INTERNATIONAL STANDARD

ISO 10139-1

Second edition
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Dentistry — Soft lining materials for removable dentures —

Part 1: Materials for short-term use

Art 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.

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, *Prosthodontic materials*.

This second edition cancels and replaces the first edition (ISO 10139-1:1991), 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

Clinically, short-term denture-lining materials are used commonly as tissue conditioners and as temporary soft lining materials. It is believed that their use as functional impression materials is now less common. 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 its earliest stage, the soft lining material is usually removed from the mouth so that it can be adjusted and tidied. If the material attains a particular level of elastic recovery, removal from the mouth will not result in unacceptable distortion. Therefore, denture lining materials for short-term use are classified in this part of ISO 10139 according to the time at which 10 % elastic recovery is established. (When stating the time at which 10 % elastic recovery is established, the manufacturer is to take, as zero time, the end of mixing.)

The other classification is related to initial compliance.

Although it is not claimed that any particular time at which 10 % elastic recovery is attained or level of compliance is superior to another, these classifications are intended to assist clinicians who will now have more information with which to make an informed choice.

In an attempt to establish some degree of harmony with the procedures used to evaluate related dental materials, the displacement rheometer, which is used to measure the setting characteristics of elastomeric impression materials, has been adopted to measure elastic recovery of the short-term soft lining materials (ISO 4823:2000). This method supersedes the consistency test.

This part of ISO 10139 does not include specific qualitative and quantitative requirements for freedom from biological hazard. When possible biological or toxicological hazards need to be assessed, refer to ISO 7405 (see the Bibliography).

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 denture lining materials suitable for short-term use.

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

3 Terms and definitions

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

3.1
tissue conditioning material
soft lining material, placed in the fitting surface of a denture, that is 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
temporary soft lining material for dentures
soft lining material for dentures that is intended to be used for a limited period to improve fit, retention and comfort

4 Classification

4.1 Types

Materials for short-term use shall be classified into the following types according to development of elastic recovery (see 5.1) as determined in accordance with 7.2:

— Type A: allows short time before removal from the mouth (5 min or less than 5 min);

— Type B: allows extended time before removal from the mouth (more than 5 min).

4.2 Classes

The materials shall be further subdivided into classes according to their initial compliance as measured by initial resistance to indentation (see 5.2) determined in accordance with 7.3:

— Class 1: high initial compliance;

— Class 2: low initial compliance.

5 Requirements

5.1 Development of elastic recovery

When specimens are subjected to the displacement rheometer test in accordance with 7.2, two of the three specimens of the material shall conform to the requirement for the relevant type as shown in Table 1. If only one specimen meets the requirement, the material shall be deemed not to conform to this part of ISO 10139.

Table 1 — Development of elastic recovery

Type	Time at which 10 % recovery is attained at test carried out at 37 °C t min
A	$t \leqslant 5$
B	$t > 5$

5.2 Change in compliance with age as measured by depth of penetration

5.2.1 Depth of penetration at 2 h

When 2-h old test specimens are subjected to the depth of penetration test in accordance with 7.3, two of the three specimens of the material shall conform to the requirements of the particular class as shown in Table 2. If only one specimen meets the requirement, the material shall be deemed not to conform to this part of ISO 10139.

Table 2 — Depth of penetration

Class	Depth of penetration at 2 h mm
1	$\geqslant 1{,}5$
2	$< 1{,}5$

5.2.2 Depth of penetration at 7 d

The depth of penetration at 7 d shall be no less than 0,5 mm. If only one specimen meets this requirement the material shall be deemed not to conform to this part of ISO 10139.

6 Sampling

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

7 Test methods

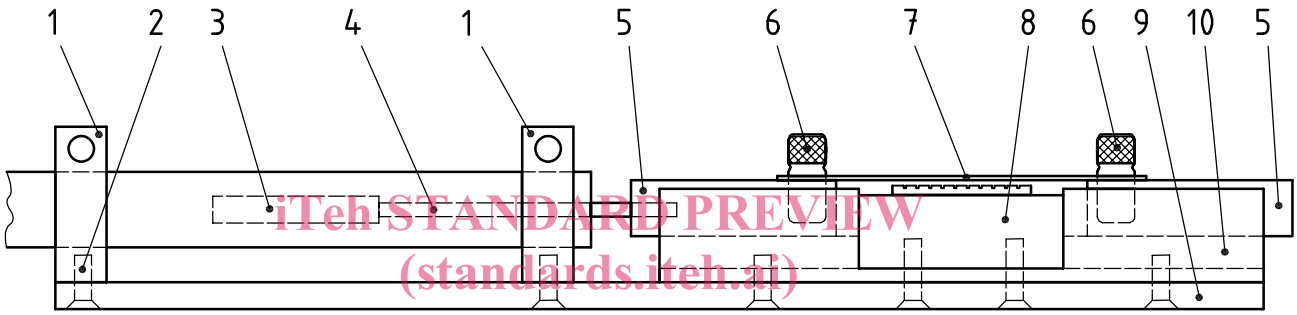
7.1 Ambient conditions for testing

All tests shall be conducted at (23 ± 1) °C unless othewise stated.

7.2 Measurement of elastic recovery

7.2.1 Apparatus

7.2.1.1 Displacement rheometer (see Figure 1).



Key

1	LVDT support	6	plate aligning and locking pins
2	flat head assembly screws	7	perforated test plate
3	LVDT core	8	slotted test specimen pedestal
4	core carrier rod	9	instrument base
5	sliding polymer blocks	10	glide track

Figure 1 — Displacement rheometer

NOTE See ISO 4823:2000 for further figures which contain full details and dimensions of the displacement rheometer.

No lubricants shall be used in attempts to reduce friction between the bearing surfaces [(5) and (10) of Figure 1] of the test instrument.

Before using the instrument, the following procedure to determine whether the friction between bearing areas of the instrument is within acceptable limits shall be used.

a) Detach the linear variable displacement transducer (LVDT) core carrier rod [(4) of Figure 1] from the sliding polymer blocks [(5) of Figure 1].

b) Clean and dry the bearing surfaces and examine them for defects that can be detected by touch (burrs, nicks, etc). Eliminate any such defects.

c) Seat the sliding blocks in the glide track [(10) of Figure 1], and use the perforated test plate [(7) of Figure 1] and the plate aligning and locking pins [(6) of Figure 1] to connect the parts for testing.

d) Elevate one end of the instrument so that the base is at 20° to horizontal.