a brass alloy) and producing a specimen with a length, l_3 = (100,0 ± 0,1) mm. The apparatus is fitted with a device which measures a change in length to within 0,01 mm and exerts a measuring force which is no greater than 0,8 N. The internal cross-section of the

trough is square having a depth and width, $l_1 = l_2 = (20{,}0 \pm 0{,}1)$ mm. One end of the trough is blocked with an immovable end-piece and the other with a movable end-piece having a mass of (95 ± 5) g.

7.4.1.2 Polytetrafluoroethylene (PTFE) sheet, 0,1 mm to 0,2 mm thick.

7.4.1.3 Mould-release agent.

7.4.1.4 Length measuring instrument, that is capable of a measurement up to 105 mm to an accuracy of 0,01 mm (such as a travelling microscope, vernier calliper or micrometer).

7.4.2 Procedure

7.4.2.1 Triangular cross-section trough

Line the trough walls completely with the PTFE sheet.

Apply the mould-release agent to the trough end-pieces that contact the material being tested. Place the movable end-piece on the PTFE lining and adjust its position to establish the (100,0 ± 0,1) mm measuring length. Lock the dial gauge in the gauge support.

Add (200 ± 1) g of powder to the recommended quantity of water (ISO 3696, Grade 3), dispensed to an accuracy of 0,5 ml, in a mixing bowl and mix as described in 6.3. Pour the mix into the trough until the dental gypsum product is level with the scribed line in the trough. Cover the top surface of the trough with PTFE sheet. Record the dial gauge reading to the nearest 0,01 mm, the initial position of the end of the specimen (a reading that is required to determine the linear setting expansion). Take this initial reading (60 ± 1) s prior to the setting time as determined in 7.3.

Take the second reading at (120 ± 1) min from the start of mixing and determine the change in length to the nearest 0,01 mm.

Remove the specimen from the trough and measure the overall length to the nearest 0,01 mm. Subtract the change in length from this measurement to determine the original length.

Calculate the linear setting expansion as a percentage of the original length, to the nearest 0,01 %.

For Type 4 material, take a third reading on the dial gauge at 24 h ± 5 min from the start of mixing and determine the linear setting expansion at this time in the same way as above. For such a material, the specimen should not be removed from the trough (for overall length measurement) until the 24 h reading has been taken.

NOTE If the movable end-piece is displaced from its position during filling of the trough, a clamp such as that shown in Figure 4 can be used to prevent this. It should be released immediately after the mould has been filled then removed from the apparatus by sliding it off the trough over the fixed end-piece.

7.4.2.2 Square cross-section trough

Line the trough floor and sides completely with the PTFE sheet.

Apply the mould-release agent to the trough end-pieces that contact the material being tested. Place the movable end-piece in position (to establish the (100,0 ± 0,1) mm measuring length) and lock the securing bolts. Lock the dial gauge in position and zero.

Add (200 ± 1) g of powder to the recommended quantity of water (ISO 3696, Grade 3), dispensed to an accuracy of 0,5 ml, in a mixing bowl and mix as described in 6.3. Pour the mix into the trough until the dental gypsum product is level with the top of the trough. Cover the top surface of the trough with PTFE sheet. Release the securing bolts. Record the dial gauge reading to the nearest 0,01 mm, the initial position of the end of the specimen (a reading that is required to determine the linear setting expansion). Take this initial reading (60 ± 1) s prior to the setting time as determined in 7.3.

After this follow the same procedure as that used in 7.4.2.1 after the initial reading has been taken.

7.4.3 Evaluation

Perform two tests. Compare the setting expansions that have been calculated (both values for Type 4 material) for compliance with the respective requirement(s) given in Table 1. If the results of both tests comply, then the product meets the requirement for linear setting expansion. If neither complies, then the product fails to meet the requirement for linear setting expansion. If the result of only one test complies with the respective requirement given in Table 1, carry out three more tests. If the results of these three additional tests comply with the respective requirement given in Table 1, then the product meets the requirement for linear setting expansion. Otherwise it fails.

NOTE For Type 4 material, compliance applies to both times, not just one.

