INTERNATIONAL STANDARD

ISO 4823

Fifth edition
2021-02

Dentistry — Elastomeric impression and bite registration materials

Médecine bucco-dentaire — Produits pour empreintes et matériaux pour enregistrement des rapports intermaxillaires à base d'élastomères

Reference number
ISO 4823:2021(E)

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Published in Switzerland

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthodontic materials,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This fifth edition cancels and replaces the fourth edition (ISO 4823:2015), which has been technically revised and enhanced with regard to elastomeric bite registration materials. The following changes have been applied:

— the title and scope have been changed to reflect the inclusion of elastomeric bite registration materials;

— ISO 48-4:2018 has been added as a normative reference;

— a description of minimum time in the oral cavity for bite registration materials has been added;

— a description of hardness of bite registration materials has been added.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Dentistry — Elastomeric impression and bite registration materials

1 Scope

This document specifies the requirements and their test methods for elastomeric impression and bite registration materials.

NOTE This document does not address possible biological hazards associated with the materials. Assessment of these hazards is addressed in ISO 7405 and the ISO 10993 series.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 48-4:2018, *Rubber, vulcanized or thermoplastic — Determination of hardness — Part 4: Indentation hardness by durometer method (Shore hardness)*

ISO 1942, *Dentistry — Vocabulary*

ISO 6873:2013, *Dentistry — Gypsum products*

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at http://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

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

3.2
elastic recovery
elastic properties required to recover adequately after deformation

3.3
extrusion mixing
method by which two or more material components are extruded simultaneously from their separate primary containers through a mixing nozzle from which the material 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
hardness
resistance to indentation

Note 1 to entry: In this document, it is Shore hardness according to ISO 48-4:2018, Type A.

[SOURCE: ISO 1382:2020, 3.247, modified – Note 1 to entry added.]

3.6
minimum time in the oral cavity
minimum time span the material stays in the oral cavity to sufficiently minimize deformation

3.7
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 1 to entry: 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.

3.8
outer package
wrapping or carton, used to cover one or more primary containers in preparation for retail marketing

Note 1 to entry: Legislation or specific standards can apply.

3.9
primary packaging
container designed to come into direct contact with the product

[SOURCE: ISO 21067-1:2016, 2.2.3, modified — "packaging" replaced with "container" in the definition.]

3.10
strain in compression
flexibility/stiffness property ranges of the materials that determines whether the set materials, when formed as impressions, can be removed from the mouth without injury to the impressed oral tissues and have adequate stiffness in the more flexible portions of impressions to resist deformation when model-forming products are poured against them

3.11
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 prevents 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 document are classified according to the following consistencies determined immediately after completion of mixing according to the manufacturer's instructions (see 5.3):

— Type 0: putty consistency;

— Type 1: heavy-bodied consistency;

— Type 2: medium-bodied consistency;

— Type 3: light-bodied consistency;

— Type B: bite registration materials.

5 Requirements

5.1 Packaging requirements

No packaging requirements are specified in this document, but it is important for manufacturers to take into account that the packaging should be such that it does not contaminate or permit contamination of ingredients of the material components during recommended storage conditions. Structure of the primary packaging 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.

NOTE Additional information can be supplied at the discretion of the manufacturer or as required by regulation.

5.2 Labelling requirements

5.2.1 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 and address 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 (see Clause 4) (the type number can 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, 2014-09, where the first four digits indicate the year (2014) and the last two digits indicate the month (September);

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

NOTE Additional information can be supplied at the discretion of the manufacturer or as required by regulation.

5.2.2 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 for extrusion mixing are supplied in separate but joined primary containers);

d) manufacturer’s batch references.

NOTE Additional information can be supplied at the discretion of the manufacturer or as required by regulation.

5.3 Requirements for information in the manufacturer's instructions

5.3.1 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.

NOTE Additional information to that specified in 5.3.2 and 5.3.3 can be supplied at the discretion of the manufacturer or as required by regulation.

5.3.2 Identifying information

The following identifying information is required:

a) trade name 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).

5.3.3 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 primary containers;

b) statements indicating that working time and other characteristics of the material can be affected significantly by the following factors, as 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;

   — 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 5.3.3, d) and Annex B];

f) working time;

g) minimum time the material should remain in the mouth before removal.

The following items only apply to impression materials:

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 6873:2013, 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 and 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.

5.4 Requirements for characteristics and properties

5.4.1 Component colours (hand-spatulated or hand-kneaded mixes)

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.

5.4.2 Mixing time (hand-spatulated or hand-kneaded mixes)

When the material components are combined according to the manufacturer's instructions and the results of the mixing are evaluated according to 7.1, the average time required to achieve a homogeneous mixture (essentially streak-free) shall not exceed the time stated by the manufacturer.

5.4.3 Consistency

When tested according to 7.2, the test disc diameter shall be in the range given in Table 1 for the consistency assigned to the material by the manufacturer.

5.4.4 Working time

When tested according to 7.3, the working time shall not be less than that stated in the manufacturer's instructions.

5.4.5 Detail reproduction

When tested according to 7.4, the line width reproduced shall not exceed the appropriate value given in Table 1.

5.4.6 Linear dimensional change

When tested according to 7.5, the linear dimensional change shall not exceed the appropriate value given in Table 1.

5.4.7 Compatibility with gypsum

The impression material shall impart a smooth surface to and separate cleanly from the gypsum model material poured against it. When tested according to 7.6, the line width reproduced shall not exceed the appropriate value given in Table 1.

5.4.8 Elastic recovery

When tested according to 7.7, the elastic recovery shall be greater than or equal to the value given in Table 1.

5.4.9 Strain in compression

When tested according to 7.8, the strain in compression shall be in the appropriate range given in Table 1.

