INTERNATIONAL STANDARD

ISO 10139-2

Second edition
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Dentistry — Soft lining materials for removable dentures —

Part 2: Materials for long-term use

Art dentaire — Produits souples pour intrados de prothèses dentaires amovibles —
Partie 2: Produits pour usage à long 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.

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

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 10139-2 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthodontic materials*.

This second edition cancels and replaces the first edition (ISO 10139-2:1999) which has been technically revised.

ISO 10139 consists of the following parts, under the general title *Dentistry — Soft lining materials for removable dentures*:

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

— *Part 2: Materials for long-term use*

Introduction

Denture lining materials for long-term use are classified in this part of ISO 10139 according to their softness. Although it is not claimed that any particular level of softness is superior to another, this classification is intended to assist clinicians because clinicians will have more information with which to make an informed choice.

In this second edition of this part of ISO 10139, additional requirements for bond strength to denture base are added, as well as requirements for water sorption and solubility. A new test for the determination of the softness of the lining materials, the Shore A hardness test, has been introduced. This test cancels and replaces the penetration test of the first edition of this part of ISO 10139.

Specific qualitative and quantitative requirements for freedom from biological hazard are not included in this part of ISO 10139. Information relevant to assessing possible biological or toxicological hazards is given in ISO 7405 and ISO 10993-1.

Dentistry — Soft lining materials for removable dentures —

Part 2:
Materials for long-term use

1 Scope

This part of ISO 10139 specifies requirements for softness, adhesion, water sorption and water solubility as well as for packaging, marking and manufacturer's instructions for soft denture lining materials suitable for long-term use. These materials may also be used for maxillofacial prostheses.

2 Normative references

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

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

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

ISO 20795-1, *Dentistry — Base polymers — Part 1: Denture base polymers*

3 Terms and definitions

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

3.1
soft denture lining material
soft resilient material bonded to the fitting surface of a denture to reduce trauma to the supporting tissues

3.2
long-term use
use for a period of more than 28 d

3.3
immediate container
container that is in direct contact with the material

4 Classification

Soft lining materials for long-term use are classified into the following types according to Shore A hardness of 24 h specimens (see 5.1) as determined in accordance with 7.2.

— **Type A**: soft;

— **Type B**: extra soft.

5 Requirements

5.1 Shore A hardness, 24 h

When 24 h test specimens are subjected to a 5 s Shore A hardness test in accordance with 7.2.3.2, the material shall conform to the requirements for the relevant type as shown in Table 1. For a material to be classified as a particular type, the mean Shore A hardness for at least two of the three specimens shall conform to the requirements for that type, as specified in Table 1. If the results for two or more specimens are greater than 50, the material shall be deemed not to conform to this part of ISO 10139.

Table 1 — Shore A hardness, 24 h – 5 s

Type	Shore A (24 h – 5 s)
A (soft)	$25 < \text{Shore A} \leqslant 50$
B (extra soft)	Shore A $\leqslant 25$

5.2 Shore A hardness, 28 d

When 28 d test specimens are subjected to a 5 s Shore A hardness test in accordance with 7.2.3.3, the material shall conform to the requirements for the relevant type as shown in Table 2 for at least two of the three specimens. If the results for two or more specimens are greater than 55 for Type A materials, or greater than 35 for Type B materials, the material shall be deemed not to conform to this part of ISO 10139.

Table 2 — Shore A hardness, 28 d – 5 s

Type	Shore A (28 d – 5 s)
A (soft)	$\leqslant 55$
B (extra soft)	$\leqslant 35$

5.3 Bond strength

The bond strength of the lining material to denture base shall be at least 1,0 MPa for eight out of ten tested specimens for Type A materials, and at least 0,5 MPa for eight out of ten tested specimens for Type B materials when tested in accordance with 7.3.

5.4 Sorption

The increase in mass per volume (water sorption) shall not exceed 20 µg/mm^3 for at least four out of five tested specimens when the processed lining material is tested in accordance with 7.4.

5.5 Solubility

The loss in mass per volume (water solubility) shall not exceed 3 µg/mm^3 for at least four out of five tested specimens when the processed lining material is tested in accordance with 7.4.

If the loss in mass per volume (water solubility) does exceed 3 µg/mm^3 for at least two out of five tested specimens when the processed lining material is tested in accordance with 7.4, the manufacturer of the material shall state the amount and the nature of the solubles from the material.

6 Sampling

The test sample shall consist of a retail package, or packages, from the same batch and containing enough material to carry out the specified tests, plus an allowance for any repeat tests, if necessary.

7 Test methods

7.1 Test conditions

Unless specified otherwise by the manufacturer, prepare and test all specimens at a temperature of (23 ± 2) °C. Measurement equipment shall be used in a calibrated condition.

7.2 Shore A hardness

7.2.1 Apparatus

7.2.1.1 **Shore A hardness equipment**, corresponding to ISO 7619-1 with a precision of ± 1 HS.

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

7.2.1.3 **Mould**, suitable for producing test specimens of at least 35 mm diameter and at least 6 mm thick, constructed using a smooth metal or polymer disc as a template. A mould release agent, e.g. Teflon spray, may be used to avoid the adherence of material.

7.2.1.4 **Timing device**, accurate to 0,1 s.

7.2.2 Preparation of test samples

Prepare each test specimen in the mould cavity in accordance with the manufacturer's instructions. Remove the specimen from the mould (7.2.1.3) and store it in the water bath (7.2.1.2) at (37 ± 1) °C for (24 ± 1) h prior to testing. Prepare three test specimens.

