
Dentistry — Refractory investment and die material

*Médecine bucco-dentaire — Revêtements et matériaux pour
modèles réfractaires*





COPYRIGHT PROTECTED DOCUMENT

© ISO 2016, Published in Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

	Page
Foreword	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Classification	3
5 Requirements	3
5.1 General	3
5.2 Material consistency and freedom from contamination	3
5.3 Fluidity	3
5.4 Initial setting time	4
5.5 Compressive strength	4
5.6 Linear thermal dimensional change	4
5.7 Adequacy of expansion of Type 1 and Type 2 materials	4
6 Sampling, test conditions and mixing	4
6.1 Sampling	4
6.2 Test conditions	4
6.3 Mixing	5
6.3.1 Apparatus	5
6.3.2 Procedure	5
7 Test methods	5
7.1 Material consistency and freedom from contamination	5
7.1.1 Test procedure	5
7.1.2 Test report	5
7.2 Fluidity	5
7.2.1 Apparatus	5
7.2.2 Number of test-pieces	6
7.2.3 Test procedure	6
7.2.4 Evaluation of results	6
7.2.5 Test report	6
7.3 Initial setting time	7
7.3.1 Apparatus	7
7.3.2 Procedure	9
7.3.3 Number of determinations	9
7.3.4 Evaluation of results	10
7.3.5 Test report	10
7.4 Compressive strength	10
7.4.1 Apparatus	10
7.4.2 Number of test-pieces	10
7.4.3 Preparation of test-pieces	11
7.4.4 Test procedure	11
7.4.5 Evaluation of results	12
7.4.6 Test report	12
7.5 Linear thermal dimensional change	12
7.5.1 Apparatus	12
7.5.2 Number of test-pieces	13
7.5.3 Preparation of the test-piece	13
7.5.4 Test procedure for the measurement of linear thermal expansion of Types 1, 2 and 3 products	14
7.5.5 Test procedure for the measurement of linear thermal dimensional changes of a Type 4 product	15
7.5.6 Evaluation of results	15
7.5.7 Test report	16

7.6	Adequacy of expansion of Type 1 and Type 2 products.....	16
7.6.1	General.....	16
7.6.2	Type 1 and Type 2 products intended for casting of dental metallic materials.....	17
7.6.3	Type 1 products intended for dental pressable-ceramic products.....	18
7.6.4	Evaluation of results.....	20
7.6.5	Test report.....	20
8	Manufacturer's instructions.....	20
8.1	General.....	20
8.2	Information for use.....	20
8.3	Physical properties.....	21
8.4	Safety labelling and instructions for a product containing silica.....	22
9	Marking.....	22
9.1	General.....	22
9.2	Powder container.....	22
9.2.1	Outer container.....	22
9.2.2	Individual packets.....	23
9.3	Liquid container.....	23
10	Packaging.....	23
10.1	Powder.....	23
10.2	Liquid.....	24
	Bibliography.....	25

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.

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).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: [Foreword - Supplementary information](#)

The committee responsible for this document is ISO/TC 106 *Dentistry*, Subcommittee SC2, *Prosthetic Materials*.

This second edition cancels and replaces the first edition (ISO 15912:2006), which has been technically revised. It also incorporates the Amendment ISO 15912-1:2006/Amd 1:2011.

In this edition, dental pressable-ceramic investment materials are included in the Scope for the first time. These products are intended for the production of ceramic crowns and inlays and, as such, the same requirements as those for an investment product intended for the production of metallic crowns and inlays by casting are relevant (Type 1, according to the classification in this standard).

The previous edition contained requirements and test methods that had been developed for discontinued composition specific standards. In recent years products have been introduced that have other chemistries (for the binder and the refractory phase), specifically to minimize chemical reaction between the mould and the molten casting metallic material. A number of technical changes have been made to enable all dental casting investment products, regardless of their composition, to seek compliance with this International Standard and maintains the agreed philosophy that this International Standard should be inclusive, application-driven and not be limited by composition considerations.

Where appropriate, aspects of the test procedures have been changed to follow the manufacturer's instructions for use. The requirement for thermal dimensional change now takes into account the cooling of some products (after burn-out) to a lower casting temperature. The specification for the dilatometer has been changed for it to be compatible with the heating — and where relevant, the cooling after burn-out — of the product to the casting temperature.

The procedure for determining the initial setting time has been revised to harmonize with that present in the latest edition of the standard for dental gypsum products, ISO 6873:2013.^[1] Although substantially editorial, there are technical changes.

Information for use now requires a statement of the type of refractory phase(s) that is (are) present.

ISO 15912:2016(E)

Labelling requirements for products that contain silica have been revised to comply with the current United Nations Globally Harmonized System for Classification and Labelling of Chemicals (UN GHS)^[2] and recommendations for silica as a hazardous material.

Containers of liquid must be marked to indicate the use to which the liquid is put.

Dentistry — Refractory investment and die material

1 Scope

This International Standard gives requirements and test methods for determining the compliance of dental casting investment, dental brazing investment, dental pressable-ceramic investment and dental refractory die materials used in the dental laboratory, regardless of the composition of the refractory powder, the composition of the binder, or the particular application.

This International Standard classifies such products into types and classes, according to their intended use and the burn-out procedure recommended by the manufacturer.

It also gives requirements for marking, labelling and manufacturer's instructions.

It specifies requirements for the essential physical and mechanical properties of the products and the test methods to be used for determining them.

NOTE 1 Compliance with all of the requirements presented in [Clause 5](#) may not be necessary for some products, and a requirement might not be applicable to a product with a particular binder chemistry or be intended for an application in which that requirement is irrelevant. When this is the case, a clear statement to this effect is given according to [Clause 5](#).

NOTE 2 A specific quantitative requirement for setting expansion is not included in this International Standard. If the setting expansion of gypsum-bonded investment is measured, then the procedure given in ISO 6873[4] can be considered — a procedure not recommended, however, for investment materials with other binders.

2 Normative references

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

ISO 286-2, *Geometrical product specifications (GPS) — ISO code system for tolerances on linear sizes — Part 2: Tables of standard tolerance classes and limit deviations for holes and shafts*

ISO 1942, *Dentistry — Vocabulary*

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

ISO 6344-1, *Coated abrasives — Grain size analysis — Part 1: Grain size distribution test*

ISO 6872, *Dentistry — Ceramic materials*

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

ISO 15854, *Dentistry — Casting and baseplate waxes*

ISO 22674, *Dentistry — Metallic materials for fixed and removable restorations and appliances*

3 Terms and definitions

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

3.1 dental casting investment material
powdered particulate refractory and binder system that is mixed with a specified liquid to produce a pourable fluid that sets around a pattern to form the mould for casting a dental metallic prosthesis

Note 1 to entry: In some products, the binder may be dispersed in the refractory powder and the product is supplied as a mixed powder. Alternatively, the chemistry of the binder may lead to it being present in a solution (to be used with the powder that is supplied) with part or none of it being dispersed in the refractory powder, as received.

Note 2 to entry: The specified liquid may be pure water, an aqueous binder solution, or an aqueous solution to enhance expansion.

3.2 dental refractory die material
powdered particulate refractory and binder system that is mixed with a specified liquid to produce a fluid that sets (and is designed specifically) to form of a hard die, suitable for the production of a dental ceramic prosthesis using the sintering technique

3.3 dental brazing investment material
powdered particulate refractory and binder system that is mixed with a specified liquid to produce a fluid that sets (and is designed specifically) to form a cast upon which metallic components are held, or are partly embedded, accurately in place while they are joined by brazing

Note 1 to entry: The cast may be referred to as the model, though that is a deprecated term.