5.4.10 Minimum time in the oral cavity for bite registration materials

When tested according to 7.9, the minimum time in the oral cavity shall be smaller than or equal to the value given by the manufacturer in the instructions for use.

5.4.11 Compression set of bite registration materials

When tested according to 7.9, the compression set after load removal shall be less or equal to the value given in Table 1.

5.4.12 Hardness of bite registration materials

When tested according to 7.10, the hardness of the material shall be greater than or equal to the value given in Table 1.

Table 1 — Characteristic and physical property requirements

Type	Test subclause no. and description								
	7.2		7.4	7.5	7.6	7.7	7.8	7.9	7.10
	Consistency (test disc diameter) mm		**Detail reproduction** (line width reproduced)[a] µm	**Linear dimensional change** % max.	**Compatibility with gypsum** (line width reproduced)[a] µm	**Elastic recovery** %	**Strain in compression** %	**Compression set** mm	**Hardness** Shore A
	min.	max.				min.	min. | max.	max.	min.
0	—	35	75	1,5	75	96,5	0,8 | 20,0	-	-
1	—	35	50	1,5	50	96,5	0,8 | 20,0	-	-
2	31	41	20	1,5	50	96,5	2,0 | 20,0	-	-
3	36	—	20	1,5	50	96,5	2,0 | 20.0	-	-
B	-	-	-	1,5	-	-	- | -	0,1	50

[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 A.4.

6 Pre-test planning approaches

The information in this Clause is provided to help test operators avoid losses of time due to trial and error efforts occurring when such information is not considered before test procedures, such as those described in Clause 7, are begun.

6.1 Sampling

Observe the following guidelines when procuring samples of materials for testing.

a) Procure only samples that have been packaged for retail or franchise marketing and that have labelling **Use by** dates that have not expired.

b) Wherever possible, select only those samples that have the same lot (batch) number [see 5.2.1 e)].

c) Sample size required

— as much as 900 ml might be needed for conducting all required tests and for the considerable practice that might be necessary for the test operator to become proficient in specimen preparation and testing, and

— for the gypsum materials needed for the impression material compatibility with gypsum test, at least 1 000 g.

6.2 Pre-test product examinations

These examinations are helpful in determining whether the sample procured (6.1) is fit for objective testing.

6.2.1 Examinations for compliance with labelling requirements

Examine the consumer packaging components for compliance with the labelling requirements before any attempt to open a packaging component has defaced or obliterated any labelling entry information needed for storage or use of the product (for example, **Use by** date).

At this point, it is recommended that the following information about the product be recorded for future reference in a test record format, if possible:

a) brand name, type, and class of the product, if applicable, along with an added numeric or alpha numeric symbol for the sample;

b) **Use by** date for the product;

c) lot number for each component.

6.2.2 Examinations for effectiveness of the packaging

Before opening any primary packaging container, examine it for possibilities that the quality of the content might have been compromised since its manufacture. For example, evidence such as the following:

a) loose tube caps or canister lids or leakage;

b) container rupture or punctures;

c) shrinkage of the content of a container such as can be detected by sight, sound, or touch.

Caution — Do not use any compromised materials for preparing specimens.

6.2.3 Examinations for compliance with requirements for instructions for use

a) Before discarding any secondary packaging:

— examine the labels to determine whether they include any of the instructions for use information specified in 5.3, and

— locate and retain any instruction sheet that might have been provided outside the primary container.

b) Examine the instructions for use for compliance with requirements stated in 5.3.3.

6.3 Essential pre-test preparatory practices

6.3.1 Laboratory conditions

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

6.3.2 Apparatus function verification steps

a) Examine all accessories, instruments, and equipment for functional effectiveness before they are used in a test.

b) Clear all instrumentation or equipment surfaces that will come in contact with the specimen material of any contaminants that might influence the test result.

c) Perform whatever calibration steps necessary to ensure that the items comply with specifications stated for them in this document or in ISO 6873:2013.

6.3.3 Volume of materials to be mixed for each specimen

Unless otherwise specified in this document, the volume mixed for each specimen shall be (15 ± 0,5) ml.

6.3.4 Standardized approaches to proportioning, mixing, and handling of hand mixed materials to be tested

See Annex B.

6.3.5 Timing for the specimen preparation and test procedures

A timing device such as a stop watch accurate to 1 s over a 30 s period shall be used for timing each requiring specimen preparation and test step.

6.3.6 Simulated oral time/temperature treatment of specimens formed in completely closed mould assemblies

NOTE For the detail reproduction, linear dimensional change, elastic recovery, and strain in compression test specimens.

Immediately after the specimen forming material has been completely enclosed in the specimen forming assembly, the entire assembly shall be conditioned at (35 ± 1) °C for the time period recommended by the manufacturer for leaving the material in the mouth.

6.4 Pass/fail determinations

The minimum number of specimens to be tested for pass/fail determinations shall be five. 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 four of the second series of specimens comply, the material passes. Otherwise, the material fails.

6.5 Expression of test results

Record the number of specimens tested and whether the material passes or fails.

7 Test methods — Specific

7.1 Mixing time

7.1.1 Apparatus

7.1.1.1 Recommended mixing apparatus [see 5.3.3, d)].

7.1.1.2 Timing device (see 6.3.5).

7.1.2 Specimen preparation and test procedure (five specimens)

Proportion and mix the required volume of material (see 6.3.3) 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 can be used to provide increments of material needed for the consistency test (see 7.2).

7.1.3 Pass/fail determination and expression of results

Determine whether the mean result obtained in accordance with 7.1.2 complies with 5.4.2, and report the results.

7.2 Consistency

7.2.1 Apparatus and materials

7.2.1.1 Two glass plates, a loading plate of approximately 60 mm by 60 mm and at least 3 mm thick, and a base plate of dimensions equal to or greater than those of the loading plate.

