INTERNATIONAL STANDARD

ISO 4823

Third edition
2000-12-15

Dentistry — Elastomeric impression materials

Art dentaire — Produits pour empreintes, à base d'élastomères

Reference number
ISO 4823:2000(E)

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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 3.

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.

Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 4823 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthodontic materials*.

This third edition cancels and replaces the second edition (ISO 4823:1992), which has been revised to reflect the following technical differences:

— the 60 s limit on **Mixing time** (5.4, second edition) has been eliminated;

— the **Consistency test** requirement for **Type 1** and **Type 2** impression materials has been relaxed (see Table 1, both editions);

— a more realistic approach for making pass/fail determinations (8.4);

— apparatus and procedures specified for the **Working-time test** (9.3) and the **Elastic recovery tests** (9.7) provide for more objective test results than those specified in 7.4 and 7.6 of the second edition;

— Figure 2 illustrates how the instrument depicted in Figure 4 of the second edition can be modified to make it suitable for use in the **Consistency test** as well as for the **Strain-in-compression test**;

— Figure 15 illustrates how the **split mould** shown in Figure 5 of the second edition can be modified to provide for more uniformly shaped specimens.

Annex A of this International Standard is for information only.

Dentistry — Elastomeric impression materials

1 Scope

This International Standard specifies requirements and tests for evaluating elastomeric dental impression materials.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 1942, *Dental vocabulary.*

ISO 6873, *Dental gypsum products.*

3 Terms and definitions

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

3.1
consistency
degree of firmness with which particles of a material, prepared for use, cohere so as to allow the material to flow, or resist flow, as required to achieve the purpose for which it is intended

3.2
elastic recovery test
compression set (deprecated)
permanent deformation (deprecated)
recovery from deformation (deprecated)
⟨elastic impression materials⟩ method of determining whether the materials possess the elastic properties required to recover adequately after deformation occurring when the materials, used for forming impressions, are removed from the mouth

3.3
extrusion mixing
method by which two or more material components are extruded from their separate immediate containers through a special mixing tip, from which the components emerge as a homogeneous mixture

3.4
hand mixing
method of mixing the components of a material by means of manual kneading or spatulation

3.5
immediate container
container which is in direct contact with a material or a component thereof

NOTE An immediate container may be an unlabelled container protected by a more durable labelled outer packaging component such as a can, carton or drum. If it is strong enough to protect its contents without outer packaging, an immediate container can also serve as a primary container on which labelling may be required.

3.6
mixing time
time, measured from first contact between different components of a material being mixed, required to achieve a homogeneous mixture when the components are mixed according to the manufacturer's instructions

NOTE The time of first contact between extrusion-mixed material components is defined as the time when the material components can be seen entering into the mixing nozzle.

3.7
outer package
wrapping or carton, which may be required by law or a standard to bear specified labelling, used to cover one or more immediate or primary containers in preparation for retail marketing

3.8
primary container
retail marketing packaging component, such as a bottle, carton, drum, jar, tube, etc., which may be required by law or a standard to bear specified labelling

NOTE A primary container may also be an immediate container.

3.9
strain-in-compression test
⟨elastic impression materials⟩ method of measuring the flexibility/stiffness property ranges of materials so as to determine whether the set materials, when formed as impressions, 1) can be removed from the mouth without injury to impressed oral tissues, and 2) will have adequate stiffness, in the more flexible portions of impressions, to resist deformation when model-forming products are poured against them

3.10
working time
period of time, beginning with the commencement of mixing and ending before the material being mixed has begun to exhibit elastic properties that will prevent the material from being manipulated as required to form an impression or a mould having the desired surface detail and dimensional characteristics

4 Classification

Materials covered by this International Standard are classified according to consistencies determined immediately after completion of mixing according to the manufacturer's instructions (10.3):

— Type 0: putty consistency

— Type 1: heavy-bodied consistency

— Type 2: medium-bodied consistency

— Type 3: light-bodied consistency

5 Biocompatibility advisory

Specific qualitative and quantitative requirements for freedom from biological hazards are not included in this International Standard. It is recommended that, in assessing possible biological or toxicological hazards, reference be made to ISO 7405 and ISO 10993-1 (see Bibliography).

6 Requirements for characteristics and properties

6.1 Component colours

Different components intended for use in the same mixture shall be supplied in contrasting colours to provide a means of determining when the components have been thoroughly mixed.

6.2 **Mixing time** (hand-spatulated or hand-kneaded mixes)

When the impression material components are combined according to the manufacturer's instructions given in 10.3 e) and the results of the mixing are evaluated according to 9.1, the average time required to achieve a homogeneous mixture (essentially streak free) shall not exceed the time stated by the manufacturer in 10.3 e).

6.3 Working time

When tested according to 9.3, the working time shall not be less than that stated in the manufacturer's instructions given in 10.3 f), and shall be at least 30 s longer than the time required to obtain a homogeneous mix (see 6.2 and 9.1).

6.4 Compatibility with gypsum

The impression material shall impart a smooth surface to, and separate cleanly from, the gypsum model material poured against it (see Table 1).

Table 1 — Additional characteristic and physical property requirements

Type	Test subclause No. and description							
	9.2		9.4	9.5	9.6	9.7	9.8	
	Consistency (Test disc diameter) mm		Detail reproduction (Line width reproduced) [a]	Linear dimensional change %	Compatibility with gypsum (Line width reproduced) [a]	Elastic recovery %	Strain-in-compression %	
	min.	max.	µm	max.	µm	min.	min.	max.
0	—	35	75	1,5	75	96,5	0,8	20
1	—	35	50	1,5	50	96,5	0,8	20
2	31	41	20	1,5	50	96,5	2,0	20
3	36	—	20	1,5	50	96,5	2,0	20

[a] The line reproduction shall be considered satisfactory if the required line a, b, or c is continuous between the lines d_1 and d_2. See test block in Figure 12.

NOTE Requirements for information to be included in the manufacturer's instructions for use, packaging and labelling are listed in clauses 10 and 11.

7 Sampling

Samples of materials to be tested shall be procured from a single manufacturing batch as packaged for retail marketing.

NOTE A volume of about 900 ml of the mixed material will usually be enough for conducting all the tests and for the considerable practice which may be necessary for the test operator to become proficient in specimen preparation and testing.

CAUTION — Before opening any packaging component, examine the labelling for compliance with 11.2 and for any precautions that should be observed in use and storage of the material. Before opening any immediate container examine the instructions for compliance with clause 10.

8 Test methods — General

8.1 Laboratory conditions

Unless otherwise specified in this International Standard, conduct all specimen preparation and testing under ambient laboratory conditions of (23 ± 2) °C and (50 ± 10) % relative humidity, and bring all equipment and materials used in the tests to the ambient temperature before use in specimen preparation and testing.

8.2 Apparatus function verification

Examine all accessories, instruments, and equipment before they are used to determine whether they are in acceptable working order. Perform whatever calibration steps are necessary to ensure that the items comply with specifications stated for them in this International Standard or in any normative document quoted therein.

8.3 Material manipulation and specimen preparation

Unless otherwise specified:

— use the equipment and procedures recommended in the manufacturer's instructions when preparing and manipulating the materials used for forming the test specimens. For materials requiring hand mixing, use only mass/mass proportioning of ingredients [10.3 c)];

— when the instructions specify manual kneading as a means of combining putty material components, cover the hands with gloves or polymer sheeting [10.3 d)] which will not react with the material to alter its behaviour;

— mix a volume of at least 15 ml for each specimen (the approximate amount required for a medium-sized complete arch impression);

— time the schedules for specimen preparation and testing using an instrument such as a stop-watch accurate to 1 s over a 30 s period.

8.4 Pass/fail determinations

The minimum number of specimens required for pass/fail determinations shall be either three or five, as indicated beside the related specimen preparation or test procedure headings. Unless otherwise specified, the following rules apply:

— for a three-specimen minimum, make a series of three specimens initially. If at least two of the three specimens comply with the related requirement, the material passes. If none complies, the material fails. If only one specimen complies, make three additional specimens. If all three of the additional specimens comply, the material passes; otherwise the material fails;

— for a five-specimen minimum, make and test a series of five specimens initially. If at least four of the five specimens comply with the related requirement, the material passes. If only one or two specimens comply, the material fails. If only three specimens comply, make a series of five additional specimens. If all five of the second series of specimens comply, the material passes; otherwise the material fails.

8.5 Expression of test results

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

9 Test methods — Specific

9.1 Mixing-time test

9.1.1 Apparatus

9.1.1.1 Recommended mixing apparatus [10.3 d)]

9.1.1.2 Timing device (8.3)

9.1.2 Specimen preparation and test procedure (five specimens)

Proportion and mix the required volume of material (8.3) for each specimen. Record the time required to obtain a homogeneous mixture for each specimen. Calculate the mean of the results for the five specimens.

NOTE Mixes made for this test may be used to provide increments of material needed for the consistency test (9.2)

9.1.3 Pass/fail determination and expression of results

Determine whether the mean result obtained in accordance with 9.1.2 complies with 6.2 and report the results.

9.2 Consistency test

9.2.1 Apparatus and materials

9.2.1.1 Two glass plates, one to serve as a base plate, and one to serve as a loading plate (Figure 2).

Dimensions for the loading plate shall be approximately 60 mm by 60 mm and at least 3 mm thick. Dimensions of the base plate may be greater.

9.2.1.2 Material delivery system, such as the one illustrated in Figure 1, for delivering a volume of $(0,5 \pm 0,02)$ ml of the material onto the base plate.

9.2.1.3 Polyethylene sheets, wrinkle-free, approximately 60 mm by 60 mm and 0,035 mm thick (one per specimen).

9.2.1.4 Polyethylene sheet discs, approximately 10 mm in diameter and 0,035 mm thick (two per specimen).

9.2.1.5 Elastomeric plug, for forming the floor of the test increment-containing cavity.

9.2.1.6 Test instrument for applying a force of $(14,7 \pm 0,1)$ N (Figure 2).

The mass of the glass loading plate shall be included as part of the test load.

NOTE The dial indicator illustrated as a part of the test instrument in Figure 2 plays no part in the consistency test.