3.4 dental pressable ceramic investment
powdered particulate refractory and binder system that is mixed with a specified liquid to produce a pourable fluid that sets around a pattern to form a mould into which a dental pressable-ceramic, softened by heating, can be forced under pressure

3.5 special liquid
liquid, other than water, supplied by the manufacturer for mixing with the dental casting investment powder for the purpose of increasing the expansion of the mould

3.6 slow- or step-heating method
heating method in which (at a time after setting that is recommended by the manufacturer) the dental casting investment mould, or dental pressable-ceramic mould, or dental brazing investment cast or dental refractory die is placed in a burn-out furnace set at room temperature, after which the temperature of the furnace is increased to the end temperature in a series of stages and at a programmed rate recommended by the manufacturer

3.7 quick-heating method
heating method in which (at a time after setting that is recommended by the manufacturer) the dental casting investment mould, or dental pressable-ceramic mould, or dental brazing investment cast, or dental refractory die is placed directly into the hot burn-out furnace that is set and held at the burn-out temperature recommended by the manufacturer

3.8 burn-out temperature
<Types 1 and 2 materials> temperature to which the mould is heated to burn off the pattern material and expand the mould

3.9 burn-out temperature
<Type 3 material> temperature to which the cast is heated to burn off any material used for shielding and accurately locating the components to be brazed, and to expand the cast

3.10**burn-out temperature**

<Type 4 material> temperature to which the die is heated initially to burn off the pattern material

3.11**casting temperature**

<Types 1 and 2 materials intended for casting a dental metallic material> temperature of the mould at which the molten metallic material is forced into the mould

3.12**ceramic pressing temperature**

<Type 1 investment materials intended for use with dental pressable-ceramics> temperature at which the mould and ceramic ingot are taken and at which the ceramic is pressed into the mould

Note 1 to entry: The mould is placed in a burn-out furnace at a lower temperature and held at this temperature before the pressable-ceramic ingot is placed in the crucible of the mould, after which both are transferred to the pressing furnace, that is at, or is raised to, a higher temperature to soften the ceramic ingot

3.13**green state**

condition of the material immediately after setting before structural changes are brought about by aging or burn-out, changes that produce increased strength or further dimensional changes

4 Classification

For the purposes of this International Standard, dental casting investment, dental brazing investment, dental pressable-ceramic investment and dental refractory die materials are classified into the following types, according to the intended application:

- Type 1, for the construction of inlays, crowns and other fixed prostheses;
- Type 2, for the construction of complete or partial dentures or other removable appliances;
- Type 3, for the construction of casts used in brazing procedures;
- Type 4, for the construction of refractory dies.

In addition, the materials are divided into two classes: Class 1 is recommended for burn-out by a slow- or step-heating method; Class 2 is recommended for burn-out by a quick-heating method.

5 Requirements**5.1 General**

If a manufacturer claims suitability for both classes, then the material shall satisfy the requirements when it is subjected to both heating techniques. This applies to requirements [5.5](#) and [5.6](#) and, if appropriate, requirement [5.7](#).

5.2 Material consistency and freedom from contamination

When examined in accordance with [7.1](#), the powder shall be uniform and free of lumps and foreign matter. If a special liquid is supplied, it shall be free of sediment.

5.3 Fluidity

When measured in accordance with [7.2](#), the fluidity shall not vary by more than 30 % from the value stated by the manufacturer [according to [8.3 a](#)]).

This requirement does not apply to silica bonded investments (i.e. products in which an alcoholic solution of ethyl silicate is used in the binding system).

5.4 Initial setting time

When measured in accordance with 7.3, the initial setting time shall not vary by more than 30 % from the value stated by the manufacturer [according to 8.3 b)]. If the manufacturer gives a range for the initial setting time, then the measured initial setting time shall not vary by more than 30 % from the mid-point of this range.

5.5 Compressive strength

When measured in accordance with 7.4, the compressive strength of a test-piece shall not be less than 70 % of the value stated by the manufacturer [according to 8.3 c)] and in no case shall be lower than 2 MPa.

5.6 Linear thermal dimensional change

When measured in accordance with 7.5, the linear thermal expansion, for all four Types, shall not vary by more than 20 % from the value stated by the manufacturer [according to 8.3 d)]. If the manufacturer gives a range for the linear thermal expansion, then the measured linear thermal expansion shall not vary by more than 20 % from the mid-point of this range.

When measured in accordance with 7.5, the linear firing shrinkage for a Type 4 material shall not vary by more than 15 % from the value stated by the manufacturer [according to 8.3 e)]. If the manufacturer gives a range for the linear firing shrinkage, then the measured linear firing shrinkage shall not vary by more than 15 % from the mid-point of this range.

5.7 Adequacy of expansion of Type 1 and Type 2 materials

When cast in accordance with 7.6, the diameter of the cast metallic disc, or when pressed in accordance with 7.6, the diameter of the pressed ceramic disc (as is appropriate) with respect to the diameter of the pattern from which it was made, shall be

- a) no smaller than 99,5 % in case of a Type 1 material;
- b) no smaller than 99,0 % in case of a Type 2 material.

This does not apply to either dental brazing investment material, Type 3, or dental refractory die material, Type 4.

6 Sampling, test conditions and mixing

6.1 Sampling

Use material from a single lot in packages that have been produced for retail. Use only sealed, undamaged packages (i.e. packets and containers) that have not exceeded the “use before” date.

6.2 Test conditions

Carry out all testing in a controlled atmosphere: $(23 \pm 2) ^\circ\text{C}$, $(50 \pm 10) \%$ relative humidity and free from obvious draughts.

Holding the material and all test equipment under these controlled conditions for a minimum period of 15 h prior to testing is recommended.

6.3 Mixing

Mix according to the manufacturer's instructions. When a special liquid is supplied, use it at the manufacturer's recommended dilution according to 8.2 d). If water is required, use water that complies with Grade 3 according to ISO 3696.

If a range is given in 8.2 e) for the powder to liquid ratio, or in 8.2 d) for the dilution of the special liquid, use the midpoint of this range to produce a mix for determining compliance with requirements 5.3, 5.4, 5.5 and 5.6.

6.3.1 Apparatus

The following items may be needed, depending on the manufacturer's instructions:

- a) **mixing bowl**, clean, dry, flexible, for hand mixing;
- b) **spatula**, rigid for hand mixing;
- c) **vacuum mixer** with an appropriate clean and dry mixing bowl;
- d) **timer**, capable of measuring time to an accuracy of 1 s.

6.3.2 Procedure

Measure the required mass of powder and the recommended volume of liquid, each to an accuracy of 1 %.

Pour the liquid into the mixing bowl and add the powder. Commence timing when liquid and powder make first contact.

Hand spatulate and/or mix mechanically (with a vacuum, if specified) for the appropriate period, according to manufacturer's instructions. If the manufacturer recommends a range of mixing times, use the mid-point of the range.

7 Test methods

7.1 Material consistency and freedom from contamination

7.1.1 Test procedure

Examine the material, as received, visually without the aid of magnification. Use eyesight that has nominally normal visual acuity. Corrective (non-magnifying) lenses may be worn.