7.2.1.2 Material delivery system, for delivering a volume of (0,5 ± 0,2) ml of the material onto the base plate (see Figure A.1).

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

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

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

7.2.1.6 Test apparatus, for applying a force of (14,7 ± 0,1) N (see Figure A.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 A.2 plays no part in the consistency test.

7.2.1.7 Linear measuring instrument, accurate to 0,5 mm, for measuring diameters of the test specimen disc (7.2.3).

7.2.1.8 Timing device (see 6.3.5).

7.2.2 Advance preparation steps

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

a) adjust the test apparatus (7.2.1.6) so that the contact surface of the loading shaft foot can descend within 5 mm of the top surface of the apparatus base;

b) cover the top surface of the base plate (7.2.1.1) with a polyethylene sheet (7.2.1.3);

NOTE 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.

c) use the depth-gauge end of the plunger (see Figure A.1) to push the elastomeric plug (7.2.1.5) into the tapered end of the dispensing tube to the depth allowed by the stop;

d) use the depth-gauge end of the plunger to seat two of the polyethylene sheet discs (7.2.1.4) to cover the cavity floor formed by the plug.

7.2.3 Specimen preparation and test procedure (5 specimens)

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

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

b) 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;

c) centre the increment on the base of the test apparatus (7.2.1.6) directly under the elevated loading-shaft foot;

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

e) allow the (14,7 ± 0,1) N load to descend slowly onto the increment.

NOTE 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. Separate the loading plate from the assembly so as to leave the specimen on the base plate. Use the measuring instrument (7.2.1.7) 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.

7.2.4 Pass/fail determination and expression of results

See 6.4 and 6.5.

7.3 Working-time

7.3.1 Apparatus

7.3.1.1 Specimen forming ring mould, height, (9 ± 0,1) mm, internal diameter (25,0 ± 0,2 or 40,0 ± 0,2) mm.

7.3.1.2 Flat glass, polymeric or metal specimen forming base plate, approximately 50 mm by 50 mm and about 6 mm thick.

7.3.1.3 Mould release agent, such as silicone grease that will not react with the material being tested.

7.3.1.4 Clay or soft wax, capable of being moulded so as to fix the ring mould (7.3.1.1) to the base plate (7.3.1.2).

7.3.1.5 Timing device, such as a stop watch (see 6.3.5).

7.3.1.6 Working time test apparatus (see Figures A.2 and A.3), which allows for a load application according to Table 2 and has a loading shaft which can be fixed with its foot resting at a point 10 mm above the floor of the specimen forming mould assembly, the height from which the loading shaft foot shall travel on its way to penetration of the specimen material. The apparatus has been adapted to

provide for a pre-test fiducial measurement to be made with loading shaft foot in contact with the top surface of the ring mould in the specimen forming assembly and to provide for a test measurement, to be made 10 s after contact of the test specimen material with the foot of the loading shaft, for the purpose of determining whether the loading shaft foot has descended into the specimen material in the mould to a depth of at least 4 mm (5 mm above the floor of specimen forming mould cavity). The test apparatus shall be equipped with the required weights, a dial indicator having divisions of 0,1 mm, and a loading shaft having a foot 16 mm in diameter.

Table 2 — Load and mould dimensions for the working time test

	Type 0	Type 1	Type 2	Type 3	Type B
Mould diameter, mm	40	40	25	25	-
Load[a], N	12,75 ± 0,1 (1 300 g)	7,85 ± 0,1 (800 g)	5,88 ± 0,1 (600 g)	2,45 ± 0,1 (250 g)	5,88 ± 0,1 (600 g)
[a] Overall load, including the force applied by the dial gauge and the loading shaft itself.					

7.3.1.7 Modified table fork, for initial incorporation of base and accelerator components.

7.3.1.8 Nitrile protective gloves

7.3.2 Working time test

7.3.2.1 Test procedure

a) Clear the ring mould (7.3.1.1, types 0 - 3), the base plate (7.3.1.2), and the loading shaft foot of the apparatus (7.3.1.6) of contaminants and coat them with a thin film of the mould release agent (7.3.1.3).

b) Centre the required ring mould (see Table 2) on the base plate and use clay or wax (7.3.1.4) to fix the two components in this relationship so as to form the specimen forming mould cavity assembly.

c) Load the required weights (see Table 2) on the weight support or collar of the loading shaft.

d) Proportion the hand mixed materials preparatory to mixing.

e) Position the specimen forming assembly beneath the foot of the loading shaft such that the following steps can be completed preparatory to testing.

   — At the beginning of testing, the holding pin is plugged and the loading shaft is let down until the holding pin rests on the rest. In this position, the distance in between the lower base of the test plate and the surface base plate shall be (5,0 ± 0,1) mm.

   — In this position, record the dial gauge reading resulting from the dial indicator spindle contact as reading a (target position).

   — Now, pull up the loading shaft and tighten the knurled-head screw when the lower face of the test plate is resting (10 ± 0,1) mm above the surface of the base plate.

   — At this time, the additional mass producing a load according to Table 2 is placed onto the weight rest (see Figure A.3).

7.3.2.2 Specimen formation and positioning steps

Complete the following steps in quick succession:

a) cover the hands with protective gloves (7.3.1.8);

b) use the modified fork (7.3.1.7) for initial mixing of putty components;

c) use the gloved hands to knead the putty mixture until it is streak-free;

d) **Type 0 to 3:**

— slightly overfill the specimen forming mould cavity with the mixed material and strike off the excess level with the top of the specimen forming ring mould;

— centre the filled assembly beneath the centre of the loading shaft foot;

Type B:

— completely fill the space between the base plate and the loading shaft foot within 5 s with the bite registration material;

e) unlock the loading shaft and carefully let it descend until the foot is close to but not in contact with the test material and lock the shaft in this position.