9.2.1.7 Linear measuring instrument, accurate to 0,5 mm, for measuring diameters of the test specimen disc (9.2.3).

9.2.1.8 Timing device (8.3).

9.2.2 Advance preparation steps

Accomplish the following steps before beginning any of the test procedures:

— adjust the test instrument (9.2.1.6.) so that the contact surface of the loading shaft foot can descend within 5 mm of the top surface of the instrument base;

— cover the top surface of the base plate (9.2.1.1) with a polyethylene sheet (9.2.1.3). A thin film of silicon grease applied to the bottom of the loading plate will secure the polyethylene sheet covering in place, as required for the test;

— use the depth-gauge end of the plunger (Figure 1) to push the elastomeric plug (9.2.1.5) into the tapered end of the dispensing tube to the depth allowed by the stop;

— use the depth-gauge end of the plunger to seat two of the polyethylene sheet discs (9.2.1.4) to cover the cavity floor formed by the plug.

9.2.3 Specimen preparation and test procedure (3 specimens)

Accomplish the following steps within 25 s after the completion of mixing:

— slightly overfill the cavity in the dispensing tube (Figure 1) with the mixed material and strike off the excess to form the test increment;

— push the increment-extruding end of the plunger against the elastomeric plug to expel the test increment, along with one, or both, of the polyethylene discs, onto the centre of the base plate. Do not attempt to separate the discs from the test increment;

— centre the increment on the base of the test instrument (9.2.1.6) directly under the elevated loading-shaft foot;

— place and hold the glass loading plate centred and in contact with the shaft foot;

— allow the 14,7 N load to descend slowly onto the increment.

To obtain a more uniformly circular specimen disc, keep the glass plates as parallel as possible during loading and keep rotation of the plates to a minimum.

Allow the total load to rest on the specimen-forming assembly for 5 s. Lift the foot of the loading shaft from contact with the loading plate and allow the assembly to remain at room temperature for at least 15 min. Then separate the loading plate from the assembly so as to leave the specimen on the base plate. Use the measuring instrument (9.2.1.7) to make two diametral measurements of the specimen, one across the major diameter of the disc and one across the minor diameter. Report the average of the two measurements as the diameter to be considered when determining whether the specimen complies with the diameter requirement specified in Table 1.

9.2.4 Pass/fail determination and expression of results

See 8.4 and 8.5.

9.3 Working-time test

9.3.1 Apparatus and materials

9.3.1.1 Working-time test instrument, including the parts illustrated in Figure 3 through to Figure 10, as well as the three electronic components listed immediately below.

9.3.1.2 Linear variable displacement transducer (LVDT), having a linear working range > 12,5 mm. The transducer shall be passive, i.e. not spring-loaded.

9.3.1.3 DC power supply, (+ 15 V and – 15 V regulated), for modulating the LVDT signals.

9.3.1.4 Chart recorder, compatible with the LVDT and associated equipment.

9.3.1.5 Mixing apparatus [10.3 d)].

9.3.1.6 Timing device (8.3).

9.3.2 Pretest instrumentation function verification and assembly

9.3.2.1 Check for friction

Before using the test instrument (9.3.1.1), use the following procedure to determine whether the friction between the bearing areas of glide track (Figure 5) and the sliding polymer blocks (Figure 7) is within acceptable limits (see also Figure 3):

— do not use lubricants in attempts to reduce friction;

— detach the LVDT core carrier rod (Figure 3) from the polymer block 4_L;

— clean and dry the bearing surfaces of the sliding blocks and glide track and examine them for defects that can be detected by touch (burrs, nicks, etc.). Eliminate any such defects;

— seat the sliding blocks in the glide track, and use the perforated test plate (Figure 8) and the plate aligning and locking pins, Parts 5_L and 5_R (Figure 3 and Figure 9) to relate the parts as for testing;

— elevate one end of the instrument so that the base is at an approximate 20° angle to horizontal;

— move by hand the sliding block/perforated test plate assembly in the glide track to the upper extreme position and release it immediately.

If the assembly moves freely to the lower extreme position under the pull of gravity, the friction is within acceptable limits.

Repeat the steps described above, with the opposite end of the instrument elevated, to determine whether freedom of movement in the opposite direction is also acceptable.

If the friction cannot be reduced to acceptable limits by removal of burrs, contaminates, etc., it may be necessary to resurface the bearing areas to eliminate binding interferences that may be contributing to the friction.

Upon achieving acceptable limits for friction, remove the test plate, reattach the core carrier rod to the sliding block 4_L in Figure 3 and proceed with assembly of the instrumentation.

9.3.2.2 Instrumentation assembly

Connect the LVDT (9.3.1.2) to the recorder (9.3.1.4) through the power supply (9.3.1.3). Then adjust the LVDT body position as required to establish a body/core relationship whereby a full-scale deflection of the recorder pen indicates a rheometer displacement of 3,5 mm. Confirm that the recorder pen reflects a linear function of the rheometer displacement.

9.3.3 **Test procedure** (five specimens)

When combining hand-mixed materials, start the timing device (9.3.1.6) at the commencement of mixing. For the extrusion mixed materials, delay starting the timing device until the material components can be seen entering into the mixing nozzle. After completion of mixing, accomplish the following steps within 55 s:

— deposit an increment of about 2 ml of the material centred on the slotted surface of the test specimen pedestal (Figure 3 and Figure 6);

— force the perforated test plate into the centre of the impression material increment until the undersides of both ends of the plate contact the upper surfaces of the sliding polymer blocks, 4_L and 4_R, and so that the mixed material extrudes through at least 28 of the perforations;

— align the locking pin holes in the perforated plate with the pin holes in the sliding blocks and insert the locking pins, 5_L and 5_R (Figure 3), to secure the parts in the relationship for testing;

— zero the chart recorder pen before activating the recorder chart drive as required to begin the test schedule described below.

For materials having a stated working time of 3 min or less [10.3 f)], begin testing at 60 s to 90 s after commencement of mixing. For materials having a greater stated working time, begin testing 2 min before the end of the stated working time. Apply finger pressure or another controlled force against the sliding block, 4_R, so as to displace the sliding block/perforated plate assembly 0,25 mm, as reflected by the chart recorder tracing. Remove the force immediately after completing this displacement and observe behaviour of the recorder pen.

Repeat the displacement procedure at 15 s intervals until the chart recorder pen tracing (Figure 11) first indicates that the specimen has begun to exhibit elastic properties that can adversely affect impression quality.

The chart recorder reading, at 15 s before the first recorded indication that the specimen has begun to exhibit elastic properties, shall be reported as the end of the effective working time.

9.3.4 Pass/fail determination and expression of results

See 8.4 and 8.5.

9.4 Detail reproduction test

9.4.1 Apparatus and materials

9.4.1.1 **Test block** (Figure 12) and **ring mould accessory** (Figure 13). Clean the test block ultrasonically before each use.

9.4.1.2 **Oven**, set at (35 ± 1) °C, for dry heat conditioning of the test block prior to use.

9.4.1.3 **Flat glass or metal plate**, approximately 50 mm by 50 mm and at least 3 mm thick.

9.4.1.4 **Polyethylene sheets**, approximately 50 mm by 50 mm and 0,035 mm thick (one per specimen).

9.4.1.5 **Water bath**, for maintaining a temperature of (35 ± 1) °C in simulation of a mouth temperature environment.

9.4.1.6 **Microscope**, equipped for ×4 to ×12 magnification and low angle illumination.

9.4.1.7 **Timing device** (8.3).

9.4.2 Specimen preparation (three specimens)

Before mixing the material for each of the three specimens, place the test block and ring mould (9.4.1.1), in the oven (9.4.1.2) for conditioning for at least 15 min.

Cover the underside of the glass or metal plate (9.4.1.3) with a polyethylene sheet (9.4.1.4).

NOTE 1 A thin film of silicone grease spread over the plate will help secure the polyethylene sheet to the plate during specimen formation.

Accomplish the following steps within 60 s after completion of mixing:

— remove the test block and ring mould from the oven;

— seat the ring mould on the test block to form the specimen forming cavity;

— introduce an increment of the mixed material (enough to slightly overfill the cavity) along one side of the cavity such that it can be directed to first enter the scribed lines a, b, and c on one side of the test block, and then be gradually forced, via application of pressure applied by the glass or metal plate, to flow into the lines to their opposite ends;

— press the polyethylene-covered plate down against the top of the ring mould so as to expel the excess material;

— at 60 s after completion of the mix, place this specimen-forming assembly in the water bath (9.4.1.5) for the minimum time recommended by the manufacturer's instructions for leaving the impression in the mouth [10.3 g)].

After completion of the water bath treatment, separate the impression material specimen in the ring mould from the specimen forming assembly and flush the specimen surface with distilled or deionized water. Then use a gentle stream of clean air to blow away moisture. The lines on the specimens will be positive copies (raised lines) of the lines scribed in the test block surface.

NOTE 2 For elastomeric impression materials which may adhere to the test block, the lined surface may be treated with an anti-adherent substance, providing the anti-adherent does not react with the test specimen or test block to cause some other undesirable test result.

9.4.3 Test procedure

Immediately after blowing moisture from the specimen, use the microscope (9.4.1.6) to examine the specimen for compliance with the related requirement shown in Table 1.

NOTE Differences in colours of the materials may make it necessary to use different light intensities or different colour filters, or both, when viewing specimens, to determine whether the required lines have been reproduced in surfaces of the impression material specimens and in gypsum specimens made for the compatibility with gypsum test.

Specimens found to be in compliance with the related requirements for this test can be used for the linear dimensional change test (9.5).

9.4.4 Pass/fail determination and expression of results

See 8.4 and 8.5.

9.5 Linear dimensional change test

9.5.1 Apparatus and materials

9.5.1.1 Detail reproduction test specimens, made according to 9.4.2, examined according to 9.4.3, and found to be in compliance with the related requirement specified in Table 1.

9.5.1.2 Glass plate approximately 50 mm by 50 mm, and at least 3 mm thick (one for each specimen).

9.5.1.3 Talcum powder.

9.5.1.4 Measuring microscope, accurate to 0,01 mm, equipped for ×4 to ×12 magnification, low angle illumination, and a measuring travel of at least 27 mm.

9.5.2 Test block line-length measurement procedure

9.5.2.1 Test block preparation and positioning

Prepare and position the test block as follows:

— clean the test block ultrasonically before beginning the procedure;

— position the test block on the microscope stage (9.5.1.4) with line d_1 to the right and with line c appearing as the lower line as shown in Figure 14 a);

— relate the X axis of the microscope cross hair parallel to, and approximately 0,03 mm below line c as shown in Figure 14 c). This will place the Y axis of the cross hair parallel to lines d_1 and d_2;

— move the microscope slide or stage to bring the Y axis of the cross hair at least 0,1 mm outside and to the right of line d_1 on the test block.

