



SLOVENSKI STANDARD
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**Zobozdravstvo - Mehki materiali za prevleko snemnih zobnih protez - 1. del:
Materiali za kratkotrajno uporabo (ISO/DIS 10139-1:2017)**

Dentistry - Soft lining materials for removable dentures - Part 1: Materials for short-term use (ISO/DIS 10139-1:2017)

Zahnheilkunde - Weichbleibende Unterfütterungswerkstoffe für Prothesen - Teil 1: Werkstoffe für kurzzeitige Anwendungen (ISO/DIS 10139-1:2017)

Médecine bucco-dentaire - Produits souples pour intrados de prothèses dentaires amovibles - Partie 1: Produits pour usage à court terme (ISO/DIS 10139-1:2017)

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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*

ICS: 11.060.10

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Contents

	Page
Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Classification	2
4.1 Types.....	2
4.2 Classes.....	2
5 Requirements	2
5.1 Shore A0 hardness.....	2
5.1.1 Shore A0 hardness at 2 h.....	2
5.1.2 Shore A0 hardness at 7 d.....	2
5.2 Consistency.....	2
5.3 Detail reproduction.....	3
6 Sampling	3
7 Test methods	3
7.1 Ambient conditions for testing.....	3
7.2 Shore A0 hardness.....	3
7.2.1 Apparatus.....	3
7.2.2 Procedure.....	3
7.3 Consistency test.....	5
7.3.1 Test conditions.....	5
7.3.2 Apparatus.....	5
7.3.3 Test procedure.....	5
7.4 Detail reproduction test.....	5
7.4.1 Apparatus.....	5
7.4.2 Procedure.....	6
8 Requirement for packaging, marking and instructions supplied by the manufacturer	8
8.1 Packaging.....	8
8.2 Marking and manufacturer's instructions for use.....	8
Bibliography	10

ISO/DIS 10139-1:2017(E)

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 10139-1 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.

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*

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Introduction

Clinically, short-term denture-lining materials are used commonly as tissue conditioners and as temporary soft lining materials. 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 International Standard, 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 part of ISO 10139 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 1942, *Dentistry — Vocabulary*

ISO 4823, *Dentistry — Elastomeric impression materials*

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 interchange — 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 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 <http://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 may 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.

ISO/DIS 10139-1:2017(E)

3.2

short-term use

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

3.3

functional impression taking

use of a soft denture lining material 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 according to their hardness (softness) as measured by the Shore A0 hardness test at 2 h, [5.1](#):

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

4.2 Classes

The materials shall be further subdivided into classes according to the consistency test, [7.2](#):

- 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 [7.22](#), the individual mean Shore A0-value for four of the five specimens of the material shall conform to the requirements in Table 1. If only three or fewer specimens meet the requirement, the material shall be deemed not to conform to this part of ISO 10139.

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 three or fewer specimens meet this requirement the material shall be deemed not to conform to this part of ISO 10139.

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 part of ISO 10139.