7.3.2.3 Test procedure steps

At 1 s before the working time stated in the instructions, unlock the loading shaft and allow the foot to descend into the material in the ring mould cavity over a period of 10 s.

The end position of the test plate is read from the dial gauge as reading b.

7.3.2.4 Pass/fail determination and expression of results

If the test plate has reached the target position (Abs(a-b) ≤ 0,1 mm), the specimen has passed the test. Otherwise, it fails. Additionally, see 6.4 and 6.5.

7.4 Detail reproduction

7.4.1 Apparatus and materials

7.4.1.1 Test block (see Figure A.4) **and ring mould accessory** (see Figure A.5). Clean the test block ultrasonically before each use.

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

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

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

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

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

7.4.1.7 Timing device (see 6.3.5).

7.4.2 Specimen preparation

Before mixing the material for each of the five specimens, place the test block and ring mould (7.4.1.1) in the oven (7.4.1.2) for conditioning, for at least 15 min.

Cover the underside of the glass or metal plate (7.4.1.3) with a polyethylene sheet (7.4.1.4).

NOTE 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:

a) remove the test block and ring mould from the oven;

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

c) 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 be gradually forced through application of pressure applied by the glass or metal plate to flow into the lines to their opposite ends;

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

e) 60 s after completion of the mix, place this specimen-forming assembly in the water bath (7.4.1.5) for the minimum time recommended by the manufacturer's instructions for leaving the impression in the mouth [see 5.3.3 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. 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.

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

7.4.3 Test procedure

Immediately after blowing moisture from the specimen, use the microscope (7.4.1.6) to examine the specimen for compliance with the related requirement shown in Table 1.

NOTE Differences in colours of the materials can 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 that conform to the related requirements for this test can be used for the linear dimensional change test (see 7.5).

7.4.4 Pass/fail determination and expression of results

See 6.4 and 6.5.

7.5 Linear dimensional change

7.5.1 Apparatus and materials

7.5.1.1 Detail reproduction test specimens, made according to 7.4.2, examined according to 7.4.3, and found to conform to the related requirement specified in Table 1.

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

7.5.1.3 Talcum powder

7.5.1.4 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.

7.5.2 Test block line-length measurement procedure

7.5.2.1 Test block preparation and positioning

Prepare and position the test block as follows:

a) clean the test block ultrasonically before beginning the procedure;

b) position the test block on the microscope stage (see 7.5.1.4) with line d_1 to the right and with line c appearing as the lower line as shown in Figure A.6 a);

c) relate the X axis of the microscope cross hair parallel to, and approximately 0,03 mm below line c as shown in Figure A.6 c). This will place the Y axis of the cross hair parallel to lines d_1 and d_2;

d) 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.

7.5.2.2 Test block line-length measurement steps

Proceed with the following steps taking into account that after positioning the test block according to the last step in 7.5.2.1, 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:

a) 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 [see Figure A.6 c)];

b) 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;

c) 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.

7.5.3 Specimen preparation

Dust the underside of each detail reproduction test specimen (7.5.1.1) and the top surface of the glass plate (7.5.1.2) with talcum powder (7.5.1.3). 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 7.5.4.1.

7.5.4 Test specimen measurement

7.5.4.1 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 [5.3.3 h)], between removal of the impression from the mouth and pouring of the gypsum product:

a) 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;

b) 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.

7.5.4.2 Measuring procedures

Follow the procedure described in 7.5.2.2 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 A.6 b), thus ensuring that line c will appear as the lower line. Record this measurement as L_2.

7.5.4.3 Calculation of results

Calculate the percentage of dimensional change, ΔL, for each specimen to the nearest 0,05 %, using Formula (1):

$$\Delta L = 100 \cdot \left(\frac{L_1 - L_2}{L_1} \right) \quad (1)$$

where

L_1 is the distance measured between lines d_1 and d_2 on the test block (see 7.5.2.2);

L_2 is the distance measured between lines d_2 and d_1 on the impression material specimen (see 7.5.4.2).

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

7.5.4.4 Pass/fail determination and expression of results

See 6.4 and 6.5.

7.6 Compatibility with gypsum

7.6.1 Apparatus and materials

7.6.1.1 Detail reproduction test specimens, made according to 7.4.2, examined according to 7.4.3, and which have been found to conform to the related detail reproduction requirement shown in Table 1.

7.6.1.2 Ring mould (7.4.1.1).

7.6.1.3 Riser, see Figure A.5 b).

7.6.1.4 Slit mould (see Figure A.5 c), 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.

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

7.6.1.6 Two dental gypsum products [see 5.3.3 i) and ISO 6873:2013],

a) one Type 3, dental stone, model,

b) 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.

7.6.1.7 Mould release agent, such as silicone grease, which will be non-reactive with the slit mould (7.6.1.4) and the gypsum products.

7.6.1.8 Microscope (7.4.1.6).

7.6.1.9 Timing device (see 6.3.5).

7.6.2 Specimen preparation

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

7.6.2.1 Advance preparation

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

a) treat the inner surface of the slit mould (7.6.1.4), including the slit surfaces, with a thin film of the mould release agent (7.6.1.7) and use the clamping mechanism to close the slit;

b) position the specimen (7.6.1.1) in the ring mould (7.6.1.2) and press the riser (7.6.1.3) 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 (7.6.1.5) and invert the entire assembly.

7.6.2.2 Specimen formation

At the earliest time specified for pouring impressions after their removal from the mouth [5.3.3 h)], introduce the first increments of a gypsum mixture, through 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 be directed to flow gradually over the lines to their opposite ends. 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 7.6.1.6. Separate the gypsum specimen from the assembly.