7.5 Fracture

7.5.1 Procedure

Add (100 ± 1) g of Type 1 impression plaster to the recommended quantity of water (ISO 3696, Grade 3), dispensed to an accuracy of 0,5 ml, in a mixing bowl and mix as described in 6.3. Pour the mix into a mould, which will form a specimen approximately 25 mm × 12 mm × 3 mm. Two minutes after the setting time specified by the manufacturer [8.2.1 h) or 8.2.2 h), as is appropriate for the packaging in which the product is supplied], break the specimen, in bending by hand, into two pieces approximately 12 mm × 12 mm × 3 mm. Carry out the test twice.

7.5.2 Evaluation

Evaluate as described in 5.5. If both tests meet the requirement of 5.5 then the product passes. If neither meets the requirement then the product fails. If one meets the requirement and one does not, then perform the test three more times. If all three of these tests meet the requirement, then the product meets the requirement. Otherwise it fails.

7.6 Compressive strength

7.6.1 Apparatus

7.6.1.1 Clean, dry cylindrical split moulds, constructed from non-absorbent corrosion-resistant material, sufficient to produce five specimens. Each mould shall have a diameter of (20,0 ± 0,2) mm and a length of (40,0 ± 0,4 mm).

7.6.1.2 Flat smooth glass plates, sufficient in number and of a size to cover the top and bottom of each mould.

7.6.1.3 Compressive strength testing machine, adjusted to give a loading rate of (5 ± 2) kN/min.

7.6.2 Procedure

Make and test five specimens.

Add (200 ± 1) g of powder to the recommended quantity of water (ISO 3696, Grade 3), dispensed to an accuracy of 0,5 ml, in a mixing bowl and mix as described in 6.3. If necessary to facilitate the production of defect free specimens, use more than one such mix. Pour the mix down the inside of each inclined mould retained on a glass plate and overfill each mould slightly. Vibrate the mould gently while filling (maximum 30 s) in order to minimize the formation of air bubbles. Before the glossy surface has disappeared from the mix, level the specimen flush with the top of the mould by pressing the second glass plate firmly into contact with the top surface of the mould. At (45 ± 1) min from the start of mixing,

split the each mould, remove the specimens and store in air at (23 ± 2) °C and (50 ± 10) % relative humidity. At (60 ± 5) min after the start of mixing, apply an increasing load to the flat ends of each specimen until failure occurs by using the compressive strength testing machine. Record the maximum force (F) applied.

The maximum load applied should be used to calculate the value of compressive fracture stress (S) for the specimen involved.

NOTE To determine the minimum requirement for Type 4 and 5 products a force up to 11 kN is required. The compressive strength testing machine frame and load cell capacities should be appropriate.

7.6.3 Evaluation

For each specimen tested, calculate the compressive fracture stress (S) expressed in megapascals, using the recorded maximum force (F) expressed in newtons as follows:

$$S = F/314$$

If four of the five specimens meet the requirement for compressive strength listed in Table 1, then the product meets the requirement for compressive strength. If only three of the five specimens meet the requirement listed in Table 1, then a second series of five specimens shall be tested. If all five of this second series meet the requirement for compressive strength listed in Table 1, then the product meets the requirement for compressive strength. Otherwise, it fails.