7.1.2 Test report

Report whether the product meets, or does not meet, the requirement for material consistency and freedom from contamination (5.2). If it does not meet this requirement, state the reason.

7.2 Fluidity

7.2.1 Apparatus

7.2.1.1 Clean and dry **cylindrical ring mould**, having a length (50 ± 1) mm, an inside diameter of (35 ± 1) mm that is made from a corrosion-resistant, non-absorbent material.

7.2.1.2 Flat square **glass plate**, with a glazed surface and measuring at least 150 mm × 150 mm.

7.2.1.3 Dental vibrator.

7.2.1.4 Scale or ruler, graduated in millimetres and at least 150 mm in length.

7.2.1.5 Mould-release agent, such as silicone spray or silicone grease.

7.2.2 Number of test-pieces

Make two test-pieces from two mixes of the material.

Three more test-pieces (from three mixes of the material) are required if the result from one test-piece meets the requirement specified in [5.3](#) and the other does not.

7.2.3 Test procedure

Coat the inside of the ring mould with a thin layer of mould release agent.

Mix according to [6.3](#), using a mass of powder with the appropriate volume of liquid to produce a mix that is sufficient to fill the mould. Centre the mould on the glass plate and place the plate on the dental vibrator platform. Vibrate the mix into the mould until it is slightly overfilled. Vibrate for a further (20 ± 2) s. After this time, do not vibrate. Level the mix flush with the top of the mould and remove the excess from the plate. 30 s after the end of mixing, lift the mould vertically from the plate using a smooth action over a period of 5 s to allow the column of mix to slump onto the plate. As soon as the material has set, measure the largest and smallest diameters on the base of the set test-piece to an accuracy of 1 mm, and record the average value as the first result.

Repeat the test and record the second result, being the average of the two measurements made on the second test-piece.

7.2.4 Evaluation of results

If both results meet the requirement ([5.3](#)), the product complies.

If neither result meets this requirement, then the product fails to comply.

If the result of one test meets this requirement and one fails to do so, repeat the test three more times.

If the results of all three of these additional tests meet the requirement ([5.3](#)) then the product complies. Otherwise, it fails to comply.

7.2.5 Test report

Report

- a) the result for every test conducted in accordance with [7.2.3](#), including those for additional test-pieces (if these were required) and the average value (to 1 mm) for the results of those test-pieces that comply with the requirement ([5.3](#));
- b) the value for the fluidity given by the manufacturer according to [8.3 a](#));
- c) a statement that the product meets or does not meet the requirement for fluidity ([5.3](#)).

7.3 Initial setting time

7.3.1 Apparatus

7.3.1.1 Needle penetrometer, an example of which is shown in [Figure 1](#), meeting the specifications of [7.3.1.1.1](#) to [7.3.1.1.5](#). The total mass of all parts that move (i.e. penetrometer needle, rod, scale and compensating weight) shall be (300 ± 1) g.

7.3.1.1.1 Penetrometer needle (1), circular cross section with a squared-off end: length (50 ± 1) mm, diameter 1,00 mm with a dimensional tolerance of h6 according to ISO 286-2.

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

7.3.1.1.3 Additional (compensating) weight (3).

7.3.1.1.4 Scale (4), graduated in millimetres.

7.3.1.1.5 Base-plate (6) of plate glass, measuring about 100 mm × 100 mm.

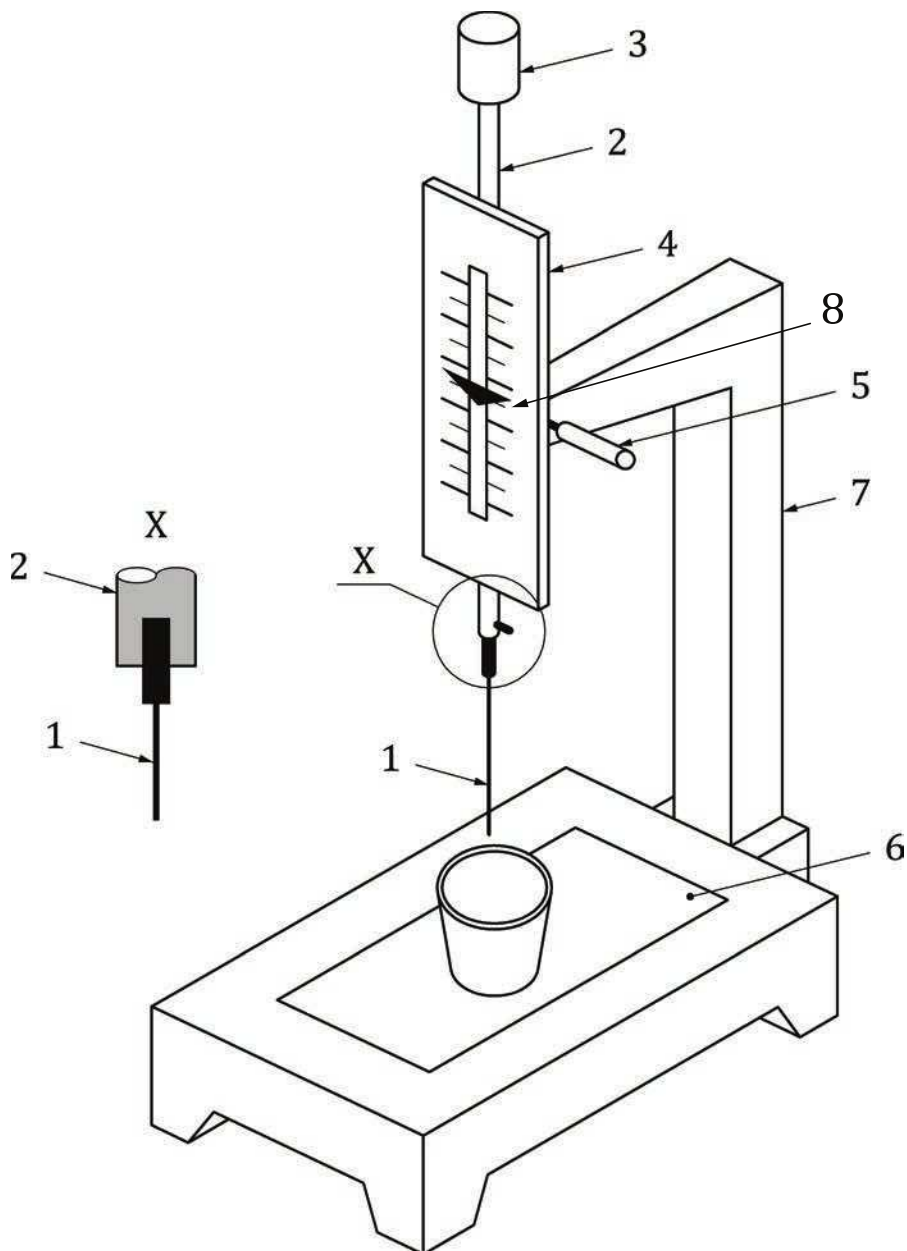
7.3.1.2 Ring mould, made from a corrosion-resistant, non-absorbent material, of which are two types.

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

7.3.1.2.2 Small cylindrical mould, with an inside diameter of 30 mm and height of 25 mm.

For effective utilization of resources, the smaller mould may be used in the place of the larger mould. The user will need to be aware that the lesser area of the small cylindrical mould allows fewer indentation sites (according to [7.3.2](#)) and as a consequence greater attention should be given to the time (relative to the anticipated setting time) of the first indentation.