7.6.3 Test procedure

Use the microscope (7.6.1.8) to examine the lined surfaces of the gypsum specimen to conform to the requirements specified in Table 1 (see also 7.4.3, Note).

7.6.4 Pass/fail determination and expression of results

See 6.4 and 6.5.

7.7 Elastic recovery

7.7.1 Apparatus and materials

7.7.1.1 Fixation ring with split mould, see Figure A.7.

7.7.1.2 Mould release agent, such as silicone grease.

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

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

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

7.7.1.6 Water bath, see 7.4.1.5.

7.7.1.7 Timing device, see 6.3.5.

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

7.7.1.9 Test apparatus, such as the one shown in Figure A.8. The dial indicator shall be accurate to 0,1 mm and shall have a capacity for contributing, along with the weight of the test plate (7.7.1.8), to the application of a total force of (0,6 ± 0,1) N. Set the stop on the test apparatus to limit compression of the test specimen to (6,0 ± 0,1) mm.

7.7.2 Specimen preparation

7.7.2.1 Advance preparation

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

a) apply a very thin film of the mould release agent (7.7.1.2) to the internal surface of the fixation ring and to all surfaces of the split mould (7.7.1.1);

b) cover one surface of each of the plates (7.7.1.3) with a polyethylene sheet (7.7.1.4);

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

7.7.2.2 Specimen formation

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

a) fill the fixation ring slightly more than half full;

b) 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;

c) press the second polyethylene-covered plate onto the material so as to expel almost all the excess and use the C-clamp (7.7.1.5) to force the plates into contact with the top and bottom surfaces of the split mould.

NOTE If glass plates (7.7.1.3) are used instead of metal plates, metal back-up plates can 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 (7.7.1.6) for the time specified in the manufacturer's instructions for leaving impressions in the mouth [5.3.3 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 (7.7.1.8) to rest on the top surface of the specimen, and seat this assembly on the test apparatus base (7.7.1.9) centred in axial alignment with the dial indicator spindle.

7.7.3 Test procedure

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

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

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

c) t + 60 s: deform the specimen (6,0 ± 0,1) mm, as limited by the stop on the test apparatus, 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;

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

e) 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 apparatus base and the test plate that will be in contact with the top and bottom surfaces of the specimen during the test.

7.7.4 Calculation of results

Calculate the percentage of elastic recovery, K, for each specimen, using Formula (2):

$$K = 100 - \left[100 \cdot \left(\frac{h_1 - h_2}{h_0} \right) \right] \tag{2}$$

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);

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.

7.7.5 Pass/fail determination and expression of results

See 6.4 and 6.5.

7.8 Strain in compression

7.8.1 Apparatus

Items listed in 7.7.1.1 to 7.7.1.7 are required for preparing the specimen together with a test apparatus, such as the one shown in Figure A.2, incorporating a dial indicator accurate to 0,1 mm.

7.8.2 Specimen preparation

Prepare five specimens according to the procedure described in 7.7.2, with the exception that the test plate (7.7.1.8) is not placed on the specimen.

7.8.3 Test procedure

Immediately after separation of the specimen from the forming assembly, position it on the base of the test apparatus (7.8.1) centred below the foot of the loading shaft. Conduct the test in accordance with the following time schedule, where t is the time when the specimen is removed from the water bath:

a) 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 (1,2 ± 0,1) N exerted by the loading shaft/weight support assembly only;

b) 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;

c) 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 (12,3 ± 0,1) N gradually over a period of 10 s;

d) 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.

7.8.4 Calculation of results

Calculate the percentage of strain in compression, E, for each specimen, using Formula (3):

$$E = 100 \cdot \left(\frac{h_1 - h_2}{h_0} \right) \tag{3}$$

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;

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 7.7.4.

7.8.5 Pass/fail determination and expression of results

See 6.4 and 6.5.

7.9 Minimum time in the oral cavity and compression set for bite registration materials

7.9.1 Apparatus

The apparatus is the same apparatus as used in the working time test (see 7.3 and Figure A.3).

7.9.2 Specimen preparation

For the preparation of the specimen, proceed as described in 7.3.

7.9.3 Test procedure

NOTE 1 The test can be combined with the working time test, as the first part is identical and the working time specified for the material is less than 45 s.

NOTE 2 As far as known, there is no bite registration material available that has a working time of more than 45 s.

Start the test as described in 7.3.2.1 to 7.3.2.4. Then proceed as follows.

a) As soon as plate has reached the target position, but not longer than 45 s after the application of the material, hot water (35 ± 1) °C is added within 5 s that shall cover the sample completely (alternatively, the entire set up can be placed into a water bath).

b) After the minimum time in the oral cavity has elapsed, as specified in the instructions for use and measured from the point of water addition, the holding pin (see Figure A.3) is removed.

c) After another 30 s, the additional load is removed and the end position is read from the dial gauge after another 60 s as reading c.

7.9.4 Evaluation

If the test plate has reached the target position (Abs(b -c) < 0,1 mm), the material has passed the test. Otherwise, the material has failed.

7.9.5 Pass/fail determination and expression of results

See 6.4 and 6.5.

7.10 Hardness of bite registration materials

7.10.1 Apparatus

7.10.1.1 Wrinkle-free **polyethylene foil**, approximately 50 mm × 30 mm, 0,035 mm in thickness (two sheets per test specimen).

