
**Dentistry — Soft lining materials for
removable dentures —**

**Part 1:
Materials for short-term use**

*Médecine bucco-dentaire — Produits souples pour intrados de
prothèses dentaires amovibles —*

Partie 1: Produits pour usage à court terme

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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 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 the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthetic materials*.

This third edition cancels and replaces the second edition (ISO 10139-1:2005), which has been technically revised. It also incorporates the Technical Corrigendum ISO 10139-1:2005/Cor.1:2006.

A list of all parts in the ISO 10139 series can be found on the ISO website.

Introduction

Clinically, short-term denture-lining materials are used commonly as tissue conditioners and as temporary soft lining materials. Furthermore, some materials are also indicated for functional impression taking. Therefore, the tests are designed to cover the more common usages.

It is recognized that the short-term material, when used as a tissue conditioner, is commonly changed every few days with the aim of returning the mucosa to a healthy condition as quickly as possible. As a temporary soft lining, the material is commonly placed in immediate dentures and in dentures that need to be modified as part of implant treatment. Therefore the specification has been so designed to necessitate that a material exhibit the required properties over a 7 d period. It is of course recognized that there are a number of clinical situations where it is appropriate to retain the soft lining in the denture for periods longer than 7 d. It is also recognized that manufacturers may wish to provide more than one set of times, temperatures, proportions and procedures to mix or prepare the material properly in order that the material can satisfy the requirements of more than one type or class.

In an attempt to establish some degree of harmony with the procedures used to evaluate related dental materials, the detail reproduction test has been adopted for materials also used for functional impression taking (ISO 4823). As well, in this revision of the standard, the Shore A0 hardness test has replaced the depth of penetration test, and the consistency test has been reintroduced as a replacement of the elastic recovery test due to complexity of this method.

Specific qualitative and quantitative test methods for demonstrating freedom from unacceptable biological hazards are not included in this document, but it is recommended that, for the assessment of possible biological hazards, reference should be made to ISO 10993-1 and ISO 7405.

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Dentistry — Soft lining materials for removable dentures —

Part 1: Materials for short-term use

1 Scope

This document specifies requirements for the physical properties, test methods, packaging, marking and manufacturer's instructions for soft denture lining materials suitable for short-term use, including functional impression taking using existing removable prosthesis.

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

ISO 4823:2015, *Dentistry — Elastomeric impression materials*

ISO 7619-1, *Rubber, vulcanized or thermoplastic — Determination of indentation hardness — Part 1: Durometer method (Shore hardness)*

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

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

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

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <https://www.iso.org/obp>

3.1

soft denture lining material

soft resilient material bonded to the fitting surface of a denture to reduce trauma to the supporting tissues

Note 1 to entry: A soft lining material can be used as a tissue conditioning material when placed in the fitting surface of a denture and intended to be in contact with the denture-supporting mucosa, commonly for a period of up to 7 d, with the aim of assisting its return to a healthy condition.

3.2

short-term use

use normally for a continuous period of between 60 minutes and 30 days

3.3

functional impression taking

use of a *soft denture lining material* (3.1) to take a functional impression using existing removable prosthesis

4 Classification

4.1 Types

Materials for short-term use shall be classified into the following types in accordance with Shore A0 hardness test at 2 h (5.1.1) as determined in accordance with 7.2:

- Type A: soft materials;
- Type B: extra soft materials.

4.2 Classes

The materials shall be further subdivided into classes in accordance with consistency (5.2) as determined in accordance with 7.3:

- Class 1: medium flow materials;
- Class 2: high flow materials.

5 Requirements

5.1 Shore A0 hardness

5.1.1 Shore A0 hardness at 2 h

When 2 h old test specimens are subjected to the Shore A0 hardness test in accordance with 7.2, the individual mean Shore A0-value for three specimens of the material shall conform to the requirements in Table 1. If only two or fewer specimens meet the requirement, the material shall be deemed not to conform to this document.

Table 1 — Shore A0 hardness

Type	Shore A0 hardness, 2 h
A (soft)	$30 < \text{Shore A0} \leq 50$
B (extra soft)	$\text{Shore A0} \leq 30$

5.1.2 Shore A0 hardness at 7 d

The individual mean Shore A0 hardness at 7 d shall be no higher than 60. If only two or fewer specimens meet this requirement the material shall be deemed not to conform to this document.

5.2 Consistency

When specimens are subjected to the consistency test in accordance with 7.3, at least three of the four specimens of the material shall conform to the requirement for the relevant type as shown in Table 2. If only one or two specimens meet the requirement, the material shall be deemed not to conform to this document.

Table 2 — Flow measured by the consistency method

Class	Diameter, <i>d</i> mm
1 (medium flow)	$25 \leq d < 60$
2 (high flow)	$60 \leq d < 100$

5.3 Detail reproduction

This requirement applies only to materials which are claimed also for functional impression taking. When tested in accordance with 7.4, the detail of reproduction shall be at least 75 µm, line c in Figure 2.