7.7 Reproduction of detail

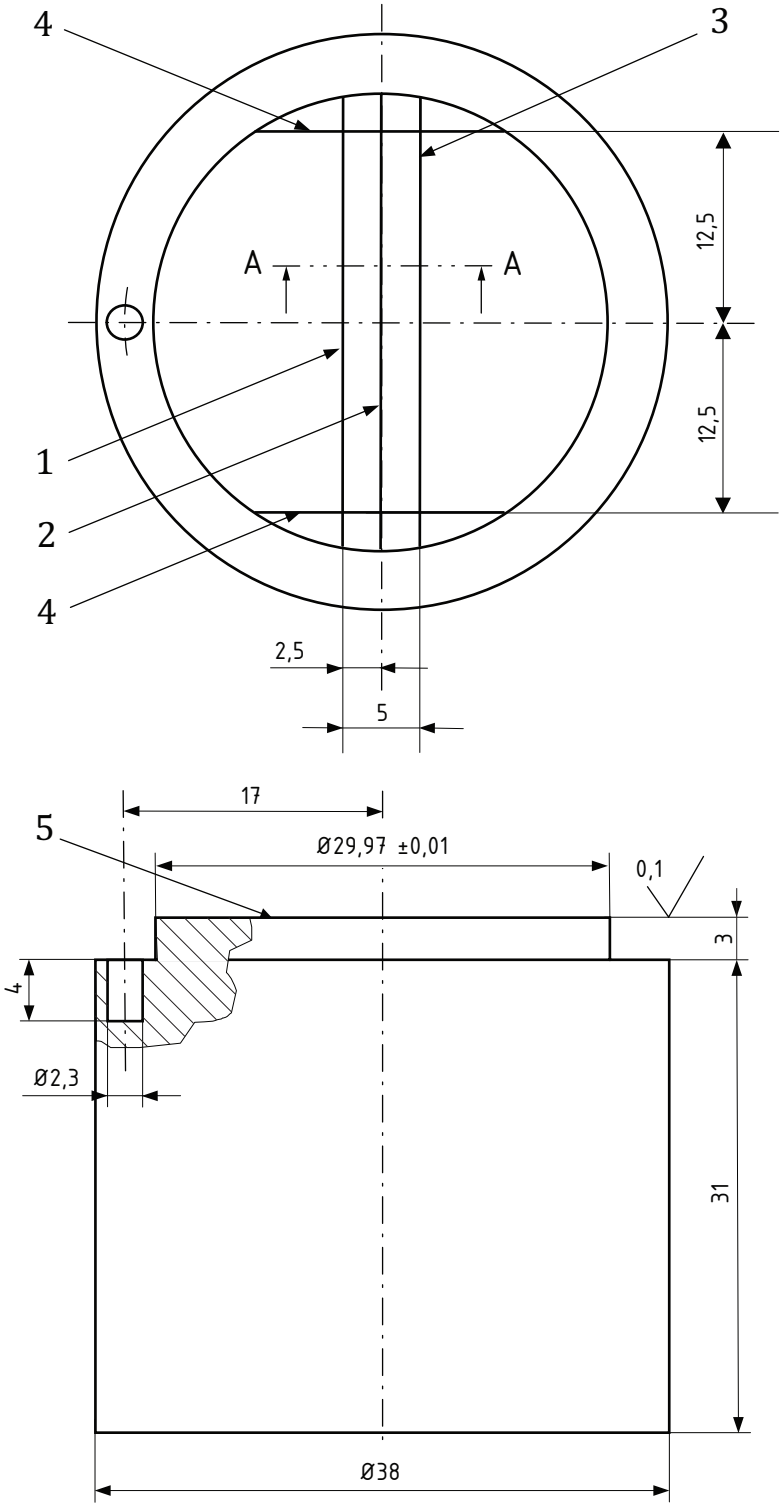
7.7.1 Apparatus

7.7.1.1 Test block, grooved as shown in Figures 6 and 7. Made in hardened stainless steel (400 VHN). The surface roughness of the grooved surface and the sides of the grooves is N3 (Ra = 0,1 µm) and for all other surfaces it is N5 (Ra = 0,4 µm) according to ISO 1302. The maximum radius of each of the grooves shall be 5 µm.