7.10.1.2 Glass, polymer or metal plates, approximately 50 mm × 30 mm, at least 3 mm in thickness.

7.10.1.3 Spacers, of metal, (> 6) mm in height, e.g. ring mould.

7.10.1.4 Water bath, (35 ± 2) °C.

7.10.1.5 Shore durometer, according to ISO 48-4:2018, Type A.

7.10.2 Specimen preparation

At least 1 ml of mixed jaw relation recording material is applied to a glass plate (7.10.1.2) covered with polyethylene foil (7.10.1.1) and spacers (7.10.1.3) on the latter. The arrangement is covered with a polyethylene foil and pressed against a glass plate to prepare a test specimen with plane and plane-parallel surfaces, (> 6) mm and at least 5 cm in diameter. The arrangement is submerged for hardening into a water bath (7.10.1.4) for the time specified as minimum duration in the instructions for use. This is immediately followed by removal of the test specimen from the mould and its setting to the temperature specified for testing (23 ± 2) °C.

7.10.3 Test procedure

Conduct the test according to ISO 48-4:2018, 60 min from start of mixing.

Place the test specimen on a hard, horizontal, plane surface. Hold the durometer (7.10.1.5) in a vertical position with the point of the indenter at least 9 mm away from any edge of the test specimen. Apply the presser foot to the test specimen as rapidly as possible, without shock, keeping the foot parallel to the

surface of the test specimen. Apply just sufficient pressure to obtain firm contact between the presser foot and the test specimen.

NOTE Better reproducibility can be obtained by using either a durometer stand or a weight centred on the axis of the indenter, or both, to apply the presser foot to the test specimen. Recommended mass is 1 kg for the type A durometer.

Read the scale of the indicating device after 3 s.

7.10.4 Evaluation

Make five measurements of hardness at different positions on the test specimen at least 6 mm apart and determine the mean value. The specimen has passed the test if the mean value is not less than the value specified in Table 1.

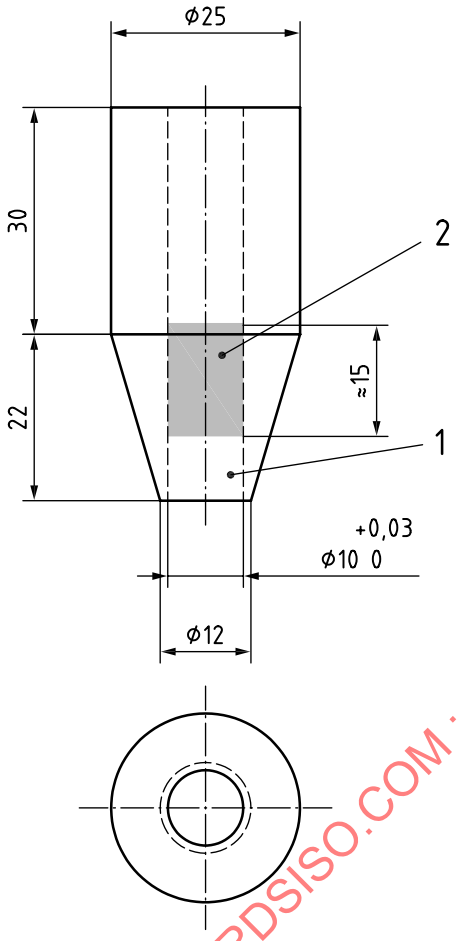
7.10.5 Pass/fail determination and expression of results

After the evaluation of five specimens, additionally make a pass/fail determination according to 6.4 and 6.5.

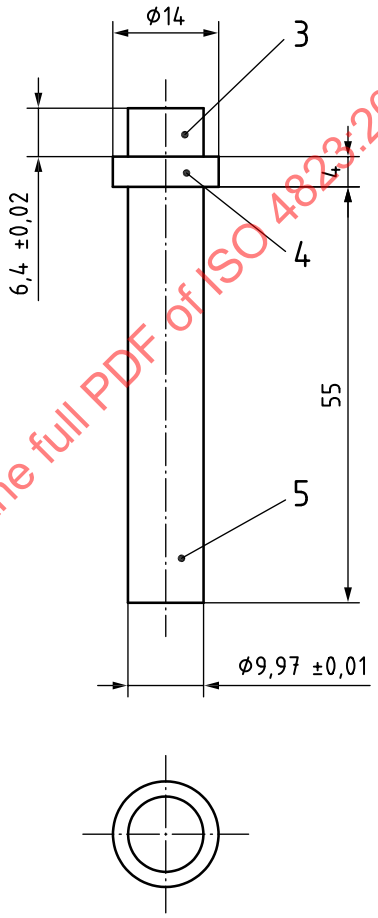
Annex A
(normative)

Figures

Dimensions in millimetres



a) Dispensing tube[a]



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

Key

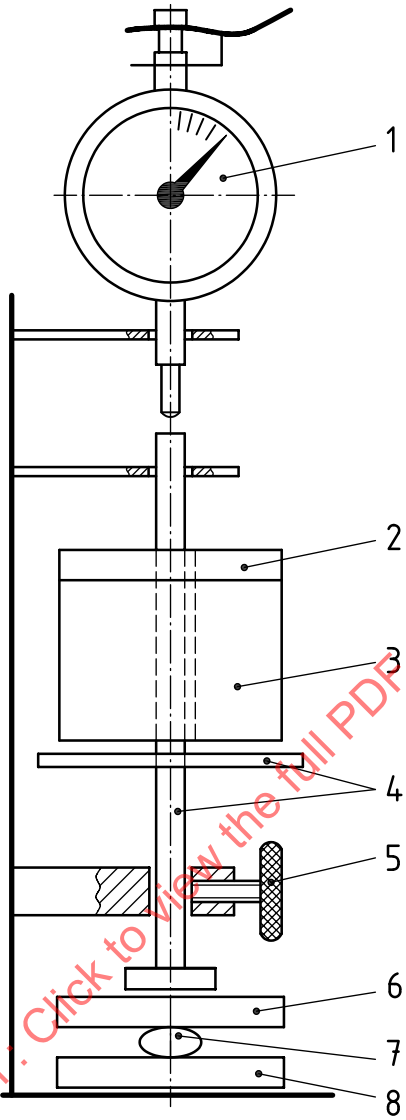
1 cavity equal in volume to that of the increment of material [(0,50 ± 0,2) ml] needed for the test
2 elastomeric plug for forming the floor of the cavity
3 depth gauge for positioning the plug
4 depth gauge stop
5 increment-extruding end of plunger

[a] Dispensing tube is made of PTFE or acetal.
[b] Plunger is made of rigid metal or polymeric material.