9.5.2.2 Test block line-length measurement steps

Proceed with the steps listed below taking into account that, after positioning the test block according to the last step in 9.5.2.1, the direction of travel of the microscope slide or stage should not be reversed at any point during subsequent travels until after the final measurements between lines d_1 and d_2 have been recorded:

— move the left edge of the Y axis of the cross hair into alignment with the inner edge of line d_1, stop the travel motion, and record the reading for this position as the initial measurement [Figure 14 c)];

— move the left edge of the Y axis of the cross hair into alignment with the inner edge of line d_2, stop the travel motion, and record the reading for this position as the final measurement;

— calculate and record the difference between the initial and final readings. Make two additional measurements for the distance between lines d_1 and d_2. Average the three values and record the result as L_1.

9.5.3 Specimen preparation (three specimens)

Dust the underside of each detail reproduction test specimen (9.5.1.1) and the top surface of the glass plate (9.5.1.2) with talcum powder (9.5.1.3). Then seat the dusted specimen to rest on the dusted plate and store this assembly in the laboratory environment until the time specified for its measurement in accordance with 9.5.4.1.

9.5.4 Test specimen measurement

9.5.4.1 Time for specimen measurement

The time at which the specimens are to be measured shall be related as follows to the permissible time lapse, recommended in the manufacturer's instructions [10.3 h)], between removal of the impression from the mouth and pouring of the gypsum product:

— when a manufacturer's instructions state that pouring of the impressions can be delayed for 24 h or more, the specimens shall be measured at 24 h after separation from the forming assembly;

— when the manufacturer states a maximum permissible time delay of less than 24 h before pouring the impressions, the specimens shall be measured at the end of the maximum permissible time delay stated.

9.5.4.2 Specimen measuring procedures

Follow the procedure described in 9.5.2.2 for measuring the distance between lines d_1 and d_2, along line c, on the specimen, with the following exception: place the specimen on the microscope stage with line d_2 positioned to the right for the initial measurement, as illustrated in Figure 14 b), thus ensuring that line c will appear as the lower line. Record this measurement as L_2.

9.5.4.3 Calculation of results

Calculate the percentage of dimensional change, ΔL, for each specimen to the nearest 0,05 %, using the equation

$$\Delta L = 100\left(\frac{L_1 - L_2}{L_1}\right)$$

where

L_1 is the distance measured between lines d_1 and d_2 on the test block (9.5.2.2); and

L_2 is the distance measured between lines d_2 and d_1 on the impression material specimen (9.5.4.2).

Report whether the percentage of change for each specimen complies with the pertinent requirement specified in Table 1.

9.5.4.4 Pass/fail determination and expression of results

See 8.4 and 8.5.

9.6 Test for compatibility with gypsum

9.6.1 Apparatus and materials

9.6.1.1 Detail reproduction test specimens, made according to 9.4.2, examined according to 9.4.3, and which have been found to be in compliance with the related detail reproduction requirement shown in Table 1.

9.6.1.2 Ring mould (9.4.1.1).

9.6.1.3 Riser (Figure 13).

9.6.1.4 Slit mould (Figure 13) with a mechanism such as a worm gear clamp for closing the slit.

Use of the slit mould requires that the mould be clamped such that the slit will be closed during formation of the gypsum specimen. Later, the clamping force is released to allow the slit to open for easy removal of the specimen. The brass alloy used for this mould should have a strain-at-elastic-limit sufficiently high to permit the mould to be closed and opened repeatedly without significant permanent reduction in width of the slit.

9.6.1.5 Flat glass or metal plate, approximately 50 mm by 50 mm and at least 3 mm thick.

9.6.1.6 Two dental gypsum products [see 10.3 i) and ISO 6873]:

— one Type 3, dental stone, model and,

— either one Type 4 or one Type 5, dental stone, high strength.

Well before their anticipated use in the test, the gypsum products shall be evaluated for compliance with the setting time (initial setting time) requirement specified in ISO 6873. Products which do not comply with the requirement shall not be used for this test. After the initial opening of their containers, and between openings thereafter, the gypsum products shall be stored in sealed containers so as to protect them from moisture contamination.

9.6.1.7 Mould release agent, such as silicone grease, which will be non-reactive with the slit mould (9.6.1.4) and the gypsum products.

9.6.1.8 Microscope (9.4.1.6).

9.6.1.9 Timing device (8.3).

9.6.2 Specimen preparation

Prepare three specimens for each of the two dental gypsum products required for use in the test.

9.6.2.1 Advance preparation

Accomplish the following steps before carrying out the test for compatibility with gypsum:

— treat the inner surface of the slit mould (9.6.1.4), including the slit surfaces, with a thin film of the mould release agent (9.6.1.7) and use the clamping mechanism to close the slit;

— position the specimen (9.6.1.1) in the ring mould (9.6.1.2) and press the riser (9.6.1.3) against the underside of the specimen so as to push the lined surface of the specimen to a position level with the top flat surface of the ring mould. Seat this assembly, with the riser in place, and the lined surface down, into the recess of the slit mould. Cover this part of the assembly with the plate (9.6.1.5) and then invert the entire assembly.

9.6.2.2 Specimen formation

At the earliest time specified for pouring impressions after their removal from the mouth [10.3 h)], introduce the first increments of a gypsum mixture, via mechanical vibration, so that they flow down along an internal surface of the mould cavity to first cover the ends of the raised lines, a, b, and c, on one side of the specimen surface and to then be directed to flow gradually over the lines to their opposite ends. Then add enough of the gypsum mixture to slightly underfill the mould cavity.

Unless otherwise specified in manufacturer's instructions for the gypsum or impression material, store the gypsum/impression material assembly in the laboratory environment until 45 min after the initial setting time previously determined for the gypsum product in accordance with 9.6.1.6. Then separate the gypsum specimen from the assembly.

9.6.3 Test procedure

Use the microscope (9.6.1.8) to examine the lined surfaces of the gypsum specimen for compliance with the requirements specified in 6.4, and in Table 1 (see also the note in 9.4.3).

9.6.4 Pass/fail determination and expression of results

See 8.4 and 8.5.

9.7 Elastic recovery test

9.7.1 Apparatus and materials

9.7.1.1 Fixation ring with **split mould** (Figure 15).

9.7.1.2 Mould release agent, such as silicone grease.

9.7.1.3 Two flat glass or metal plates, approximately 50 mm by 50 mm and at least 3 mm thick.

9.7.1.4 Polyethylene sheets (wrinkle free), approximately 50 mm by 50 mm and 0,035 mm thick.

9.7.1.5 **C-clamp**, having a minimum screw opening of 40 mm and a minimum throat depth of 30 mm.

9.7.1.6 **Water bath** (see 9.4.1.5).

9.7.1.7 **Timing device** (see 8.3).

9.7.1.8 **Small glass or metal test plate**, approximately 15 mm by 15 mm and 2 mm thick.

9.7.1.9 **Test instrument**, such as the one shown in Figure 16. The dial indicator shall be accurate to 0,01 mm and shall have a capacity for contributing, along with the weight of the test plate (9.7.1.8), to the application of a total force of $(0{,}59 \pm 0{,}1)$ N. Set the stop on the test instrument to limit compression of the test specimen to $(6 \pm 0{,}1)$ mm.

9.7.2 Specimen preparation

9.7.2.1 Advance preparation

Five specimens shall be prepared. Before preparing the specimens, carry out the following steps:

— apply a very thin film of the mould release agent (9.7.1.2) to the internal surface of the fixation ring and to all surfaces of the split mould (9.7.1.1);

— cover one surface of each of the plates (9.7.1.3) with a polyethylene sheet (9.7.1.4);

— seat the fixation ring on one of the polyethylene-covered plates.

9.7.2.2 Specimen formation

Carry out the following steps within 60 s after completing the mixing:

— fill the fixation ring slightly more than half full;

— press the split mould halves down through the impression material in the fixation ring until their bottom surfaces are in near contact with the polyethylene-covered base plate so as to force the impression material above the top of the split mould halves;

— press the second polyethylene-covered plate onto the material so as to expel almost all the excess and then use the C-clamp (9.7.1.5) to force the plates into contact with the top and bottom surfaces of the split mould;

NOTE If glass plates (9.7.1.3) are used instead of metal plates, metal back-up plates may be used between the glass plates and the C-clamp parts to minimize scratching and breakage of the glass plates.

At 60 s after completion of mixing, place this specimen-forming assembly in the water bath (9.7.1.6) for the time specified in the manufacturer's instructions for leaving impressions in the mouth [10.3 g)].

Within 40 s after completion of the water bath storage, separate the specimen from the split mould, place the glass or metal test plate (9.7.1.8) to rest on the top surface of the specimen, and then seat this assembly on the test instrument base (9.7.1.9) centred in axial alignment with the dial indicator spindle.

9.7.3 Test procedure

Conduct the test in accordance with the following time schedule, where t is the time the specimen is removed from the water bath:

— t + 45 s: gently lower the dial indicator spindle contact point to rest on the test plate on top of the specimen;

— t + 55 s: read the dial indicator and record the reading as h_1;

— t + 60 s: deform the specimen (6 ± 0,1) mm, as limited by the stop on the test instrument, within 1 s, release the deforming force slowly over a period of 5 s, and then lift and hold the contact point from contact with the test plate remaining at rest on the specimen;

— t + 170 s: gently return the contact point to rest on the test plate;

— t + 180 s: record this dial indicator reading as h_2.

NOTE Possibilities for lateral displacement of the specimen during application of the deforming force can be reduced by cementing an abrasive paper covering, about 600 grit (FEPA 1200), over the surfaces of the instrument base and the test plate that will be in contact with the top and bottom surfaces of the specimen during the test.

9.7.4 Calculation of results

Calculate the percentage of elastic recovery, K, for each specimen, using the equation:

$$K = 100 - \left[100 \left(\frac{h_1 - h_2}{h_0} \right) \right]$$

where

h_0 is the height of the split mould;

h_1 is the dial indicator reading at t + 55 s (immediately before the specimen is deformed); and

h_2 is the dial indicator reading at t + 180 s (115 s after the deforming force has been removed from the specimen).

Discard values for defective specimens. Defective specimens can be identified by sectioning each specimen axially into eight approximately equal-sized segments and examining each segment for defects such as air inclusions.

9.7.5 Pass/fail determination and expression of results

See 8.4 and 8.5.