7.2.3 Procedure

7.2.3.1 General

Carry out the test procedure in accordance with 7.2.3.2, 7.2.3.3 and ISO 7619-1 on each of three test specimens. For the measurements, place the specimens on a flat and solid base and lower the Shore A hardness tester (7.2.1.1) gradually onto the surface of the specimen in such a way that the indenter foot just touches the specimen surface. The surface of the specimens and the contact surface of the Shore A hardness tester shall be coplanar. Ensure that the indenter is normal to the specimen surface. Five measurements shall be made for each of the specimens at each testing time. The loading points shall be uniformly distributed on the surface and shall have a distance of at least 5 mm from the edge of the specimen.

7.2.3.2 Shore A hardness test, 24 h specimen

Remove the specimen from the water (7.2.1.2) bath 24 h after preparation and measure the Shore A hardness immediately. Record the values 5 s after loading, using a timing device (7.2.1.4). Make all recordings within (2 ± 1) min of having removed the specimen from the water bath. Return the specimens to the water bath. Calculate the mean of the five Shore A values for each of the three specimens (results a, b and c).

Return the specimens to the water bath and maintain them in it for an additional 27 d. Change the water every 7 d with water complying with grade 2 of ISO 3696.

7.2.3.3 Shore A hardness test, 28 d specimen

Remove the specimen from the water bath (7.2.1.2) 27 d after the first testing, and measure the Shore A hardness immediately. Record the values 5 s after the loading using a timing device (7.2.1.4). Make all recordings within (2 ± 1) min after having removed the specimen from the water bath. Use fresh loading points and ensure that no measurement is made closer than 2 mm to a previous one. Calculate the mean of the five Shore A values for each of the three specimens (results x, y and z).

7.2.4 Expression of results

Record the test results for each of the three specimens in the format illustrated in Table 3.

Table 3 — Shore A hardness

Age of specimen	Mean Shore A of specimen		
	1	2	3
24 h	a	b	c
28 d	x	y	z

7.3 Bond strength

7.3.1 Materials

7.3.1.1 **Acrylic denture base material**, in accordance with the instruction given in 8.3 g) and complying with ISO 20795-1.

7.3.1.2 **Standard metallographic grinding paper**, P500 in accordance with ISO 6344-1 (with a median grain size of 30 µm).

7.3.1.3 **Water bath**, capable of maintaining a constant temperature of (37 ± 1) °C, with water complying with grade 2 of ISO 3696.

7.3.1.4 **Collars**, made from polyethylene or other non-adhering materials, cut from suitable tubing, with an internal diameter of (10 ± 0,5) mm and a thickness of (3 ± 0,25) mm.

7.3.1.5 **Micrometer** or **calliper**, accurate to 0,01 mm and fitted with parallel anvils.

7.3.1.6 **Clamp**, such as G-cramp or similar.

7.3.1.7 **Tensile testing machine**, with a vertical set-up, capable of an even displacement of 10 mm/min.

7.3.2 Preparation of acrylic denture base plates

Prepare sufficient plates of the dimension (25 ± 3) mm square and (3 ± 0,5) mm thick of the acrylic denture base material (7.3.1.1) by the method recommended by the manufacturer. Prepare the specimens in gypsum casts using the recommended curing cycle. The plates may be made individually or cut from larger pieces (up to 80 mm × 80 mm).

Maintain the flat surfaces of the plates in plano-parallel configuration whilst the surfaces are ground (wet) using P500 paper (7.3.1.2) ensuring that the dimensions of the individual plates still conform to the dimensions above. Avoid touching the bonding surface after grinding.

Store the plates for (28 ± 2) d in the water bath (7.3.1.3) at (37 ± 1) °C before use.

Measure the internal diameter of the polyethylene collar (7.3.1.4) with the micrometer or calliper (7.3.1.5) to a precision of 0,05 mm and use this to calculate the adhesive area A, in square millimetres.

7.3.3 Preparation of test specimens

Use the lining material and the adhesive supplied by the manufacturer according to the instructions for mixing, application and setting.

Immediately after removing the acrylic plates from the storage water, dry as recommended by the manufacturer or by using the method described in 7.4.4.2, and apply the adhesive to both surfaces of the acrylic plates that will be involved in bonding, following manufacturer's instructions. Make sure not to touch the adhesive surface.

Apply the prepared (mixed) soft lining material to the adhesive surfaces of the acrylic plates using slight excess whilst being confined within the collar (7.3.1.4) (see Figure 1). Clamp (7.3.1.6) the plates during setting. Maintain the clamped arrangement at room temperature (23 ± 2) °C unless curing at a higher temperature is recommended. At 1 h after application of the soft material to the base, place the bonded specimen into the water bath (7.3.1.3) at (37 ± 1) °C for (23 ± 1) h.

Prepare a minimum of ten test specimens.

7.3.4 Procedure for tensile testing

Remove the specimen from the water bath and immediately transfer it to a tensile testing machine (7.3.1.7). Fix the specimen in the testing machine in a vertical alignment. Ensure that no torsion forces are made upon the specimen and keep the specimen in vertical alignment during testing. This may be facilitated using sections of a PMMA rod bonded to the acrylic plates with cyanoacrylate cement (see Figure 1). The PMMA rod may be applied just before testing or immediately after making the bond.

Carry out the tensile test at a displacement rate of 10 mm/min. Record the maximum load, F, recorded during debonding.

Repeat the test for a total of ten specimens and calculate each bond strength, B, (in MPa) according to the equation:

$$B = \frac{F}{A}$$

where

F is the maximum load, in newtons, before debonding;

A is the adhesive area, in square millimetres.