6 Sampling

The test sample shall consist of a retail package, or packages, from the same batch.

7 Test methods

7.1 Ambient conditions for testing

Conduct all tests at (23 ± 2) °C and relative humidity of 30 % to 70 % unless otherwise stated.

7.2 Shore A0 hardness

7.2.1 Apparatus

7.2.1.1 Shore A0 hardness equipment, in accordance with ISO 7619-1.

7.2.1.2 Water bath, capable of being maintained at (37 ± 1) °C, with water in accordance with grade 2 of ISO 3696.

7.2.1.3 Mould, suitable for producing test specimens of 50 mm to 55 mm diameter and $(8 \pm 0,5)$ mm thickness, made of smooth metal or using a polymer disc as a template.

NOTE A mould release agent, e.g. Polytetrafluoroethylene (PTFE) spray, can be used to avoid the adherence of material to the mould.

7.2.1.4 Timing device, accurate to 0,1 s.

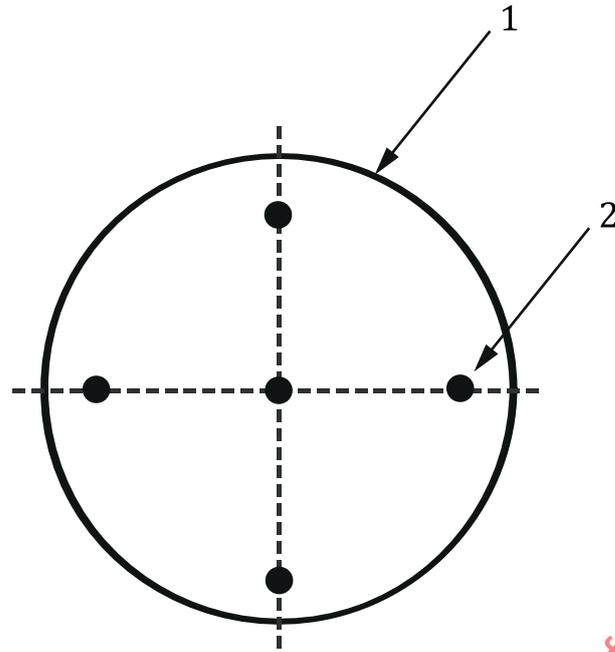
7.2.1.5 Stand, capable of supporting the durometer pressure-foot surface parallel to the test piece support table.

7.2.2 Procedure

7.2.2.1 Preparation of test specimens

Prepare each test specimen in the mould cavity in accordance with the manufacturer's instructions. Fifteen min from start of mixing, immerse the test specimens with mould into the 100 ml water-filled water bath at (37 ± 1) °C for 2 h. Prepare three test specimens.

NOTE A non-stick foil can be helpful to generate a flat surface.



Key

- 1 specimen, diameter 50 mm to 55 mm
- 2 indenter points, >15 mm from the edge and >6 mm apart

Figure 1 — Shore A0 hardness specimen and testing points

7.2.2.2 Shore A0 hardness test, 2 h specimen

After (120 ± 5) min immersion, remove the test specimen from the mould and measure the Shore A0 hardness as described below within 3 min after having removed the specimen from the water bath. Place the specimen on a flat and solid base. Using the stand, lower the Shore A0 hardness tester slowly onto the surface of the specimen, ensuring that the specimen surface is coplanar with the surface of the hardness tester, until the indenter foot just touches the specimen surface. Record the values 5 s after loading, using a timing device. Repeat the test using four more loading points ensuring that no measurement is made closer than 6 mm to a previous one. All the loading points shall be at least 15 mm inside from the edge of the specimen. Each loading point shall be 90° from another loading point and the 5th point shall be on the centre of the specimen (see [Figure 1](#)).

Return the specimens to the water bath at $(37 \pm 1)^\circ\text{C}$ and maintain them for an additional 7 d.

Carry out the test on all three specimens, and calculate the mean of the five Shore A0 values for each specimen.

7.2.2.3 Shore A0 hardness test, 7 d specimen

Remove the specimen from the water bath 7 d after the first testing, and measure the Shore A0 hardness as described in [7.2.2.2](#) on the opposite side of the 2 h measurement within 3 min after having removed the specimen from the water bath.

Carry out the test on all three specimens, and calculate the mean of the five Shore A0 values for each specimen.

7.3 Consistency test

7.3.1 Test conditions

Allow the test apparatus ("upper" glass plate and weight) to reach equilibrium in the environment of (37 ± 1) °C for at least 30 min before testing.

7.3.2 Apparatus

7.3.2.1 Delivery tube or syringe, for example, glass or polytetrafluoroethylene (PTFE), capable of dispensing a volume in excess of sample size [i.e. in excess of $(2 \pm 0,1)$ ml].