9.8 Strain-in-compression test

9.8.1 Apparatus

Items listed in 9.7.1.1 through 9.7.1.7 are required for preparing the specimen, together with a test instrument, such as the one shown in Figure 2. The dial indicator shall be accurate to 0,01 mm.

9.8.2 Specimen preparation

Prepare five specimens according to the procedure described in 9.7.2, with the exception that the test plate (9.7.1.8) is not placed on the specimen.

9.8.3 Test procedure

Immediately after separation of the specimen from the forming assembly, position it on the base of the test instrument (9.8.1.2) centred below the foot of the loading shaft. Then conduct the test in accordance with the following time schedule, where t is the time the specimen is removed from the water bath:

— t + 60 s: lower the foot of the loading shaft into direct contact with the top of the specimen, thus applying an initial load of (1,22 ± 0,1) N exerted by the loading shaft/weight support assembly only;

— t + 90 s: lock the loading shaft in place, lower the dial indicator contact point to rest on the top of the loading shaft, and record the dial indicator reading as h_1;

— t + 95 s: remove the dial indicator contact point from contact with the loading shaft, unlock the loading shaft, and increase the load to a total force of (12,25 ± 0,1) N gradually over a period of 10 s;

— t + 135 s: lock the loading shaft in place, return the dial indicator contact point to rest on the loading shaft, and record the dial indicator reading as h_2.

9.8.4 Calculation of results

Calculate the percentage of strain-in-compression, E, for each specimen, using the equation:

$$E = 100\left(\frac{h_1 - h_2}{h_0}\right)$$

where

h_0 is the height of the split mould;

h_1 is the dial indicator reading, 30 s after application of the initial load; and

h_2 is the dial indicator reading, 30 s after complete application of the increased load.

Examine any failing specimens according to the procedure described in 9.7.4.

9.8.5 Pass/fail determination and expression of results

See 8.4 and 8.5.

10 Requirements for information in manufacturer's instructions

10.1 General

Each package, in which the components of an impression material are prepared for retail marketing, shall be accompanied by the instructions and other information needed to ensure optimum performance of the material in clinical practice.

10.2 Identifying information

The following identifying information is required:

a) trade- or brand-name of the product;

b) chemical nature of the elastomeric system: for example, polyether, polysulfide, silicone (condensation type), or silicone (vinyl polysiloxane, addition type).

10.3 Specific instructions for use

Where applicable, the specific instructions for use shall include the following:

a) recommended storage conditions after the initial opening of the immediate containers;

b) statements indicating that working time and other characteristics of the material may be affected significantly by the following factors as may be applicable:

   — room temperature variations;

   — variations in the speed and friction involved in mixing;

   — hand/fingertip temperatures when kneading putty mixes;

   — moisture contamination or relative humidity; and

   — contamination, either due to direct contact with latex dam or gloves used in clinical practice, or due to the presence of such contaminants on teeth at the time they are impressed;

c) proportions for hand-spatulated mixes (mass to mass and volume to volume);

d) recommended mixing apparatus and procedures, to include the generic identification of any hand coverings (gloves or polymer sheeting) that should be used to avoid contamination of the materials during hand manipulation;

e) mixing time required to obtain a homogeneous mixture of an amount of the material having a volume of 15 ml (see 8.3);

f) working time;

g) minimum time the impression should remain in the mouth before removal;

h) minimum or maximum time lapse, or both, permitted between removal of the impression from the mouth and pouring the gypsum product into the impression;

i) identification of at least two gypsum products, complying with requirements of ISO 6873, which the impression material manufacturer has found to be compatible with the impression material being tested: one Type 3 product (dental stone, model) and either one Type 4 product or one Type 5 product (dental stone, high strength);

j) when the manufacturer's instructions state that an impression made of a material may be disinfected, the disinfecting procedure shall be described in detail. A reference indicating that the disinfection procedure will not alter the potential of the impression for optimum performance shall also be identified;

k) when a manufacturer claims that a material in itself is antimicrobial, and will remain so without further treatment after the impression is removed from the mouth, the manufacturer shall identify the reference on which the claim is based.

11 Requirements for packaging and labelling

11.1 Packaging requirements

No packaging requirements are specified in this International Standard, but it is important for manufacturers to take into account that the packaging should be such that it will not contaminate or permit contamination of ingredients of the material components during recommended storage conditions. Structure of the immediate containers should also be such that no leakage or inadvertent extrusion of the contents can occur during storage, and such that the containers will not rupture during use of the extrusion methods recommended by the manufacturer.

11.2 Labelling requirements

11.2.1 Outer packages (containing one or more primary containers)

Labelling of the outer packaging prepared for retail marketing containing one or more primary containers shall bear the following information:

a) recommended storage conditions for the unopened package;

b) brand name;

c) name of the manufacturer, or the name of another company authorized by the manufacturer to market the material under a different brand name;

d) identification of the consistency of the material, as putty, heavy-bodied, medium-bodied or light-bodied (clause 4). The Type number may also be included;

e) manufacturer's batch reference(s);

f) USE BEFORE DATE, identified as such, beyond which the material may not exhibit its best properties. The date shall be expressed as a six-digit number, for example 2001-09, where the first four digits indicate the year (2001) and the last two digits indicate the month (September);

g) the minimum volume that would result from mixing the entire component contents included in the outer package.

11.2.2 Primary containers within outer packaging

Labels for primary containers shall bear the following information:

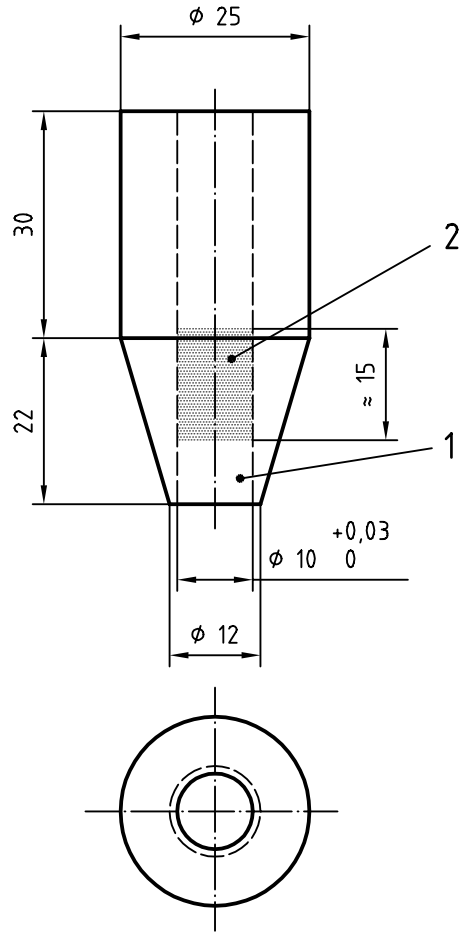
a) brand name;

b) name of the manufacturer or name of another company authorized to market the material under a different brand name;

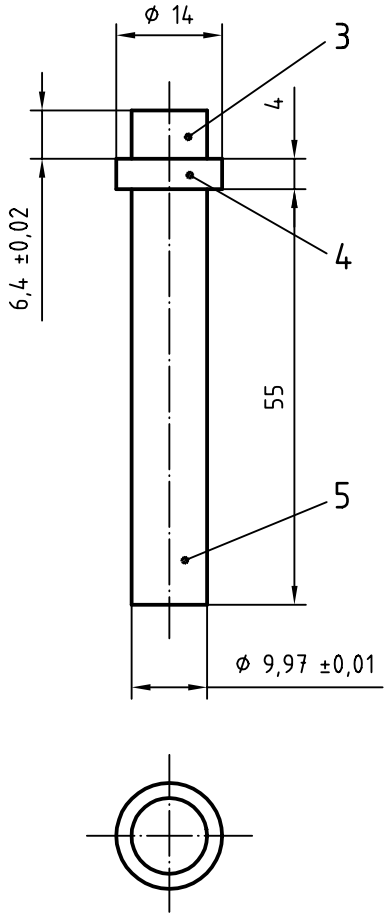
c) component identification (not required when the components are supplied as for extrusion mixing in separate, but joined, immediate containers included in the same primary container);

d) manufacturer’s batch reference.

Dimensions in millimetres



a) Dispensing tube [a]



b) Depth gauge/specimen increment-extruding plunger [b]

Key

1 Cavity equal in volume to the volume of the increment of material [(0,5 ± 0,02) ml] needed for the test

2 Elastomeric plug for forming the floor of the cavity

3 Depth gauge for positioning the plug

4 Depth gauge stop

5 Increment-extruding end of plunger

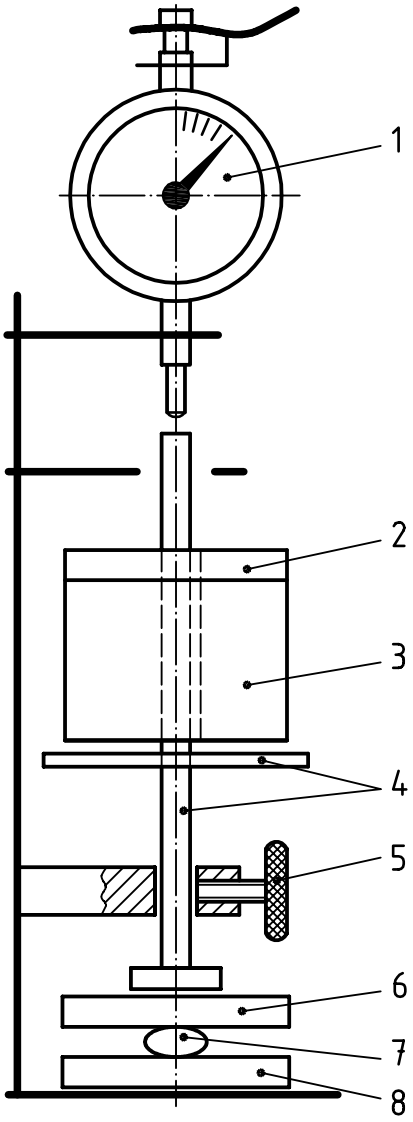
NOTE 1 Other dimensions may be used when making these parts providing that the dispensing tube bore and the depth gauge are mated such that the cavity produced has a volume of (0,5 ± 0,02) ml, and providing that lengths of the plug and the extruding end of the plunger ensure the complete extrusion of the specimen from the cavity.