7.7.1.2 Ring mould, as shown in Figure 8. The surface roughness is N5 (Ra = 0,4 µm) according to ISO 1302.

7.7.1.3 Slit mould, as shown in Figure 9. The surface roughness is N5 (Ra = 0,4 µm) according to ISO 1302.

Dimensions in millimetres

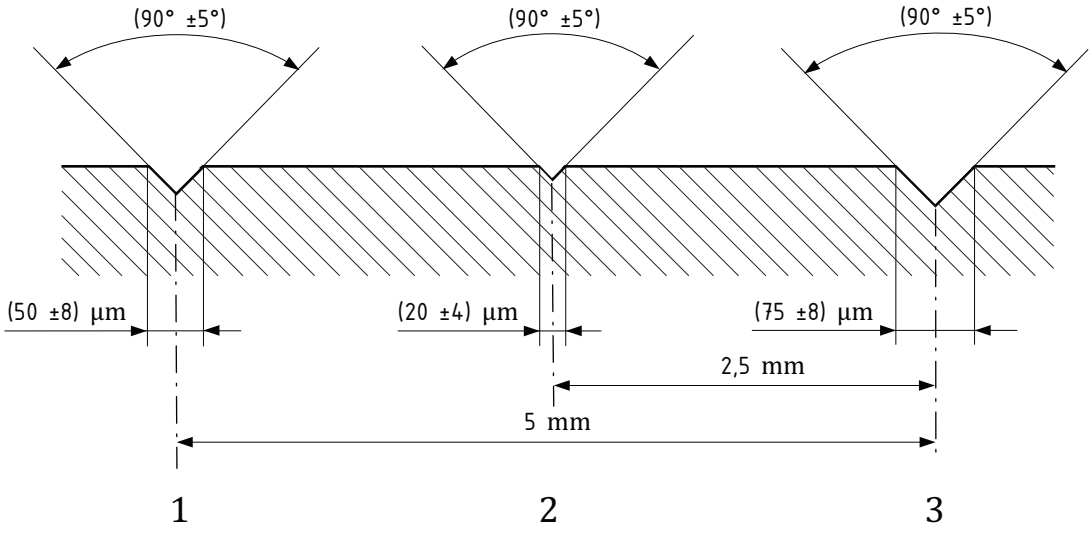


Key

1	groove a	4	groove d
2	groove b	5	grooved surface
3	groove c	A-A	section shown in Figure 7

Groove d has the same width as groove c. Tolerances are ± 0,1 mm unless otherwise specified

Figure 6 — Apparatus for reproduction of detail. Grooved test block



Key

1 groove a

2 groove b

3 groove c

Tolerances are ± 0,1 mm unless otherwise specified

Figure 7 — Apparatus for reproduction of detail. Section through A-A on the grooved surface of the test block

7.7.1.4 Dental silicone duplicating material and instructions for its use.

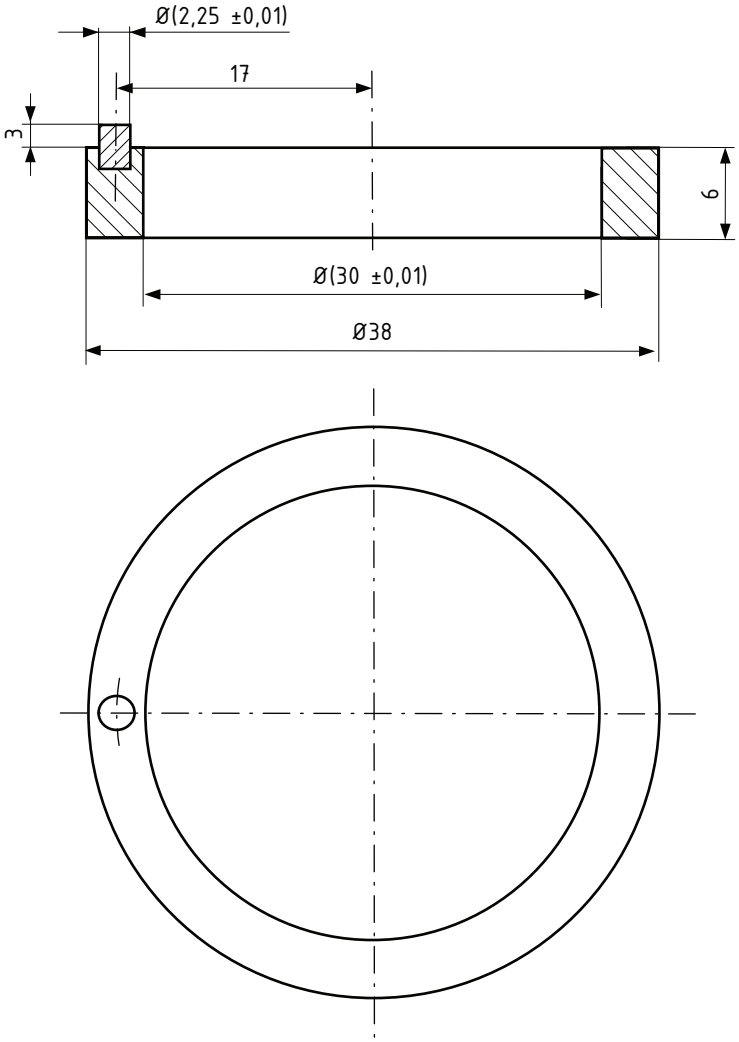
7.7.1.5 Flat and smooth metal or glass plate, sufficiently large to cover the ring mould described in 7.7.1.2.