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



Key

- 1 penetrometer needle
- 2 rod
- 3 additional (compensating) weight
- 4 scale
- 5 scale adjustment locking screw
- 6 base-plate
- 7 stand
- 8 indicator

NOTE A ring mould is shown in place on the base-plate.

Figure 1 — Example of needle penetrometer

7.3.2 Procedure

Adjust the vertical position of scale on the penetrometer for the indicator to read zero when the needle is in contact with the base-plate and then lock the scale in this position by using the scale adjustment locking screw. For this design, the scale is adjustable to allow zeroing (the zero point on the scale is at the upper end). The scale is attached to the rod and moves (relative to the fixed indicator) when the rod is raised. An alternative design is possible and permitted if it produces the same relative movement between the scale and indicator, to record the movement of the needle.

Coat the inside of the ring mould with a thin layer of mould release agent and place the mould on the base-plate.

Mix the material according to [6.3](#), using a mass of powder with the appropriate volume of liquid to produce a mix that is sufficient to fill the mould.

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

Continue to run the timer that is used during mixing after mixing is completed. Use the time displayed as the reference time for subsequent timed actions.

With the ring mould positioned beside the needle, overfill the ring mould with the mix and then level the surface to be flush with the top of the mould. Beginning at a time that is before half the initial setting time given by the manufacturer [according to [8.3 b](#))], make the first reading as follows.

- a) Raise the rod for the needle to be above the surface of the mix. Reposition the mould to allow penetration of the material at a site which is at least 10 mm from the wall of the larger mould, or 5 mm from the wall of the smaller mould.
- b) Bring the needle tip into contact with the surface of the mix and hold.
- c) Release the rod gently and record the time of this release. Allow it to sink through the material under the force from the 300 g mass. Raise the rod as soon as the needle has penetrated a depth that is within 5 mm from the base-plate.

NOTE It is not necessary to wait until the needle has touched the base-plate. Readings are taken at (15 ± 1) s intervals and for this to be achieved there must be sufficient time after raising the rod for steps [7.3.2 d](#)) and e) to be completed before the rod is released for the next penetration, [7.3.2 f](#)).

Take subsequent readings, at (15 ± 1) s intervals after the release time recorded for first reading, as follows.

- d) With the rod raised above the surface of the mix, move the mould to allow the next penetration to be on a new area, which is at least 10 mm or 5 mm from the mould wall (as is appropriate for the mould size) and 5 mm from any other penetration mark.
- e) Wipe the needle clean and then bring its tip into contact with the surface of the mix. Hold.
- f) At the appropriate time, release the rod gently. Record this time. Allow the needle to sink through the material (under the force from the 300 g mass) until it has penetrated to a depth within 5 mm from the base. Then, raise the rod.
- g) Record the setting time as the total time from the start of mixing to the time at which the needle fails to penetrate the mix to a depth within 5 mm from the base plate.

7.3.3 Number of determinations

Determine the initial setting time twice. Use the procedure in [7.3.2](#) with freshly-mixed material for each determination.

7.3.4 Evaluation of results

If both results meet the requirement (5.4), the product complies.

If neither result meets this requirement, then the product fails to comply.

If one result meets the requirement and one fails to meet the requirement, repeat the test three more times.

If all three of these additional results meet the requirement (5.4) the product complies. Otherwise, it fails to comply.

7.3.5 Test report

Report

- a) the initial setting time for every test (including additional tests) (to 0,25 min) conducted in accordance with 7.3.2;
- b) the initial setting time or setting time range, given by the manufacturer according to 8.3 b);
- c) a statement, that the product meets, or does not meet, the requirement for the initial setting time (5.4).

7.4 Compressive strength

7.4.1 Apparatus

7.4.1.1 one or more **sectional or split moulds**, the ends of which shall be parallel to within 0,05 mm, made from a corrosion-resistant material to produce cylindrical test-pieces having a diameter of $(20,0 \pm 0,2)$ mm and a length of $(40,0 \pm 0,4)$ mm.

7.4.1.2 For silica bonded investments, alone, one or more **sectional or split mould extensions**, made from a corrosion-resistant material and having an internal diameter of $(20,0 \pm 0,2)$ mm and a length of $(20,0 \pm 0,4)$ mm.

7.4.1.3 Wax: sticky wax and sheet moulding wax, to be used as appropriate.

7.4.1.4 Flat glass plates, glazed and sufficient in size and number, to cover both ends of all moulds.

7.4.1.5 Dental vibrator.

7.4.1.6 Universal mechanical testing machine, 10 kN capacity and capable of measuring force to an accuracy of $\pm 0,5$ N, with attachments for compression testing.

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

7.4.1.8 Micrometer screw gauge or similar measuring instrument, for measuring to an accuracy of 0,02 mm over a range from 0,00 mm to 25,00 mm.

7.4.1.9 for silica bonded investments alone, **dental trimmer.**

7.4.2 Number of test-pieces

Prepare five test-pieces from at least two mixes. Make a maximum of three test-pieces from a single mix.

If a sufficient number of moulds and glass plates (and if required, with mould extensions) are available, more than one test-piece may be made from a single mix.

Five more test-pieces (from at least two more mixes) are required if three test-pieces meet the requirement (5.5) and two do not.

7.4.3 Preparation of test-pieces

7.4.3.1 Products other than those that are silica bonded

Coat the inside surface of each mould with a thin layer of the mould release agent. Place each mould on a glass plate.

Mix according to 6.3, using a mass of powder with the appropriate volume of liquid that will produce a mix sufficient to fill a minimum of one mould. Slightly overfill the mould, while applying light vibration using the dental vibrator. Stop vibration before the glossy surface has disappeared from the mix. As soon as the glossy surface has completely disappeared from the mix, place a second glass plate on the top of the mould and press it down until the glass contacts the mould.

Remove the test-piece from the mould (60 ± 5) min after the start of mixing and hold in air at a temperature of (23 ± 2) °C and a relative humidity of (50 ± 10) %.

7.4.3.2 Silica bonded products

Coat the inside surface of the mould and the mould extension with a thin layer of the mould release agent. Place the mould on a glass plate. Add the mould extension to the top mould surface and attach it with wax.

Mix according to 6.3, using a mass of powder with the appropriate volume of liquid that will produce a mix sufficient to fill a minimum of one mould with the mould extension. Slightly overfill the mould and mould extension with the mix, while applying light vibration using the dental vibrator. Stop vibration before the glossy surface has disappeared from the mix. Remove the mould extension from the mould at the initial setting time indicated by the manufacturer [according to 8.3 b)]. Using the dental trimmer, trim the specimen to be flat and level with the top of the mould. If given, use the trimming technique recommended by the manufacturer in the product information. Finish using an appropriate scraping or grinding procedure, such that top surface is flat and parallel with the bottom surface, to within 0.05 mm.

Remove the test-piece from the mould (60 ± 5) min after the start of mixing and hold in air at a temperature of (23 ± 2) °C and a relative humidity of (50 ± 10) %.

If the manufacturer states [(in 8.3 b)] that the initial setting time of the product exceeds 65 min, remove the test-piece from the mould at the time given in 8.3 b) and hold in air at a temperature of (23 ± 2) °C and a relative humidity of (50 ± 10) %.

If given, follow the manufacturer's instructions on the treatment of the material following setting and prior to heating the mould to the burn-out temperature.

