

This is a preview of "ISO 10139-1:2018". [Click here to purchase the full version from the ANSI store.](#)

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 2018

This is a preview of "ISO 10139-1:2018". [Click here to purchase the full version from the ANSI store.](#)



**COPYRIGHT PROTECTED DOCUMENT**

© ISO 2018

All rights reserved. Unless otherwise specified, or required in the context of its implementation, 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  
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](mailto:copyright@iso.org)  
Website: [www.iso.org](http://www.iso.org)

Published in Switzerland

This is a preview of "ISO 10139-1:2018". Click here to purchase the full version from the ANSI store.

## Contents

	Page
<b>Foreword</b> .....	<b>iv</b>
<b>Introduction</b> .....	<b>v</b>
<b>1 Scope</b> .....	<b>1</b>
<b>2 Normative references</b> .....	<b>1</b>
<b>3 Terms and definitions</b> .....	<b>1</b>
<b>4 Classification</b> .....	<b>2</b>
4.1 Types.....	2
4.2 Classes.....	2
<b>5 Requirements</b> .....	<b>2</b>
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
<b>6 Sampling</b> .....	<b>3</b>
<b>7 Test methods</b> .....	<b>3</b>
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 General.....	5
7.4.2 Apparatus.....	5
7.4.3 Procedure.....	6
<b>8 Requirement for packaging, marking and instructions supplied by the manufacturer</b> .....	<b>8</b>
8.1 Packaging.....	8
8.2 Marking and manufacturer's instructions for use.....	8
<b>Bibliography</b> .....	<b>10</b>

## 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](http://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](http://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](http://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.

This is a preview of "ISO 10139-1:2018". [Click here to purchase the full version from the ANSI store.](#)

## 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.