7.7.1.6 Suitable means of applying a (1500 ± 5) g load.

7.7.1.7 Binocular reflection microscope, with a magnification of 4 × to 6 × and a light source capable of providing low-angle illumination.

7.7.1.8 Talcum powder (talc, magnesium silicate hydrate powder), as required.

Dimensions in millimetres



Tolerances are ± 0,1 mm unless otherwise specified.

Figure 8 — Apparatus for detail reproduction — Ring mould

Dimensions in millimetres

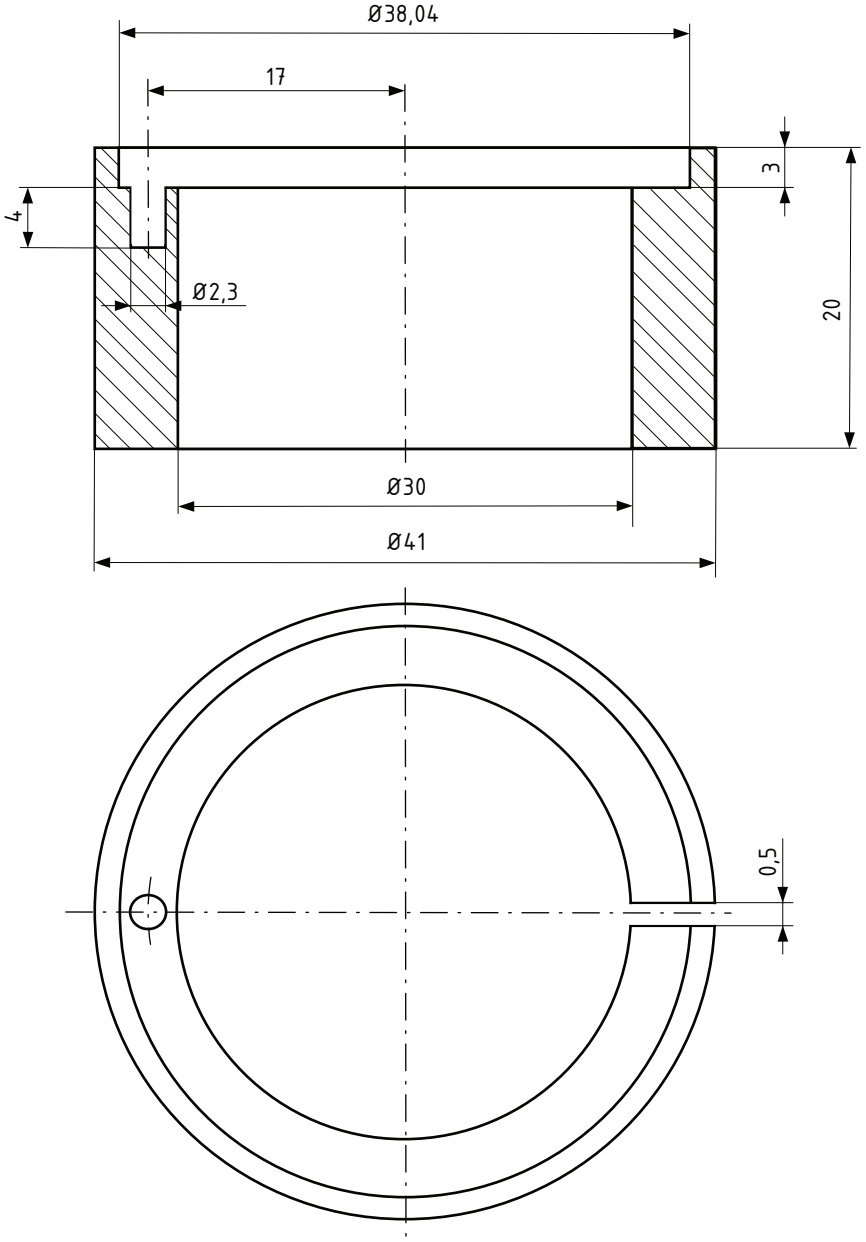


Figure 9 — Apparatus for detail reproduction — Slit mould

7.7.2 Procedure

7.7.2.1 Preparation of an impression of the grooved block

The ring mould may be coated with mould-release agent.