NOTE For example, immersion in a resin or oven drying are treatments that may be advised following setting.

7.4.4 Test procedure

Prior to testing, measure and record the diameter of each test-piece to an accuracy of 0,02 mm.

Commence the compression testing of each test-piece (120 ± 5) min from the start of mixing.

If the manufacturer's instructions on the treatment of the material following setting (before it is heated to the burn-out temperature) includes an action that leads to a time in excess of 125 min from the start of mixing before it is possible to apply the compressive force, commence the compression test immediately after the treatment has been completed. Record the time at which the force is applied.

ISO 15912:2016(E)

Position the test-piece between the compression platens of the universal mechanical testing machine such that the test-piece is loaded in an axial direction. Do not use padding between the test-piece and the platens. Apply an increasing compressive force at a loading rate of (5 ± 2) kN/min until fracture occurs. Record the compressive force at which fracture occurs, to the nearest newton.

7.4.5 Evaluation of results

For each test-piece, calculate the compressive strength as follows;

$$S = \frac{4F}{\pi D^2} \quad (1)$$

where

- S is the compressive strength (the maximum stress) in MPa;
- F is the force at which fracture occurs (the maximum recorded force) in N;
- D is the diameter of the test-piece in mm.

If the results for four or five test-pieces meet the requirement (5.5), the product complies.

If two or fewer results for test-pieces meet the requirement (5.5) the product fails to comply.

If only three results for the test-pieces meet the requirement (5.5), make a second set of five test-pieces (in accordance with 7.4.3) and load all five to fracture according to 7.4.4.

If all the results in this second set meet the requirement (5.5) the product complies. Otherwise, the product fails to comply.

7.4.6 Test report

Report

- a) the compressive strength (to a precision of 0,05 MPa) for every test-piece (including those from the second set, if these were required) loaded to fracture in accordance with 7.4.4;
- b) the compressive strength given by the manufacturer, according to 8.3 c);
- c) if a manufacturer's recommended post-setting treatment resulted in testing at a time after 125 min from the start of mixing, the time at which the test-pieces were loaded to failure, as well as details of procedures that caused this increased time before the application of force;
- d) a statement that the product meets or does not meet the requirement for compressive strength (5.5).

7.5 Linear thermal dimensional change

7.5.1 Apparatus

7.5.1.1 Dilatometer.

7.5.1.1.1 General: An instrument that exerts a measuring force to produce a stress on the test-piece no greater than 10 kPa. It allows the measurement of the change in length of the initial length of the test-piece to an accuracy of 0,02 %, over the temperature range 23 °C to the highest temperature to which the test-piece is taken. The accuracy for temperature measurements shall be better than 5 °C.

7.5.1.1.2 For Class 1 materials: an instrument that can heat the test-piece at a rate of (5 ± 1) °C/min over the range 23° C to the highest temperature to which the test-piece is taken.

7.5.1.1.3 For Class 2 materials: an instrument that can heat the test-piece at a rate of (25 ± 5) °C/min over the range 23 °C to the highest temperature to which the material is taken.

7.5.1.2 Mould, made in a corrosion-resistant material for producing a cylindrical test-piece of a size that is compatible with the dilatometer. The test-piece shall have a uniform cross section along its length. The minimum length of the test-piece shall be 20 mm. The maximum size of the test-piece shall be 50 mm in length and 12 mm in diameter.

7.5.1.3 For silica bonded investments alone, a **cylindrical mould extension**, made in a corrosion-resistant material with the same internal diameter as the mould and having a length of $(20,0 \pm 0,4)$ mm.

7.5.1.4 Wax: sticky wax and sheet moulding wax, to be used as appropriate.

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

7.5.1.6 Micrometer screw gauge or similar measuring instrument, that allows the of measurement of test-piece dimensions to an accuracy of 0,02 mm for lengths up to 50,00 mm.

7.5.1.7 For silica bonded investments alone, **dental trimmer**.

7.5.1.8 Burn-out oven, for use with Type 4 products. When set to the burn-out temperature, this temperature is to be accurate to ± 5 °C.

7.5.1.9 Glass plate, 100 mm × 100 mm with flat glazed surfaces;

7.5.1.10 Dental vibrator.

7.5.2 Number of test-pieces

Make two test-pieces from two mixes.

Three more test-pieces (from three mixes) are required if the result from one test-piece meets the requirement ([5.6](#)) and other does not.

7.5.3 Preparation of the test-piece

7.5.3.1 Products other than those that are silica bonded

Coat the inside surface of the mould with a thin layer of the mould release agent. Place the mould on the glass plate.

Mix according to [6.3](#), using a mass of powder with the appropriate volume of liquid that will produce a mix that is sufficient to fill the mould. Slightly overfill the mould with the mix, while applying light vibration using the dental vibrator. Stop the vibration before the glossy surface has disappeared from the mix. As soon as the glossy surface has completely disappeared, scrape the material to make the end of the test-piece flat and level with the top of the mould.

Before the earliest burn-out time recommended by the manufacturer, remove the test-piece from the mould.

7.5.3.2 Silica bonded products

Coat the inside surface of the mould and the mould extension with a thin layer of the mould release agent. Place the mould on the glass plate.

Add the mould extension to the top surface of the mould and attach it with wax.

Mix according to [6.3](#), using a mass of powder with the appropriate volume of liquid that will produce a mix that is sufficient to fill the mould and its extension. Slightly overfill the mould and extension, while applying light vibration using the dental vibrator. Stop the vibration before the glossy surface has disappeared from the mix. Remove the mould extension from the mould at the initial setting time indicated by the manufacturer [according to [8.3 b](#)]]. Trim the test-piece using the dental trimmer to be flat and level with the top of the mould. If given, use the trimming technique recommended by the manufacturer in the product information. Finish using an appropriate scraping or grinding procedure, such that the top surface of the test-piece is flat and parallel with the bottom surface, to within 0,05 mm.

Before the earliest burn-out time recommended by the manufacturer, remove the test-piece from the mould.

If given, follow the manufacturer's instructions on the treatment of the material following setting prior to heating the mould to the burn-out temperature.

NOTE Immersion in a resin or oven drying are examples of treatments that may be advised following setting.

7.5.4 Test procedure for the measurement of linear thermal expansion of Types 1, 2 and 3 products

7.5.4.1 General

Measure the length of the test-piece to an accuracy of 0,02 mm.

Place the test-piece in the dilatometer. At the earliest burn-out time recommended by the manufacturer, raise the dilatometer temperature to the end temperature [according to [7.5.4.2](#)]] at a rate of (5 ± 1) °C/min for Class 1 materials or (25 ± 5) °C/min for Class 2 materials. Record the dilatometer readings continuously from ambient to the end temperature with the readings for the increase in the test-piece length measured to an accuracy of 0,02 % of the initial test-piece length and those for the temperature to an accuracy of 5 °C.

Hold the test-piece at the end temperature for the time recommended by the manufacturer in the "Instructions for burn-out", [8.2 i](#)). (If the end temperature is given without a holding time, hold for 15 min.)

Follow the procedure in [7.5.4.2](#) that is appropriate for the product Type.