7.3.2.2 Two glass plates of size 100 mm by 100 mm, one of which (the "upper" plate) has a mass of (100 ± 1) g and a thickness of not less than 2 mm.

7.3.2.3 Unplasticized sheets (polyester, polyethylene, or polypropylene), 100 mm by 100 mm and (50 ± 25) µm thickness.

7.3.2.4 Weight, $(1\ 000 \pm 5)$ g.

7.3.2.5 Oven, capable of maintaining the test apparatus in an environment of (37 ± 1) °C.

7.3.2.6 Ruler, with subdivision of accuracy 1,0 mm.

7.3.3 Test procedure

Cover the underside of the glass plate with an unplasticized sheet.

Prepare a sample using the manufacturer's recommended technique. Where a range of mixing times is given, use the mean time. Using the syringe, dispense a sample of $(2,0 \pm 0,1)$ ml onto the middle of the unplasticized sheet on the glass plate at (30 ± 1) s after the end of mixing.

At the time for insertion in the mouth as given by the manufacturer, transfer the plate and the sample immediately to the environment maintained at (37 ± 1) °C and cover the upside of the sample with a unplasticized sheet and the "upper" glass plate, and compress by vertically applying the weight so that the total load becomes $(1\ 100 \pm 6)$ g. In case that the time for insertion is not given by the manufacturer, it shall be (120 ± 5) s. Maintain this load for (300 ± 1) s and then remove the weight and glass plate.

Measure the maximum and minimum diameters of the disc to an accuracy of $\pm 0,5$ mm and calculate the average of the two measurements.

Repeat the test three more times.

7.4 Detail reproduction test

7.4.1 General

Perform the detail reproduction test only on materials which the manufacturer claims may be used for functional impression taking.

7.4.2 Apparatus

7.4.2.1 Water bath, capable of being maintained at (37 ± 1) °C, with water in accordance with grade 2 of ISO 3696.

7.4.2.2 Test block and ring mould accessory (Figure 2 and Figure 3, same block and accessory as in ISO 4823:2015), cleaning the test block ultrasonically before each use.

NOTE A mould release agent, e.g. Polytetrafluoroethylene (PTFE) spray, can be used to avoid the adherence of material to the mould.

7.4.2.3 Flat glass or metal plate, approximately 50 mm by 50 mm and at least 3 mm thickness.

7.4.2.4 Unplasticized sheets (polyester, polyethylene, or polypropylene), 50 mm by 50 mm and (50 ± 25) μm thickness.

7.4.2.5 Microscope, equipped for x4 to x12 magnification and low angle illumination.

7.4.2.6 Timing device, accurate to 0,1 s.

7.4.3 Procedure

7.4.3.1 Preparation of test samples

Before mixing the material for each of the three specimens, place the test block and ring mould in the water bath or oven at (37 ± 1) °C for conditioning for at least 15 min.

Cover the underside of the glass or metal plate with an unplasticized sheet.