NOTE 2 The elastomeric plug can be made by forming approximately 1 ml of heavy-bodied elastomeric impression material in the bore of the dispensing tube.

[a] Dispensing tube is made of PFTE or acetal.

[b] Plunger is made of rigid metal or polymeric material.

Figure 1 — Delivery system for consistency test specimen material



Key

1 Dial indicator

2 Weight having a mass which, along with the masses of items 3, 4 and 6, will provide for the total force of (14,7 ± 0,1) N needed for the consistency test

3 Weight having a mass which, along with the mass of item 4, will provide for the total force of (12,25 ± 0,1) N needed to complete the strain-in compression test

4 Loading shaft, complete with weight support, having a mass that will provide for the initial force of (1,22 ± 0,1) N needed for the strain-in compression test

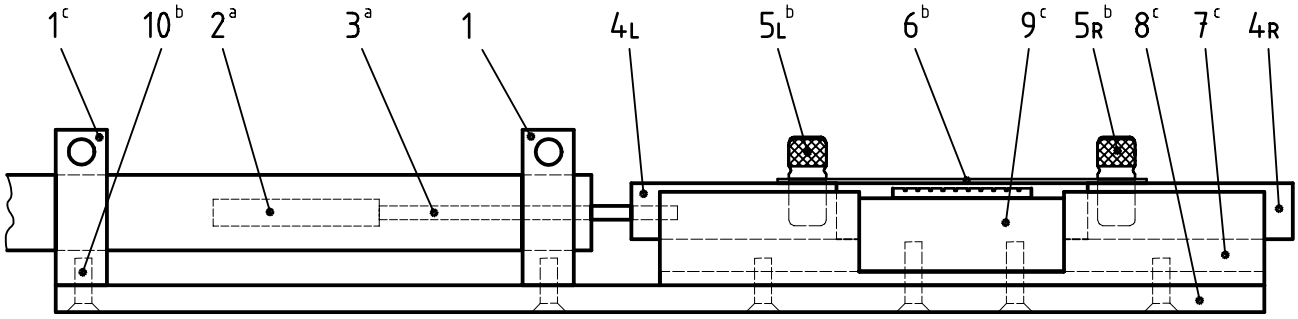
5 Locking screw

6 Loading plate

7 Specimen increment

8 Base plate

Figure 2 — Instrument for consistency and strain-in-compression tests



Key

1 LVDT support
2 LVDT core
3 Core carrier rod
4 4_L and 4_R: sliding polymer blocks
5 5_L and 5_R: plate aligning and locking pins
6 Perforated test plate
7 Glide track
8 Instrument base
9 Slotted specimen pedestal
10 Flat-head assembly screws M3,5

NOTE Location of the LVDT to the left of the other components favours right-handed use of instrument. Reversal of this relation so that the core carrier rod is attached to the sliding block 4_R favours left-handed use.

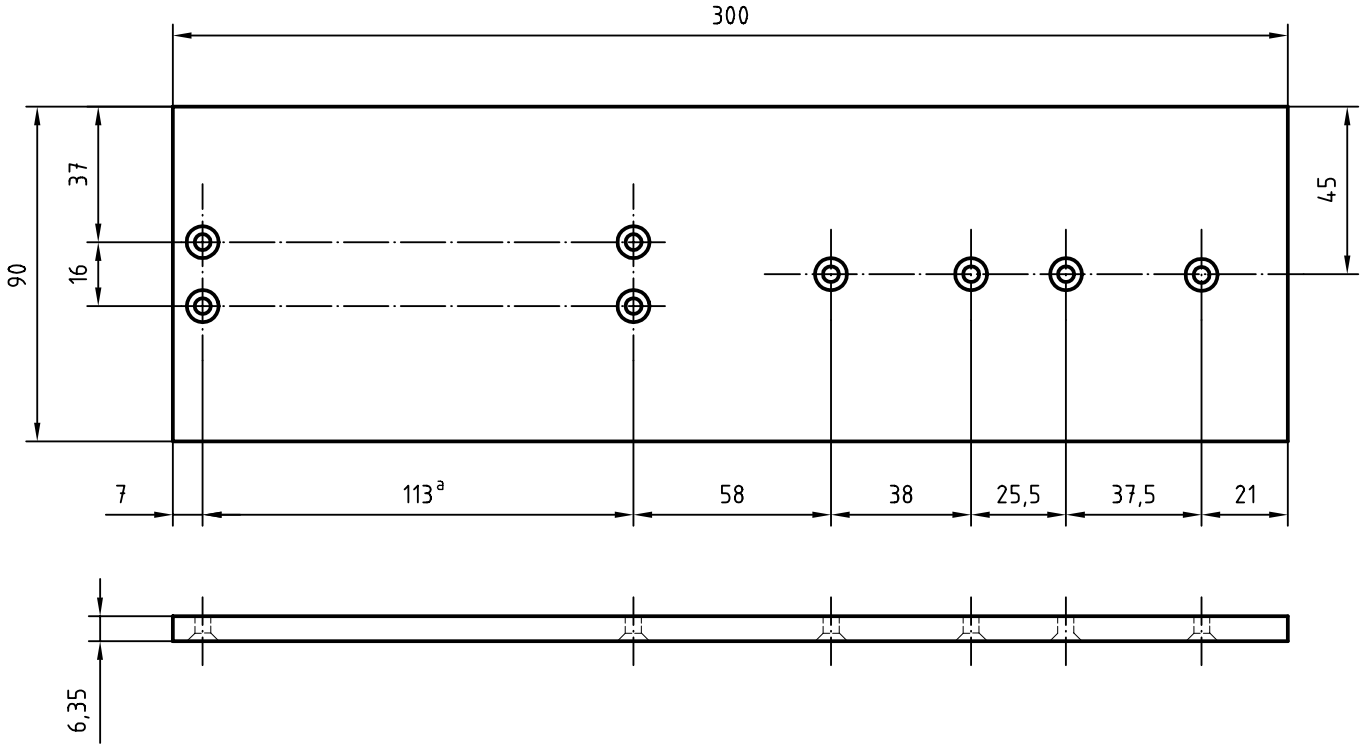
a Components supplied by the LVDT manufacturer.

b Components made of stainless steel.

c Components made of anodized aluminium.

Figure 3 — Working-time test instrument assembled

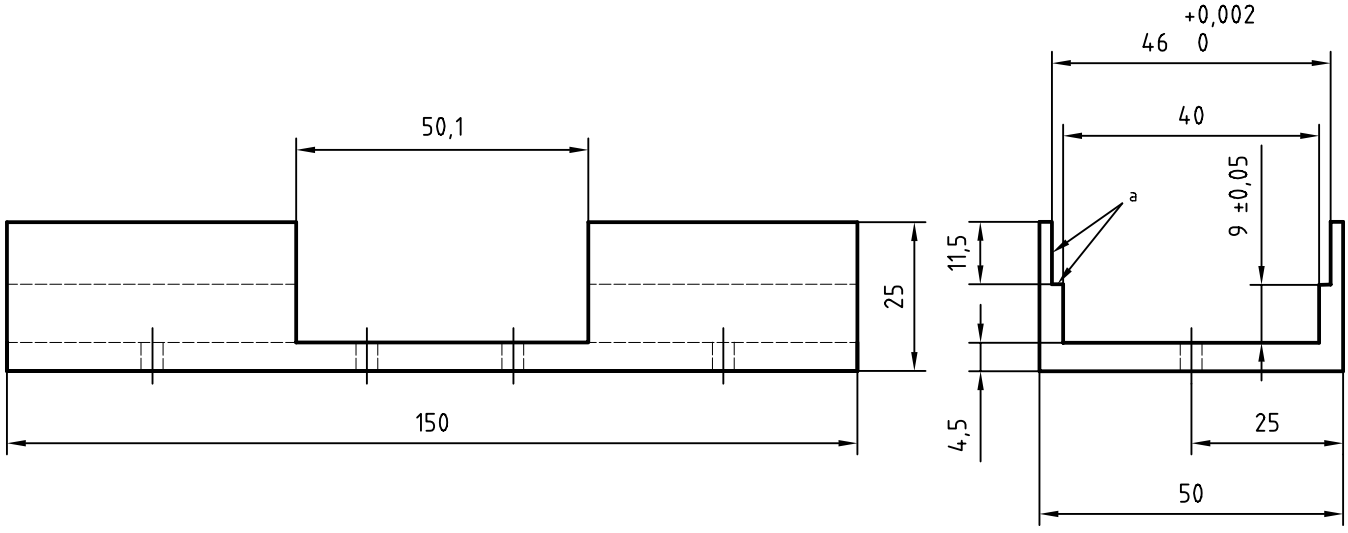
Dimensions in millimetres



a Distance between centres of the two LVDT supports. This dimension may vary depending upon the length of the LVDT used.

Figure 4 — Instrument base — Working-time test instrument

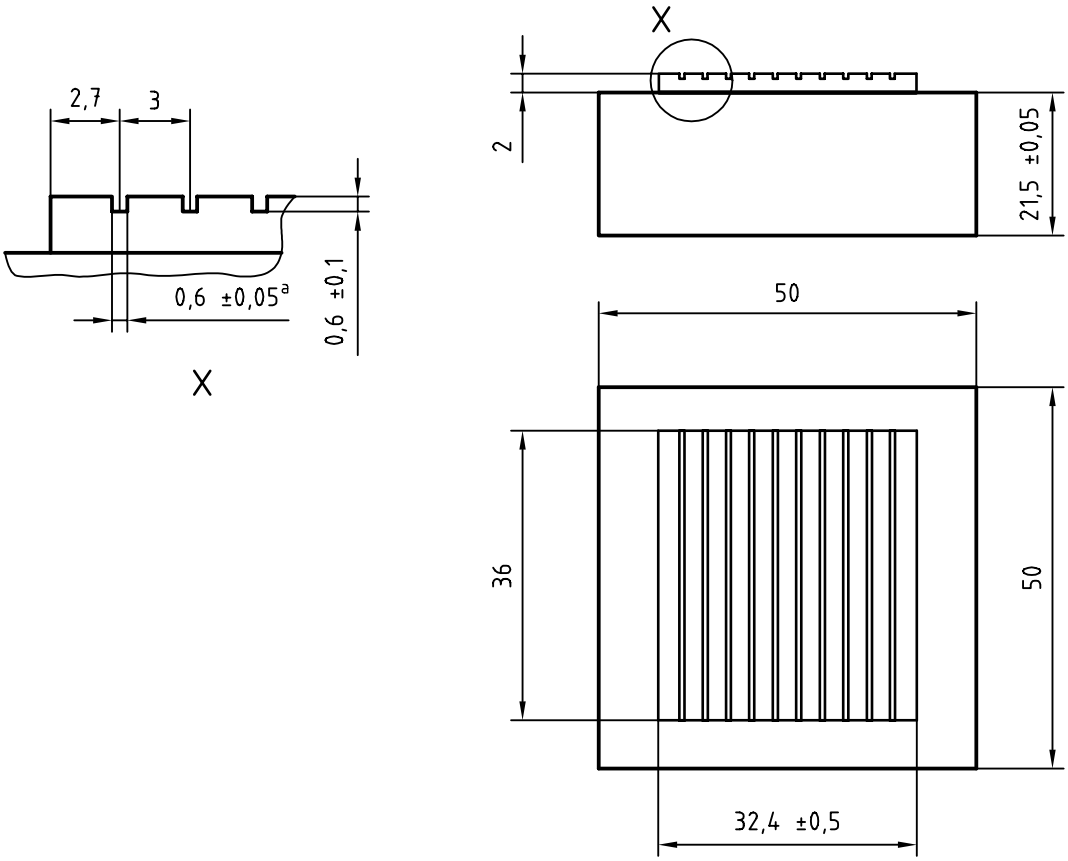
Dimensions in millimetres



a Indicates bearing surfaces of the glide track.