7.5.4.2 Specific procedures for each product Type

7.5.4.2.1 Types 1 and 2 products

For Types 1 and 2 products intended for casting dental metallic materials, the end temperature is the burn-out temperature, if the recommendation is to cast when the mould is at the burn-out temperature, according to [8.2 i](#)). Determine the change in length of the test-piece at this temperature with respect to the initial length. Use the initial length and this change in length to calculate the linear thermal expansion at the casting temperature expressed as a percentage of the original length, to the nearest 0,1 %. Record this value. If for these materials the recommendation is to cool the mould to the casting temperature following burn-out, reduce the dilatometer temperature at a rate of (5 ± 1) °C/min for Class 1 materials or (25 ± 5) °C/min for Class 2 materials until the specified casting temperature [according to [8.2 i](#)]] is reached. Record the dilatometer readings continuously during this period with the change in length of the test-piece to an accuracy of 0,02 % of the initial test-piece length and the temperature to an accuracy of 5 °C. Determine the remaining length after cooling from the burn-out temperature. Use this value and the initial length to calculate the remaining linear thermal expansion at the casting temperature and express this as a percentage of the initial length to the nearest 0,1 %. Record this value.

For Type 1 products intended for use with dental pressable-ceramics, the end temperature is the maximum recommended ceramic pressing temperature for the investment product, according to [8.2 i](#)). Determine the change in length of the test-piece at this temperature, with respect to the initial length. Use the initial length and the change in length to calculate the linear thermal expansion at the pressing temperature expressed as a percentage of the original length. Record this value to the nearest 0,1 %.

7.5.4.2.2 Type 3 products

For a Type 3 product, the end temperature is the maximum brazing temperature

Determine the change in length at the maximum brazing temperature [according to 8.2.i)] with respect to the initial length, to an accuracy of 0,02 %. Use the initial length and this change in length to calculate the linear thermal expansion at the maximum brazing temperature and express this as a percentage to the nearest 0,1 %. Record this value.

7.5.5 Test procedure for the measurement of linear thermal dimensional changes of a Type 4 product

7.5.5.1 Linear firing shrinkage

Measure the length of the test-piece to an accuracy of 0,02 mm.

For a Class 1 material: At the earliest burn-out time recommended by the manufacturer, place the test-piece in the burn-out oven and raise the temperature of the oven from its initial temperature (ambient temperature) to the final burn-out temperature [according to 8.2 i)] at a rate of (5 ± 1) °C/min.

For a Class 2 material: Follow the same procedure at the higher heating rate, (25 ± 5) °C/min. Alternatively, if the manufacturer's instruction is to place the green die directly into a heated oven, set the burn-out oven at the recommended burn-out temperature [according to 8.2 i)] and place the test-piece directly into the hot oven.

Hold the test-piece at the recommended burn-out temperature for the time recommended by the manufacturer. (If the burn-out temperature is given without a holding time, hold for 15 min.)

Cool the test-piece to the ambient temperature, following the cooling procedures that are recommended by the manufacturer.

When cool, measure the length of the test-piece to an accuracy of 0,02 mm.

The linear firing shrinkage is the change in length of the test-piece from its initial value to that after cooling from the burn-out. Express this as its ratio to the initial length and record it as a percentage to the nearest 0,1 %.

7.5.5.2 Linear thermal expansion

Take the test-piece used in 7.5.5.1 and place it in the dilatometer. Raise the dilatometer temperature to the maximum ceramic firing temperature [according to 8.2 i)] at a rate of (5 ± 1) °C/min. Record the dilatometer reading continuously to an accuracy of 0,02 % of the initial length and that for the temperature to an accuracy of 5 °C.

Hold the test-piece at the maximum ceramic firing temperature for the time recommended by the manufacturer [8.2 i)]. (If the maximum ceramic firing temperature is given without a holding time, hold for 15 min.)

The linear thermal expansion is the change in length of the test-piece from its value after burn-out and cooling (as determined in 7.5.5.1) to that after heating to the maximum ceramic firing temperature. Express this as its ratio to the length after burn-out and cooling and record as a percentage to the nearest 0,1 %.

7.5.6 Evaluation of results

7.5.6.1 Types 1, 2 and 3 products

If results from both test-pieces meet the requirement for linear thermal expansion (5.6), the product complies.

If neither result meets the requirement for linear thermal expansion (5.6), then the product fails to comply.

If the result from one of the test-pieces meets the requirement for linear thermal expansion (5.6) and the other fails to do so, repeat the test three more times using three new test-pieces, produced in accordance with 7.5.3.

If the results from all three of these additional test-pieces meet the requirement for linear thermal expansion (5.6) then the product complies. Otherwise, it fails to comply.

7.5.6.2 Type 4 products

If the results for linear firing shrinkage and linear thermal expansion from both test-pieces meet the requirements (5.6), the product complies.

If the results for both linear firing shrinkage and linear thermal expansion from at least one of the test pieces do not meet the requirement (5.6), the product fails to comply.

If the results for both linear firing shrinkage and linear thermal expansion from one test-piece meet the requirements (5.6) and either:

- a) the results for both linear firing shrinkage and linear thermal expansion from the other test-piece fail to meet the requirements,

or

- b) one of the results (linear firing shrinkage or linear thermal expansion) from the other test-piece fails to meet the requirement,

repeat the test three more times, using new test-pieces produced in accordance with 7.5.3.

If the results for linear firing shrinkage and for linear thermal expansion of all three of these additional test-pieces meet the requirements (5.6) then the product complies. Otherwise, it fails to comply.

7.5.7 Test report

Report

- a) the length and diameter of the test-piece and, since similar test-pieces are used for all measurements, their averaged dimensions;
- b) the continuous recordings of temperature / dimensional change (expressed as a percentage of the test-piece length) for every test conducted in accordance with 7.5.4 or 7.5.5;
- c) the linear thermal expansion of the test-piece (to 0,1 %) for every test conducted in accordance with 7.5.4 and 7.5.5;
- d) a statement that the product meets, or does not meet, the requirement for linear thermal expansion (5.6);
- e) the linear firing shrinkage of the test-piece (to 0,1 %) for every test conducted in accordance with 7.5.5.1, if it is a Type 4 product;
- f) a statement that the product meets, or does not meet, the requirement for linear firing shrinkage (5.6), if it is a Type 4 product.

7.6 Adequacy of expansion of Type 1 and Type 2 products

7.6.1 General

The test uses a disc form test-piece. The diameter of the disc is measured on the pattern and on the metallic casting, or on the pressed ceramic made from that pattern. These values are compared. The

technical procedures used are those recommended by the manufacturer of the dental casting investment or dental pressable-ceramic investment product. The metallic material used for the casting (base or noble) shall be one which the manufacturer of the dental casting investment product recommends as suitable for casting into moulds made in the investment material.

7.6.2 Type 1 and Type 2 products intended for casting of dental metallic materials

7.6.2.1 Materials and apparatus

7.6.2.1.1 Equipment for the preparation of the disc patterns for casting, such as a lathe for a non-wax polymeric pattern material.

7.6.2.1.2 Instrument, to measure the diameter of the disc pattern and casting to an accuracy of 0,005 mm. When a soft pattern material such as wax is used, non-contact measuring shall be performed;

7.6.2.1.3 Dental casting equipment, normally used for the manufacture of dental castings.

7.6.2.1.4 Grit blasting equipment, using grit no larger than 50 µm size, according to ISO 6344-1.

7.6.2.1.5 Dental casting wax, that complies with ISO 15854 **or a polymeric material** suitable for making disc patterns. The material used for the pattern shall not crack the mould during heating.