Clean the grooved surface of the test block with a solvent before use, but do not lubricate. If the duplicating material adheres to the block, lightly dust the block with talcum powder as an aid to separation. Blow away excess powder.

Place the ring mould upon the test block. Mix the duplicating material according to the instructions for its use and slightly overfill the ring mould. Immediately cover the mould with the flat plate and apply the load of 1500 g for (5 ± 1) s. Remove the load and allow the duplicating material to set. Remove the plate and separate the mould and test block in such a way as to minimize distortion.

View the impression of the test block using the microscope. Make sure that the groove being evaluated has been clearly reproduced as a line for its full length between the two orthogonal lines (produced from groove d). If the groove has not been clearly reproduced as a line, repeat the preparation of the impression with any necessary changes in technique until a satisfactory impression is obtained.

7.7.2.2 Preparation of the gypsum cast

Take the ring mould which retains the impression and fit the slit mould to it.

After the time given in the instructions (by the manufacturer of the duplicating material) for pouring the gypsum model or die material into an impression, add (200 ± 1) g of the dental gypsum product being tested to the recommended quantity of water (ISO 3696, Grade 3), dispensed to an accuracy of 0,5 ml, in a mixing bowl and mix as described in 6.3. Pour the mixed gypsum product against the impression with gentle vibration so as to completely fill the mould. Store the set cast in air at (23 ± 2) °C and (50 ± 10) % relative humidity for (60 ± 1) min.

Separate the gypsum cast from the duplicating material and examine the grooved surface under low-angle illumination using the microscope. Record the condition of the relevant groove.

7.7.3 Evaluation

If the relevant groove is complete, then the product meets this requirement for the reproduction of detail. If the relevant groove is not complete, then repeat this test two more times. If both repeated tests give complete relevant grooves, then the product meets this requirement for reproduction of detail. If either of these specimens gives an incomplete relevant groove, then the product does not meet the requirements for reproduction of detail.

8 Packaging, marking and information to be supplied by the manufacturer

8.1 Packaging

The material shall be packed in protective, moisture-proof containers that will neither contaminate nor alter the physical properties of the material.

8.2 Labelling

8.2.1 External container

Each outer package of the material shall be clearly marked with the following information in a font size that is easily read:

a) trade or brand name of the product;

b) the expiry date expressed in accordance with ISO 8601;

c) manufacturer or authorized representative's name and address;

d) the lot number;

e) material Type and (if applicable) Class according to Clause 4 and its application;

f) net mass of the contents, in kilograms;

g) recommended water/powder ratio, expressed as millilitres of liquid to grams of powder;

h) setting time;

i) setting expansion;

j) colour;

k) flavour, if any;

l) recommended storage conditions;

m) a statement that gypsum products are subject to deterioration when exposed to the atmosphere, particularly if the humidity is high.

Graphic symbols that are used shall be in accordance with ISO 15223-1.

8.2.2 Individual packets

When an external container contains packets that are intended to be individual units of use, each packet shall be marked with at least the following information:

a) the brand or trade name of the product;

b) the expiry date expressed in accordance with ISO 8601;

c) manufacturer or authorized representative's name and address;

d) the lot number;

e) material Type and (if applicable) Class according to Clause 4 and its application;

f) net mass of the contents, in grams;

g) required amount of liquid, in millilitres;

h) setting time;

i) setting expansion.

8.3 Instructions for use

Instructions for manipulation and use shall accompany each external package and shall include the following information:

a) recommended water/powder ratio, expressed as millilitres of liquid to grams of powder;

b) recommended mixing technique, including the recommended equipment, equipment settings where appropriate and the times allowed for adding the powder to the water, soaking the powder and spatulating the mix by hand and/or mechanical spatulation;

c) any special working methods or treatment recommended by the manufacturer.

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