INTERNATIONAL STANDARD

ISO 10139-1

Third edition
2018-03

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

Reference number
ISO 10139-1:2018(E)

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

Published in Switzerland

Contents

Page

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, *Prosthodontic 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.

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 < Shore A0 ≤ 50
B (extra soft)	Shore A0 ≤ 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, d 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 ± 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.