7.6.2.1.6 Dental casting metallic material, that complies with ISO 22674. It shall be of a type for which the casting investment product is recommended. It shall be unused previously and from a single lot.

7.6.2.1.7 Rubber bonded abrasive wheel, mounted in a dental laboratory hand-piece.

7.6.2.1.8 Dental casting ring, made in a corrosion resistant material recommended by the manufacturer according to [8.2 h](#)).

7.6.2.1.9 Mould liner, if recommended by the manufacturer, according to [8.2 g](#)).

7.6.2.2 Number of test-pieces

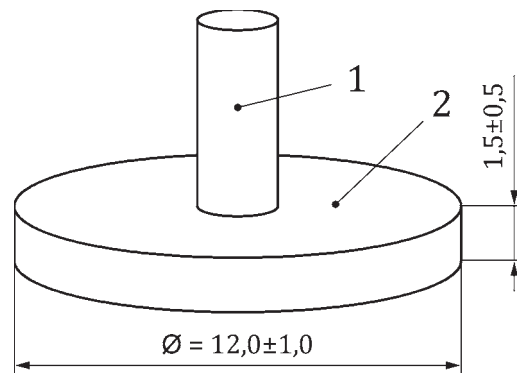
Make three test-pieces from three mixes of dental casting investment material.

Three additional test-pieces (made from three more mixes of investment) are required if the results from two of these test-pieces do not meet the requirement ([5.7](#)).

7.6.2.3 Pattern

Prepare discs (12,0 ± 1,0) mm diameter and (1,5 ± 0,5) mm thick, that deviate from circularity by no more than 0,01 mm, from wax or polymer material ([Figure 2](#)).

Measure the diameter of the pattern at six positions equidistant around the periphery (30° intervals), and record the values to the nearest 0,005 mm. Calculate the mean value to the nearest 0,001 mm.

**Key**

- 1 sprue
- 2 disc pattern

Figure 2 — Sprued disc pattern**7.6.2.4 Test procedure**

Attach a straight sprue to one of the faces the disc at its centre and right angles to the face, leaving the rim undamaged (see [Figure 2](#)).

NOTE The diameter and length of the sprue are not specified, in order to allow the technician the freedom to select a spruce size that, in his/her experience and in accordance with [7.6.1](#), results in a complete casting.

Invest a single pattern in a casting ring with the position of the sprue along the axis of the casting ring.

Mix the investment according to [6.3](#), using a mass of powder with the appropriate volume of liquid to produce a mix that will fill the casting ring. If a special liquid is supplied and recommended to be used when casting the type of metallic material that is to be used in this evaluation, use it in the dilution that is recommended. Invest, burn-out and cast following to the manufacturer's recommendations [according to [8.2 g](#)), [8.2 h](#)) and [8.2 i](#))].

Remove the cast metallic disc from the mould and clean by grit blasting.

7.6.2.5 Measurement

For each casting, lightly polish the rim with a rubber bonded abrasive wheel to remove any excrescences and measure in the same manner as that used for the pattern. Calculate the mean diameter to the nearest 0,001 mm.

Light polishing must be done with great care. Polishing should be minimal and restricted to removing protuberances. Polishing to a high finish that might be considered "normal" for prosthetic production, or polishing using greater force will remove metal from the casting and put compliance at risk

7.6.2.6 Calculation

Express the ratio of the mean diameter of the casting to the mean diameter of the pattern as a percentage and record this value to an accuracy of 0,01 % for all test-pieces.

7.6.3 Type 1 products intended for dental pressable-ceramic products**7.6.3.1 Materials and apparatus****7.6.3.1.1 Pressing ring with crucible former and base former.**

7.6.3.1.2 Dental casting wax that complies with ISO 15854 or a polymeric material suitable for making disc patterns. The material used for the pattern shall not crack the mould during heating.

7.6.3.1.3 Equipment for the preparation of the disc patterns for pressing, such as a lathe for a non-wax polymeric pattern material.

7.6.3.1.4 Instrument, to measure the diameter of the disc pattern and pressable-ceramic disc to an accuracy of 0,005 mm. When a soft pattern material such as wax is used, non-contact measuring shall be performed.

7.6.3.1.5 Dental pressable-ceramic product, that complies Type 2 Class 1 of ISO 6872 and for which the investment product under test is recommended. It shall be from a single lot.

7.6.3.1.6 Burn-out furnace.

7.6.3.1.7 Ceramic pressing rod, compatible with the crucible former.

7.6.3.1.8 Pressing furnace, a model that is recommended for use with the selected dental pressable-ceramic product.

7.6.3.1.9 Cutting disc, diamond with dental hand piece.

7.6.3.1.10 Grit blasting equipment, using grit of a composition and particle size that is recommended for use with the selected dental pressable-ceramic product. If a grit size is not specified, use one that is no larger than 50 µm size, according to ISO 6344-1.

7.6.3.2 Number of test-pieces

Make three test-pieces from three mixes of dental pressable-ceramic investment material.

Three additional test-pieces (made from three more mixes of investment) are required if the results from two of these test-pieces do not meet the requirement of [5.7](#).

7.6.3.3 Pattern

Prepare pattern discs to the same size and tolerances as described in [7.6.2.3](#) from wax or polymer material (see [Figure 2](#)).

Measure the diameter of these pattern discs as required in [7.6.2.3](#).

7.6.3.4 Test procedure

Attach a straight sprue to one of the faces of the disc at its centre and right angles to the face, leaving the rim undamaged (see [Figure 2](#)). However, if this conflicts with manufacturer's recommendation for spruing, attaching the sprue to the rim of the disc (with the axis of the spruce in the plane of the disc and pointed towards the centre) is permitted.

NOTE 1 For some products the instruction is to sprue axially with the pattern (which in the present context is in the plane of the disc) and not at an angle to it.

NOTE 2 The diameter and length of the sprue are not specified, in order to allow the technician the freedom to select a spruce size that, in his/her experience and in accordance with [7.6.1](#), results in a complete pressing.

Invest a single pattern in a pressing ring with the direction of the sprue along the axis of the crucible former.

Mix the investment according to [6.3](#), using a mass of powder with the appropriate volume of liquid that will produce a mix that will fill the pressing ring. Invest, burn-out, heat and press the ceramic ingot into the mould following to the manufacturer's recommendations [according to [8.2 h](#)) and [8.2 i](#)]).

Remove the pressed ceramic disc from the mould and clean by grit blasting following manufacturer's instructions. Inspect the rim of the disc to ensure all of the investment has been removed. No further cleaning action should be undertaken.

7.6.3.5 Measurement

Measure the diameter using the same procedure as that for the pattern measurement. Use visual inspection to ensure none of these measurements is taken where there is an asperity. Calculate the mean diameter to the nearest 0,001 mm.

7.6.3.6 Calculation

Express the ratio of the mean diameter of the ceramic disc to the mean diameter of the pattern as a percentage. Record the percentage value to an accuracy of 0,01 % for all test-pieces.

7.6.4 Evaluation of results

If two or three test results meet the requirement ([5.7](#)), the product complies.

If none of the three test results meet the requirement ([5.7](#)), then the product fails to comply.

If only one of test results meets the requirement ([5.7](#)), repeat the test three more times. If the results of all three of these additional tests meet the requirement ([5.7](#)), the product complies. Otherwise, it fails to comply.

7.6.5 Test report

Report the following.