Figure 5 — Glide track — Working-time test instrument

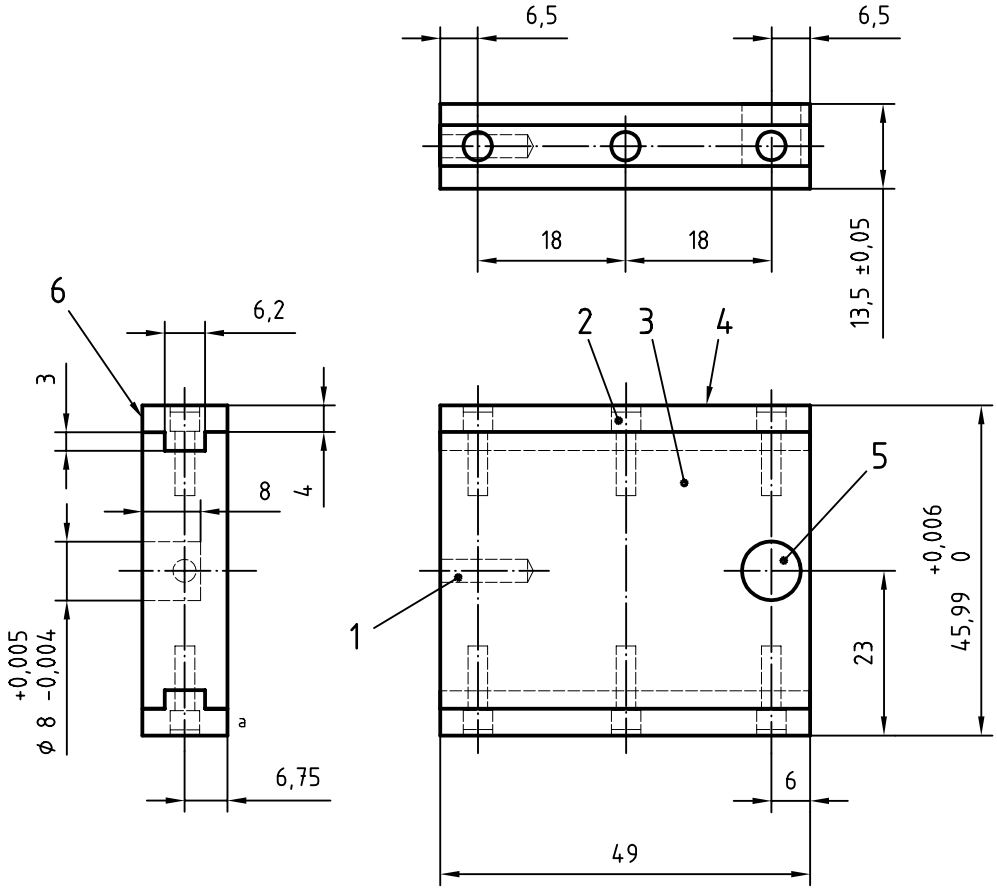
Dimensions in millimetres



a Ten slots with centres 3 mm apart.

Figure 6 — Slotted specimen test pedestal — Working-time test instrument

Dimensions in millimetres

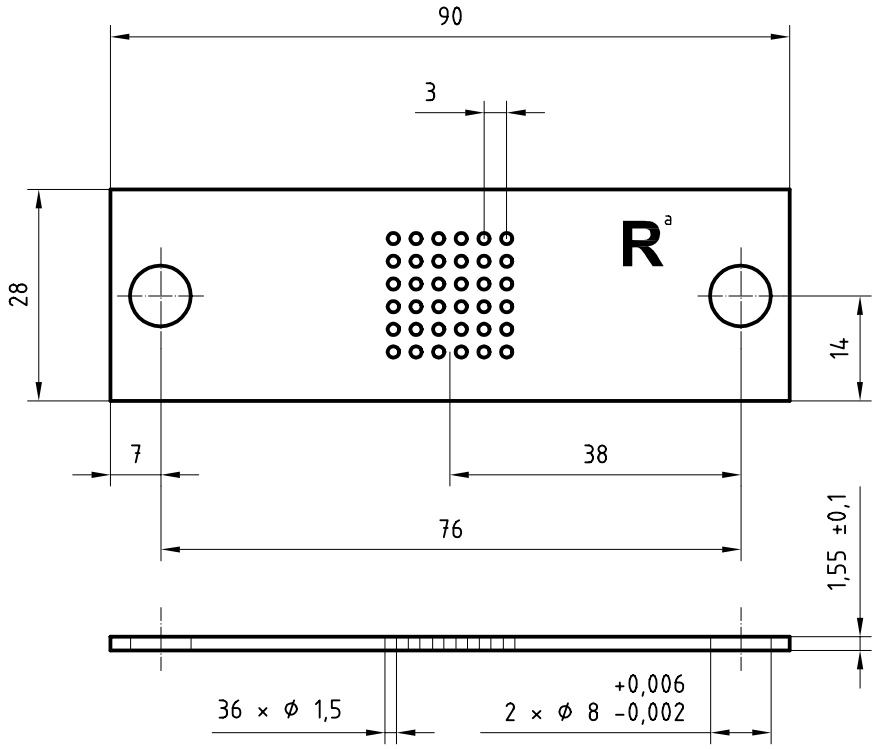


Key

1 Hole sized and threaded in one of the blocks to accommodate the thread of the core carrier rod
2 Cheese-head screws, M2,5 stainless steel (6 places)
3 Main body of block made of polyacetal
4 Lateral bearing surface made of PFTE
5 Hole to accommodate test plate aligning and locking pin
6 Underside of bearing surface

Figure 7 — Sliding polymer block — Working-time test instrument

Dimensions in millimetres



a Letter R marked in the top surface for use in positioning the test plate.

Figure 8 — Perforated test plate — Working-time test instrument

Dimensions in millimetres

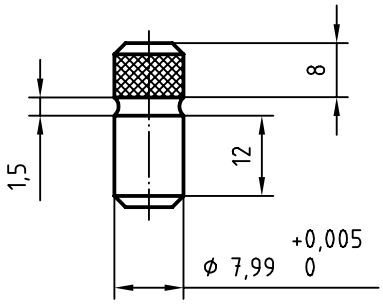
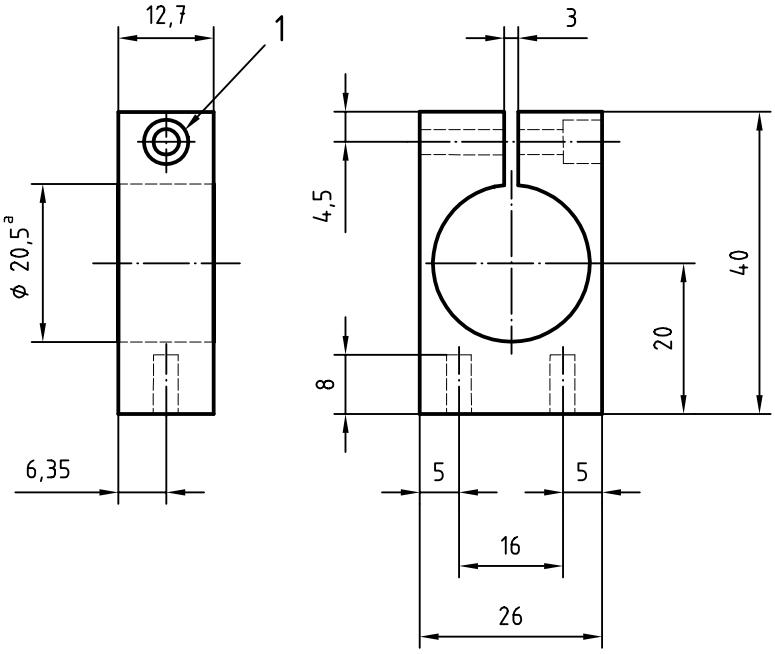