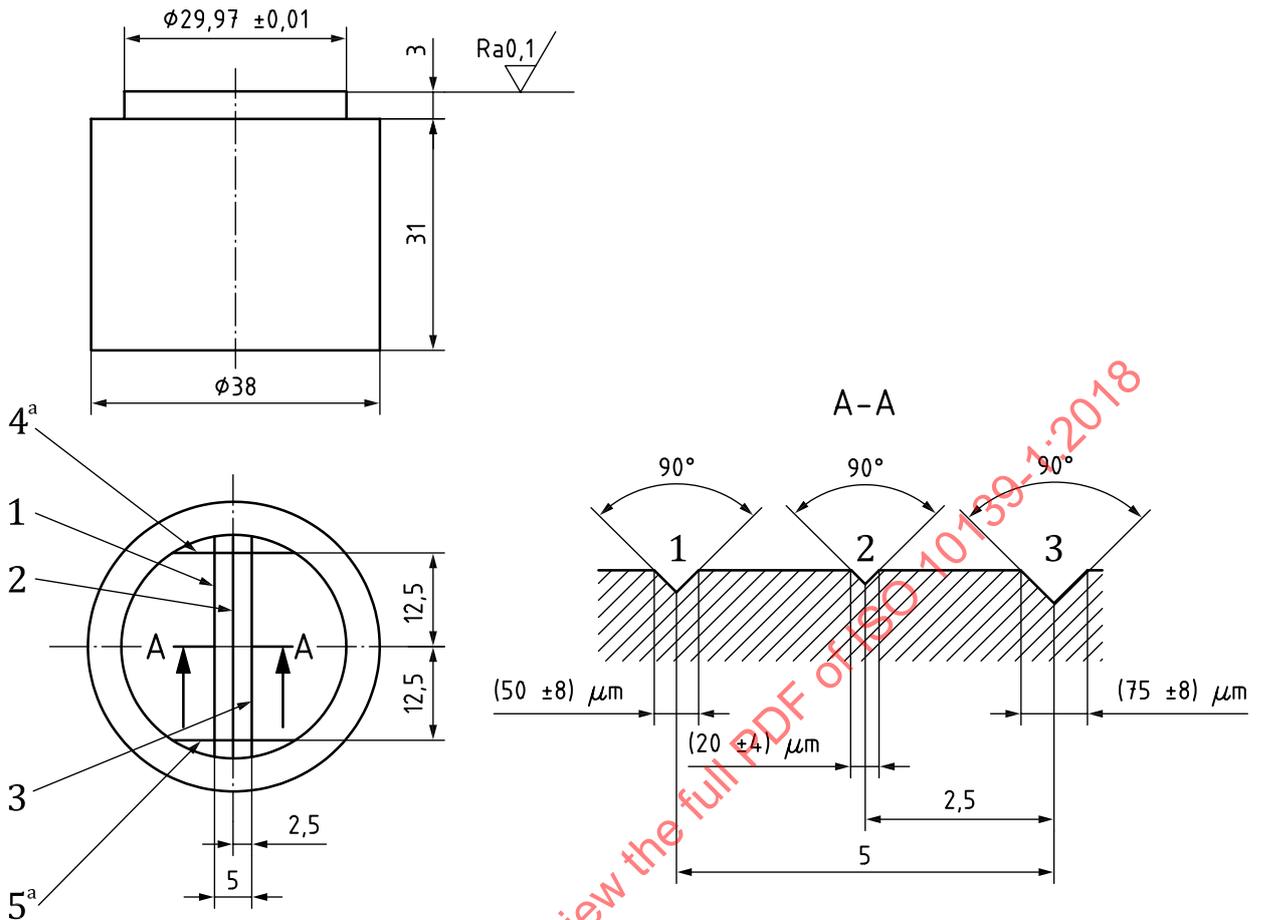
Accomplish the following steps within 60 s after completion of mixing:

- remove the test block and ring mould from water bath or oven;
- seat the ring mould on the test block to form the specimen forming cavity;
- introduce an increment of the mixed material (enough to slightly overfill the cavity) along one side of the cavity such that it can be directed to first enter the scribed lines a, b, and c on one side of the test block, and then be gradually forced, via application of pressure applied by the glass or metal plate, to flow into the lines to their opposite ends;
- press the polyethylene-covered plate down against the top of the ring mould so as to expel the excess material;
- at 60 s after completion of mixing, place this specimen-forming assembly in the water bath being maintained at (37 ± 1) °C for 48 h.

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

7.4.3.2 Test procedure

Immediately after blowing moisture from specimen, use the microscope to examine the specimen for compliance with the related line width. The line reproduction shall be considered satisfactory if the required line c is continuous between lines d_1 and d_2 .



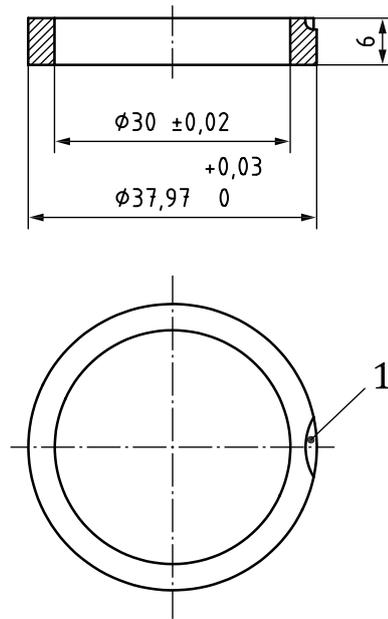
Key

- 1 line a
- 2 line b
- 3 line c
- 4 line d₁
- 5 line d₂
- 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 max. and material is cast or wrought austenitic stainless steel.

Figure 2 — Test block for detail reproduction



Key

- 1 cut-out approximately 1 mm deep
- a Made of polymer, brass or stainless steel.

Figure 3 — Ring mould accessory^a

8 Requirement for packaging, marking and instructions supplied by the manufacturer

8.1 Packaging

The components shall be supplied in sealed containers made of materials that shall neither contaminate, nor permit contamination, of the contents. The immediate containers shall be packaged so as to prevent damage or leakage during transit and storage.

An outer package may also be used to present the containers as a single unit.

8.2 Marking and manufacturer's instructions for use

The outer packages and the immediate containers or wrappings of the components shall be clearly marked with the information given in [Table 3](#).

In those cases where the size of the immediate container or package is too small to fit in all the details, reference shall be made on the outer package to a leaflet inside where the additional information shall be provided.

Instructions for use shall accompany each package and, shall at a minimum include the information given in [Table 3](#).