- a) The dental metallic material used for the test with the name of the manufacturer, the name of the product and the lot number. Confirm that it complies with ISO 22674. Alternatively, the dental pressable-ceramic material used for the test with the name of the manufacturer, the name of the product and lot number. Confirm that it complies with ISO 6872.
- b) The investing and casting conditions. Alternatively, the investing and pressing conditions.
- c) The values (to 0,01 %) obtained for all test-pieces tested in accordance with [7.6.2.6](#) or [7.6.3.6](#), as appropriate.
- d) A statement on whether the dental casting or dental pressable-ceramic investment material meets, or does not meet, the requirement for the adequacy of expansion [5.7](#).

8 Manufacturer's instructions

8.1 General

The manufacturer's (or manufacturer's authorized representative's) instructions accompanying the product shall contain at least the information specified in [8.2](#), [8.3](#) and [8.4](#), in a language that is appropriate for the country of intended sale or distribution.

8.2 Information for use

- a) The classification of the product according to [Clause 4](#) and the intended use.
- b) The type of binding system used.

- c) The refractory phase and, if appropriate, its allotropic form. If more than one refractory phase is present, only those present in concentrations greater than 5 % should be listed with the most abundant first.
- d) If a special liquid is provided, instructions for its use, storage and dilution for particular applications. If appropriate, a warning not to use the liquid if it shows a sign of degradation. (The normal appearance shall be given to help the user to decide if degradation has occurred).
- e) The recommended powder to liquid ratio (or range of permitted mixing ratios, as appropriate) expressed in grams per millilitre.
- f) Detailed unambiguous recommendations on mixing procedure, including (if applicable) mixer type, rotational frequency, mixing time and the application of a vacuum.
- g) Instructions for use of a mould liner, if applicable.
- h) Recommended investing techniques.
- i) Instructions for burn-out (and if required for cooling after this) for moulds intended for casting dental metallic material. Instructions for burn-out and further heating (if required) for moulds intended for pressing dental ceramic materials. Instructions on the burn-out of casts for brazing. Instructions on the firing procedures for refractory dies. (As is appropriate for the product Type.); materials.
- j) Recommended storage conditions.
- k) Date of issue of the latest version and version number of the instructions for use.

8.3 Physical properties

The following properties are to be defined with the values that are compatible with those of the requirements given in [Clause 5](#) and that will allow compliance to be evaluated using procedures in [Clause 7](#). Because they represent the performance of the product in general and not that of a specific lot, the use of more than one lot to produce these data is permitted.

- a) The fluidity, given as the average diameter of the disc (in mm) that is produced by the flow of a 35 mm diameter, 50 mm high column of the material before setting. For this information to be of use to the dental technician (who does not have a copy of this International Standard), both the initial and final diameters should be given. For example, use phrasing such as: “Fluidity – When tested in accordance with ISO 15912, a specified mass, 48 g, of material will flow (unaided by vibration) from an initial 35 mm diameter circle to one that xx mm diameter before setting”. Where xx is the fluidity value determined by the manufacturer. (This is not required for silica bonded products).

NOTE This detail is necessary since an empirical test procedure is used.

- b) The initial setting time.
- c) The compressive strength.
- d) The linear thermal expansion at the casting temperature (Types 1 and 2), or at the maximum recommended ceramic pressing temperature (Type 1), or the maximum brazing temperature (Type 3), or at the maximum ceramic firing temperature (Type 4). A range is permitted. Values of both the expansion and temperature shall be given.

A copy of a typical linear thermal expansion curve shall be included. In this context, the term “thermal expansion curve” includes dimensional changes up to the burn-out temperature and, if appropriate, dimensional changes that follow on cooling to the casting temperature, or on further heating to the maximum recommended ceramic pressing temperature.

- e) For Type 4 products, the linear firing shrinkage. A range is permitted.

8.4 Safety labelling and instructions for a product containing silica

If the product contains silica as the refractory phase in a concentration above 1 % (mass fraction) in the powder, the manufacturer's instructions shall carry the following labelling and instructions, according to the UN GHS[2] requirements for silica as a hazardous material:

- a) the specific target organ toxicity (STOT) repeated exposure level 1 (RE1) pictogram (see [Figure 3](#));
- b) "DANGER" as a signal word;
- c) "This material contains silica that causes damage to lungs through prolonged or repeated exposure via inhalation" as hazard information;
- d) "Do not breathe dust" as precautionary advice;
- e) "In case of inadequate ventilation, wear respiratory protection" as precautionary advice;
- f) "Dispose of contents/containers in accordance with local regulations" as precautionary advice.



Figure 3 — STOT RE1 pictogram for indicating presence of silica powder at concentrations above 1 % mass fraction

9 Marking

9.1 General

The packaging of the product shall contain at least the following information in a font size that can be read easily and in language that is appropriate for the country of intended sale or distribution.

9.2 Powder container

9.2.1 Outer container

On the outer container:

- a) the trade or brand name of the product;
- b) the classification of the product according to [Clause 4](#) and the intended use, and the binding system employed;

EXAMPLE “Gypsum-bonded dental casting investment material: Type 1, intended for casting metallic material inlays, crowns and bridges”.

- c) the manufacturer’s, or the manufacturer authorized representative’s, name and address;
- d) the lot number;
- e) the net mass of powder in grams or kilograms;
- f) the “USE BEFORE” date (year and month) beyond which the product shall not be used, in accordance with ISO 8601;
- g) safety labelling and instructions as set out in [8.4](#);
- h) recommended storage conditions.

9.2.2 Individual packets

For products supplied in individual unit dose packets, the label on each of these packages shall show at least the following information:

- a) the trade or brand name of the product;
- b) the manufacturer’s, or manufacturer authorized representative’s, name and address;
- c) the lot number;
- d) the net mass of powder in grams;
- e) the “USE BEFORE” date (year and month) beyond which the product should not be used, in accordance with ISO 8601;
- f) If the product contains silica in a concentration above 1 % (mass fraction), the safety labelling and instructions as set out in [8.4](#). If there is not enough space on small (individual) packets for the complete safety labelling, at least [8.4 a](#)), [8.4 b](#)) and [8.4 c](#)) together with advice to consult the full safety instructions (on the outer container and in manufacturer’s instructions) shall be present.

9.3 Liquid container

Each container of liquid (whether part of the binding system or a special liquid) shall be marked with the following information:

- a) the trade or brand name of the investment material for which the liquid is provided;
- b) the use for which the liquid is required (i.e. as part of the binder or for additional expansion);
- c) the manufacturer’s, or manufacturer authorized representative’s, name and address;
- d) the lot number;
- e) the net volume in litres or millilitres;
- f) the “USE BEFORE” date (year and month) beyond which the material shall not be used, in accordance with ISO 8601;
- g) recommended storage conditions.

10 Packaging

10.1 Powder

The powder shall be in moisture-resistant containers.

For products in which the powder is not subdivided into unit dose packets, this container shall be capable of being re-sealed and be moisture-resistant when resealed. If not, a recommendation shall be given, that after opening the container the powder shall be transferred to a suitable re-sealable, moisture-resistant container.

10.2 Liquid

Liquids (both for use as part of the binder or as a special liquid) shall be in re-sealable containers.

Bibliography

- [1] ISO 6873:2013, *Dentistry — Gypsum products*
- [2] Globally Harmonized System of Classification and Labelling of Chemicals (GHS). 5th. United Nations, New York, Geneva, Revised Edition, 2013