NOTE 1 Other dimensions can be used when making these parts provided that the dispensing tube bore and the depth gauge are mated such that the cavity produced has a volume of (0,5 ± 0,2) ml and provided 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.

Figure A.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 and a total force of (12,8 ± 0,1) N needed for the working time test of Type 0 materials

3 weight having a mass which, along with the mass of item 4, will provide for the total force of (12,3 ± 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 (1,2 ± 0,1) N needed for the strain in compression test

5 locking screw

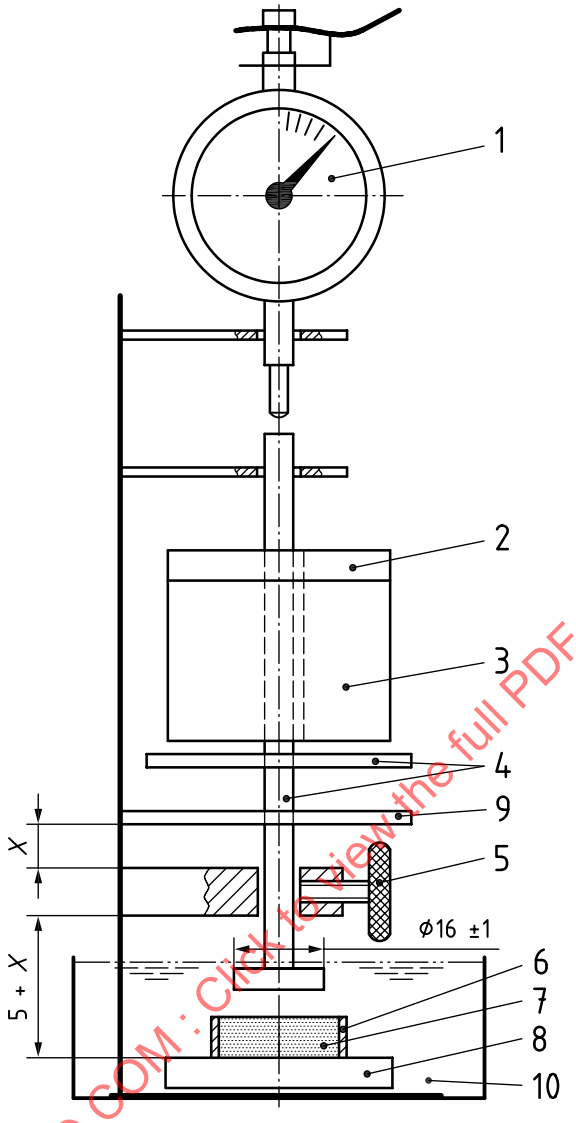
6 loading plate

7 specimen increment

8 base plate

Figure A.2 — Apparatus for consistency and strain in compression tests

Dimensions in millimetres



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 and a total force according to Table 2 needed for the working time test of Type 0 to 4 materials

3 weight having a mass which, along with the mass of item 4, will provide for the total force of (12,3 ± 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 (1,2 ± 0,1) N needed for the strain in compression test