Figure 9 — Test plate aligning and locking pin — Working-time test instrument

Dimensions in millimetres

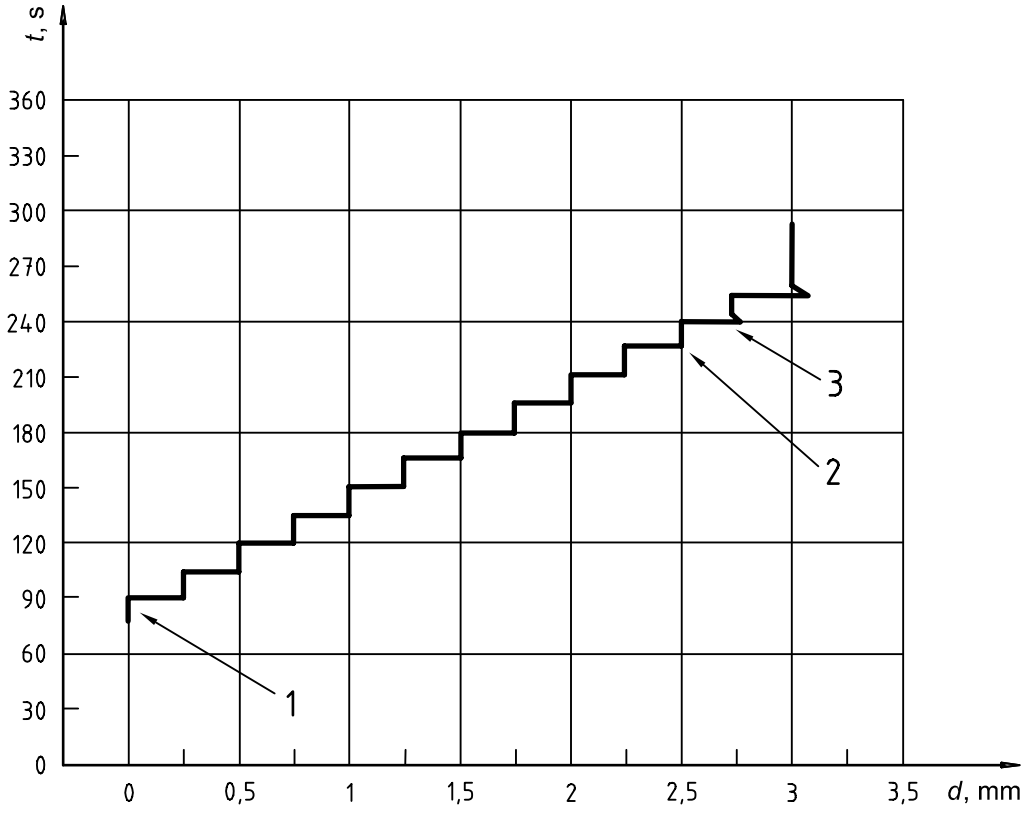


Key

1 Cap-head screws, M4,5 stainless steel

a Dimension accommodating an LVDT with an outside diameter of about 20,5 mm. The dimension varies according to the outside diameter of the LVDT.

Figure 10 — LVDT support — Working-time test instrument



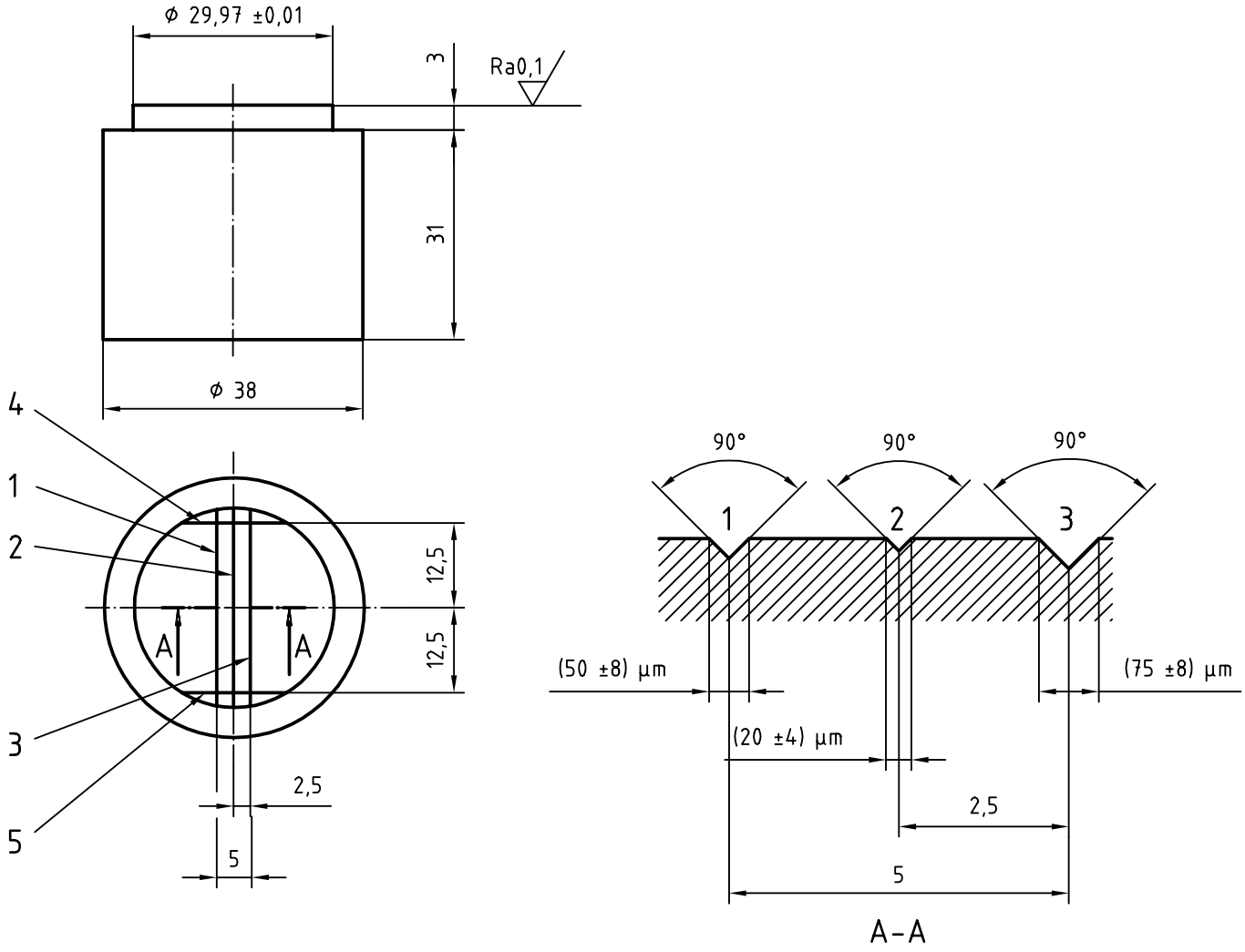
Key

1 Start chart recorder drive
2 Effective working time
3 First indication of development of elastic property

d LVDT core displacement
t Time

Figure 11 — Example of a working-time test chart tracing

Dimensions in millimetres



Key

1 Line a
2 Line b
3 Line c
4 Line d_1
5 Line d_2

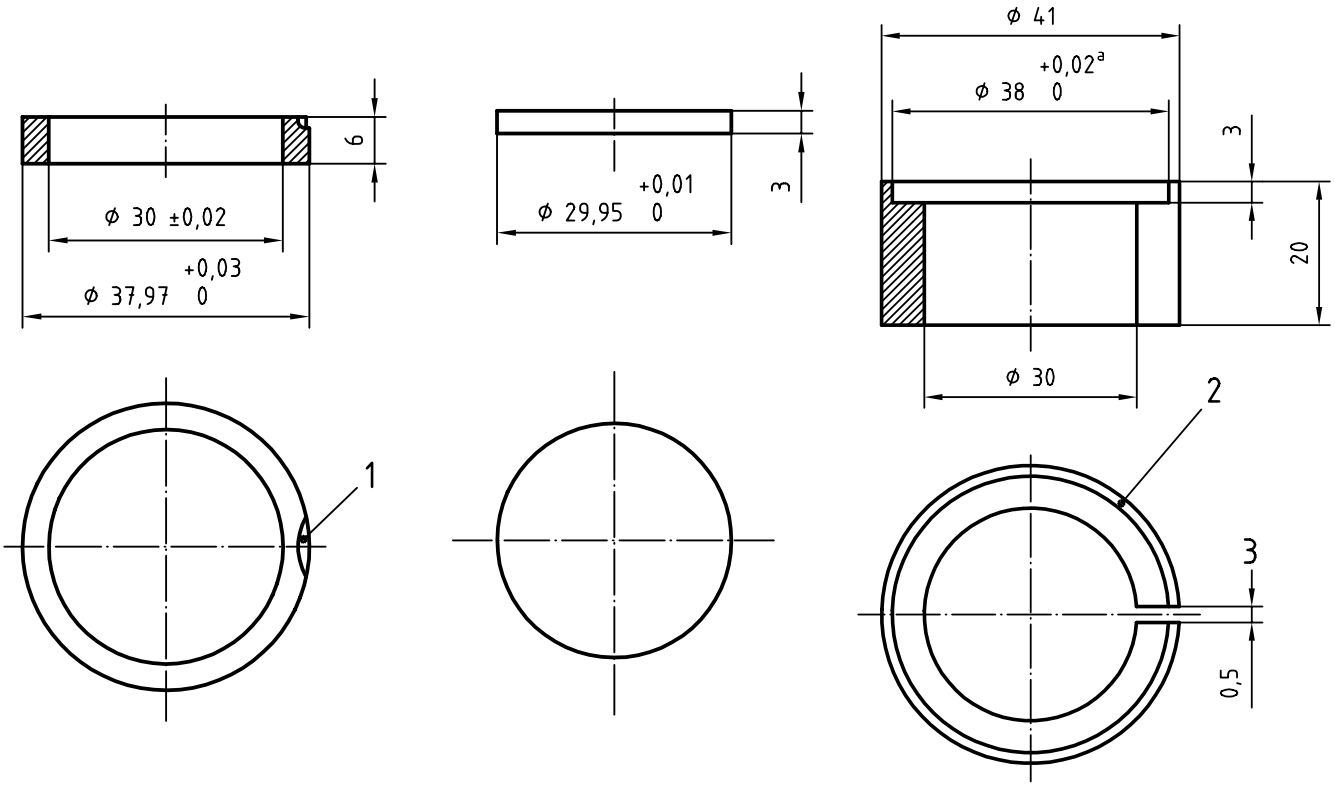
NOTE 1 Unless otherwise specified, dimensions are in millimetres.

NOTE 2 Unless otherwise specified, tolerances are ± 0,1 mm; surface roughness is 3,2 µm max. and material is cast or wrought austenitic stainless steel.

NOTE 3 Lines d_1 and d_2 are the same width as line c.