5 locking screw with lower rest

6 ring mould

7 specimen increment

8 base plate

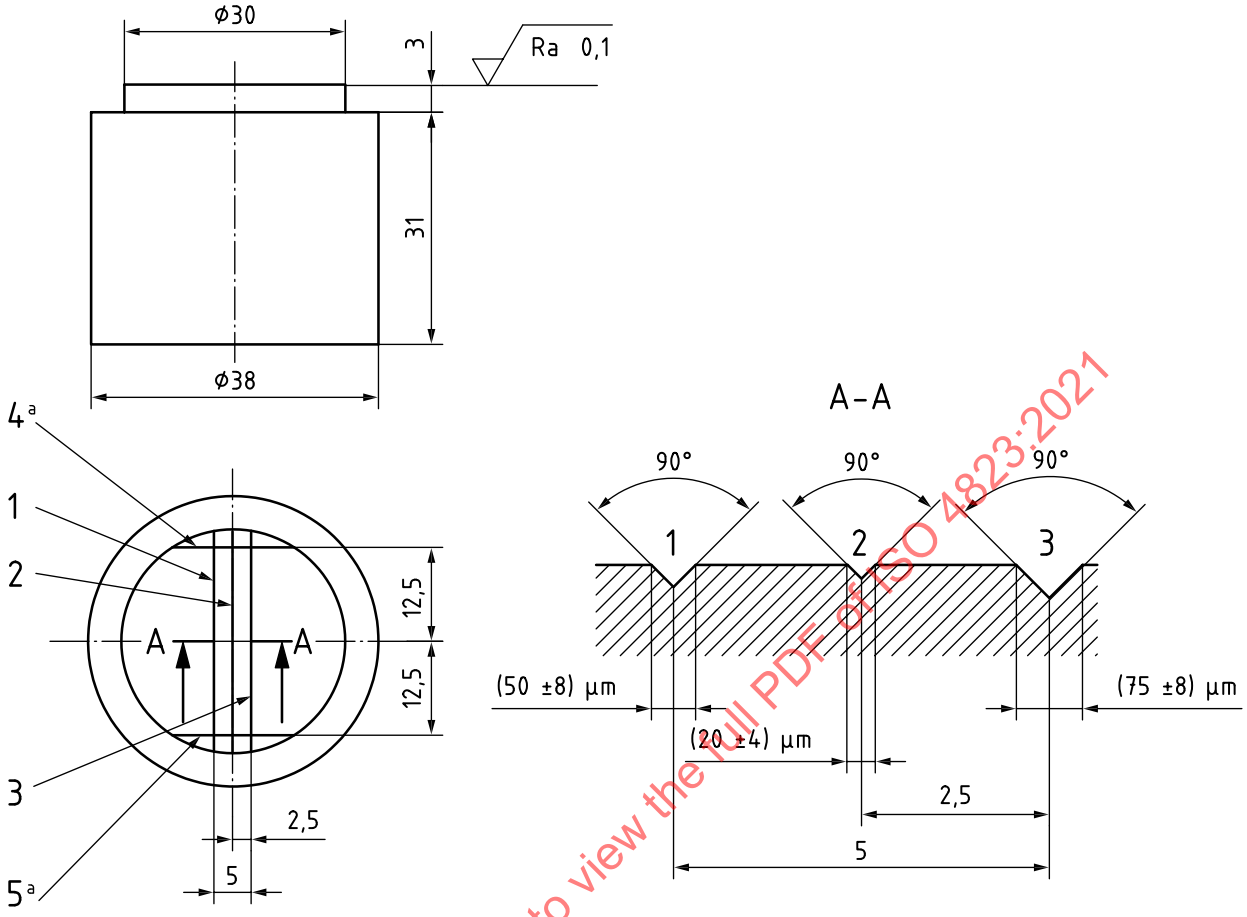
9 holding pin

10 water bath

NOTE Any other device instead of the holding pin allowing to limit the downward movement of the loading shaft to 5 mm + *x* is acceptable.

Figure A.3 — Device for working time and time in oral cavity testing (type B materials) and compression set (type B materials)

Dimensions in millimetres



Key

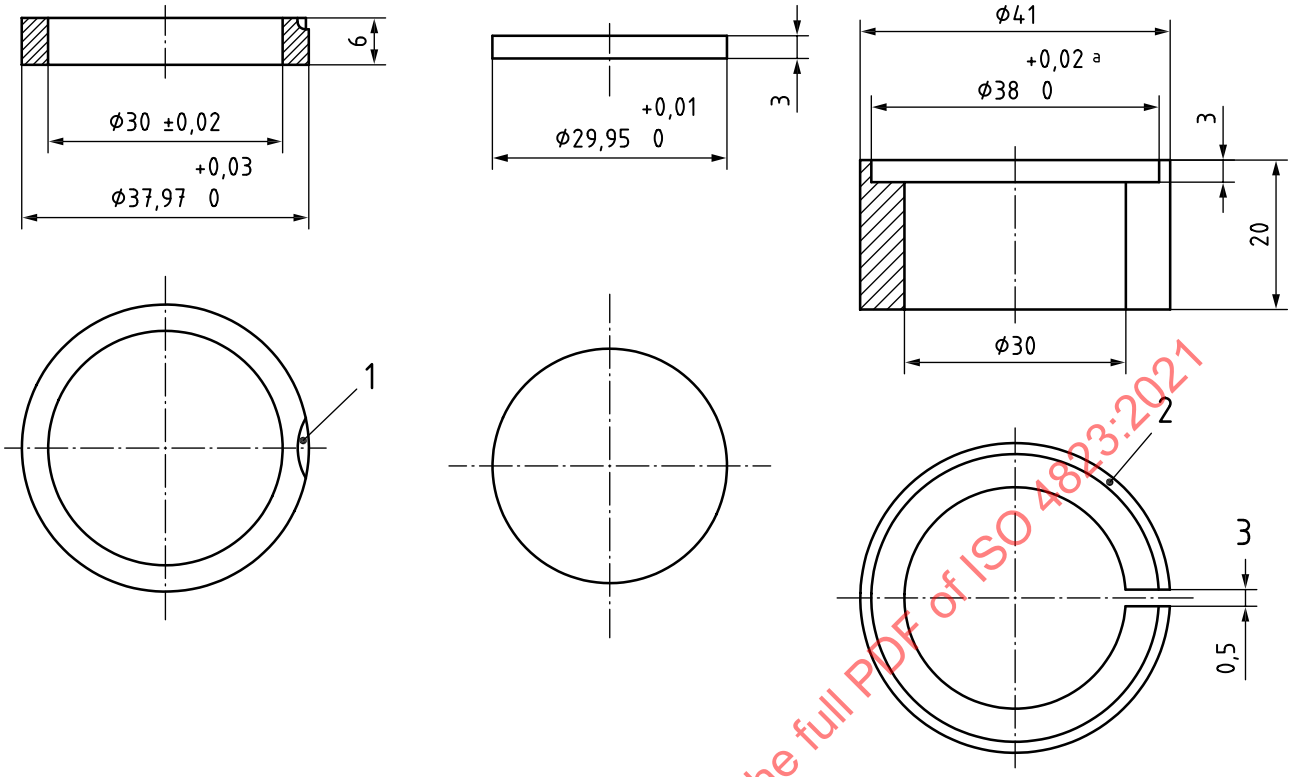
1 line a
2 line b
3 line c
4 line d_1
5 line d_2
[a] Has the same width as line c.

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 and material is cast or wrought austenitic stainless steel.

Figure A.4 — Test block for detail reproduction and tests for compatibility with gypsum

Dimensions in millimetres



a) Ring mould[a] **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 A.5 — Accessories for detail reproduction and tests for compatibility with gypsum