Figure 12 — Test block for detail reproduction and tests for compatibility with gypsum

Dimensions in millimetres



a) Ring mould [b] **b) Riser** [b] **c) Slit mould** [c]

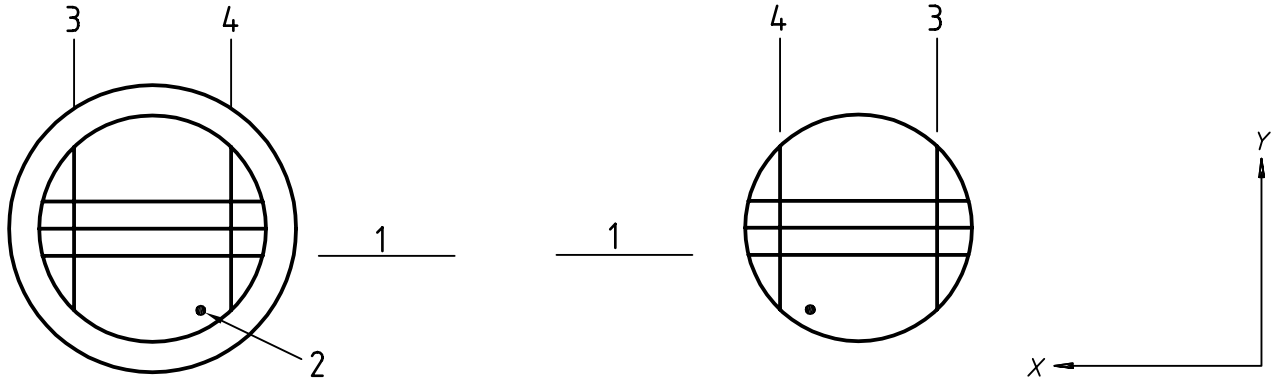
Key

1 Cut-out approximately 1 mm deep
2 Rim of recess in slit mould
3 Width of slit before it is closed

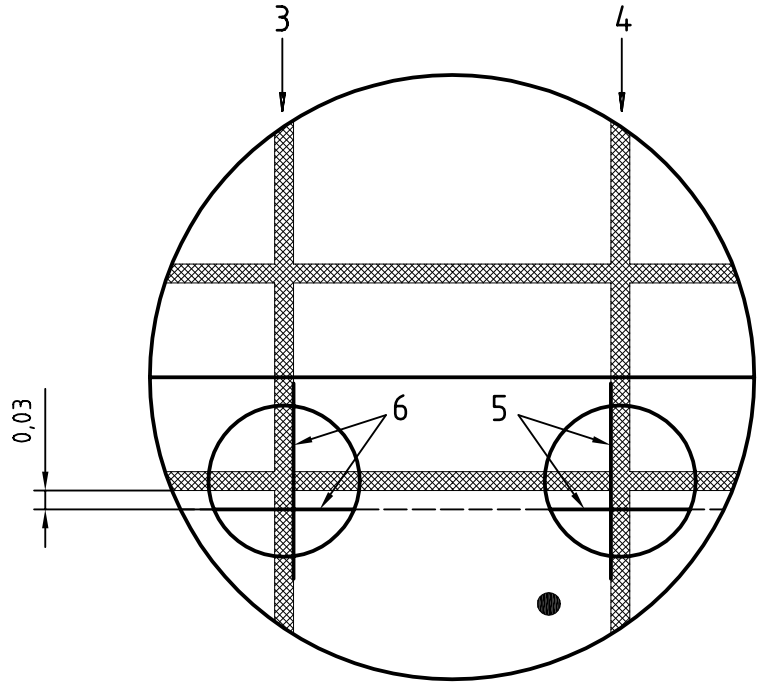
a Internal diameter of the mould after the clamping mechanism closes the slit.
b Made of polymer, brass or stainless steel.
c Made of brass.

Figure 13 — Accessories for detail reproduction and tests for compatibility with gypsum

Dimensions in millimetres



a) Position of lined block **b) Position of impression material specimen**



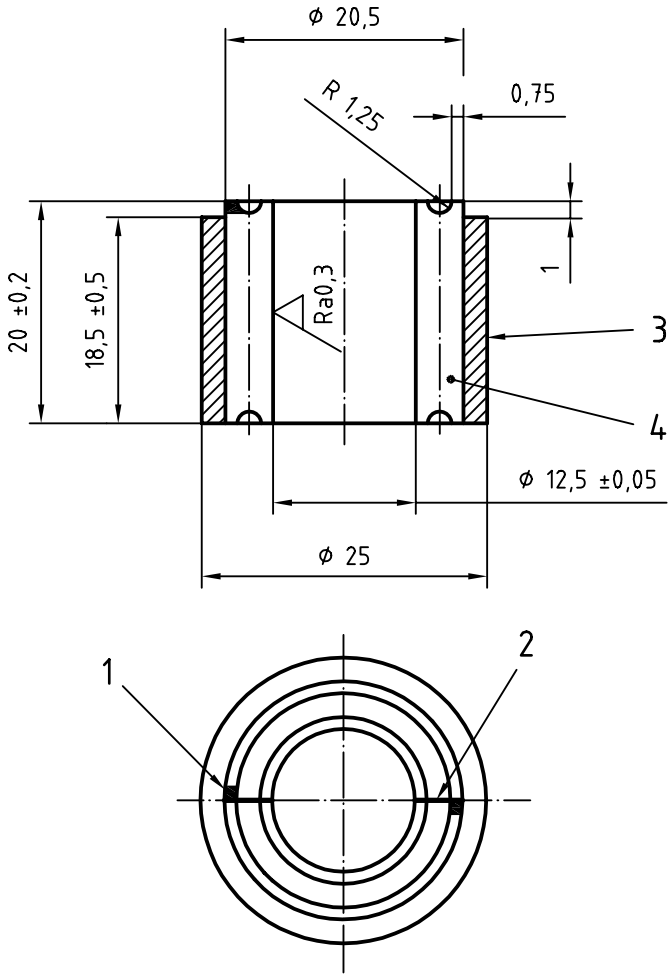
c) Relationship between lines on test block and microscope cross-hair positions

Key

1 Line c
2 Orientation mark
3 Line d_2
4 Line d_1
5 Position of X and Y microscope cross-hairs for first measurement
6 Position of cross-hairs for second measurement

Figure 14 — Linear dimensional change test — Positions of lined test block and impression material specimens on microscope stage for measurements between lines d_1 and d_2

Dimensions in millimetres



Key

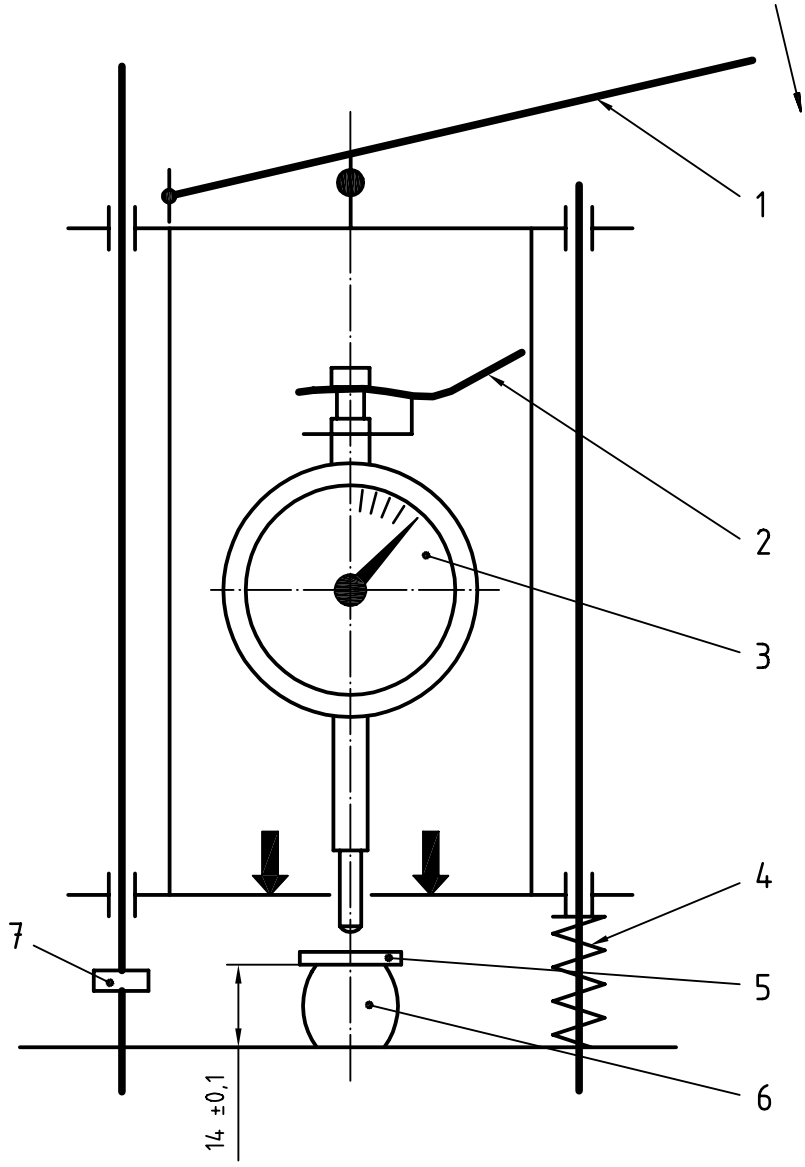
1 Cut-out approximately 1,0 mm wide, 1,0 mm deep in two places
2 Split between mould halves
3 Fixation ring
4 Split mould, two halves, no bell mouth in bore

NOTE 1 Surface texture is 3,2 μm max. unless otherwise specified.

NOTE 2 Components are made of anodized aluminium, brass or stainless steel.

Figure 15 — Split mould for forming specimens — Elastic recovery and strain-in-compression tests

Dimensions in millimetres



Key

1 Lever for compressing the specimen
2 Spindle position control lever
3 Dial indicator
4 Spring
5 Small test plate
6 Test specimen, compressed (6 ± 0,1) mm
7 Stop

Figure 16 — Elastic recovery test instrument

Annex A
(informative)

Working-time test instrument components — Possible sources

This informative annex identifies sources for the working-time test instrument (9.3.1.1) and the linear variable displacement transducer (LVTD) (9.3.1.2) needed for use with the instrument.[1)] Either LVDT identified below meets specifications stated in 9.3.1.2.

NOTE The working-time test instrument (exclusive of the LVDT component and other accessories described in the text) can be produced by any machining facility having the equipment and skills needed to build it according to the specifications shown in Figures 3 through 10 of this International Standard.

Working-time test instrument (exclusive of the LVDT component and other accessories identified in the text).

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LVDT Model 262A-0500

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U.S.A.
Tel. (610) 539-4400, Fax (610) 539-3400

1) This information is given for the convenience of users of this International Standard and does not constitute an endorsement by ISO of the products named.

Bibliography

[1] ISO 7405, *Dentistry — Preclinical evaluation of biocompatibility of medical devices used in dentistry — Test methods for dental materials.*

[2] ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing.*

ICS 11.060.10

Price based on 33 pages