INTERNATIONAL STANDARD

ISO 10139-2

First edition
1999-10-15

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 utilisation de longue durée

Reference number
ISO 10139-2:1999(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 3.

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.

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

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

— *Part 1: Short-term materials*

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

International Organization for Standardization
Case postale 56 • CH-1211 Genève 20 • Switzerland
Internet iso@iso.ch

Printed in Switzerland

Introduction

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

Although water sorption and solubility are also important properties of these materials, the fact that equilibrium within the material is not achieved for months or even years discounts the usefulness of any tests for specification purposes, and requirements for these properties have therefore not been included.

It was recognized that reasons for clinical failure of this group of materials included breakdown of the bond of the soft material to the denture base and tearing of the material. Although tests for bond strength have been reported in scientific literature, it has not been possible, at the present time, to select one which ensures acceptable reproducibility when used by different test centres. It is hoped that a future revision of this part of ISO 10139 will benefit from work on this problem.

Specific qualitative and quantitative requirements for freedom from biological hazard are not included in this International Standard. Information relevant to assessing possible biological or toxicological hazards is given in ISO 7405.

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 and elasticity of soft denture lining materials suitable for long-term use.

2 Normative reference

The following normative document contains provisions which, through reference in this text, constitute provisions of this part of ISO 10139. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 10139 are encouraged to investigate the possibility of applying the most recent edition of the normative document indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 3696:1987, *Water for analytical laboratory use — Specification and test methods.*

3 Terms and definitions

For the purposes of this part of ISO 10139, the following terms and definitions 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
immediate container
container which is in direct contact with the material

4 Classification

4.1 Types

Materials for long-term use are classified into the following types according to depth of penetration (see 5.1) as determined in accordance with 6.3.

— Type A: stiff;

— Type B: medium;

— Type C: soft.

4.2 Classes

The materials are further subdivided into classes according to their resistance to flow, as indicated by the depth of penetration ratio (see 5.2) determined in accordance with 6.3.

— Class I: high resistance to flow;

— Class II: low resistance to flow.

5 Requirements

5.1 Depth of penetration

When 24-h test specimens are subjected to a 5-s penetration test in accordance with 6.3.2, 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 depth of penetration for a 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 less than 0,20 mm or are greater than 2,50 mm, the material shall be deemed not to conform to this part of ISO 10139.

Table 1 — Depth of penetration in a 5-s penetration test

Type	Depth of penetration P mm
A	$0{,}20 \leqslant P < 0{,}40$
B	$0{,}40 \leqslant P < 0{,}80$
C	$0{,}80 \leqslant P < 2{,}50$

If the difference between the mean depth of penetration at 24 h and at 28 days in two or more specimens is greater than 20 %, when tested in accordance with 6.3.2 and 6.3.4, the material shall be deemed not to conform to this part of ISO 10139-2.

5.2 Depth of penetration ratio

When tested in accordance with 6.3.2 and 6.3.3, the depth of penetration ratio for the material, calculated in accordance with 6.4, shall conform to requirements shown in Table 2. For a material to be placed in a particular Class, the depth of penetration ratio for a least two of the three specimens shall conform to the requirements for that Class, as specified in Table 2. If the ratios for two or more specimens are greater than 1,75, the material shall be deemed not to conform to this part of ISO 10139.

Table 2 — Depth of penetration ratio

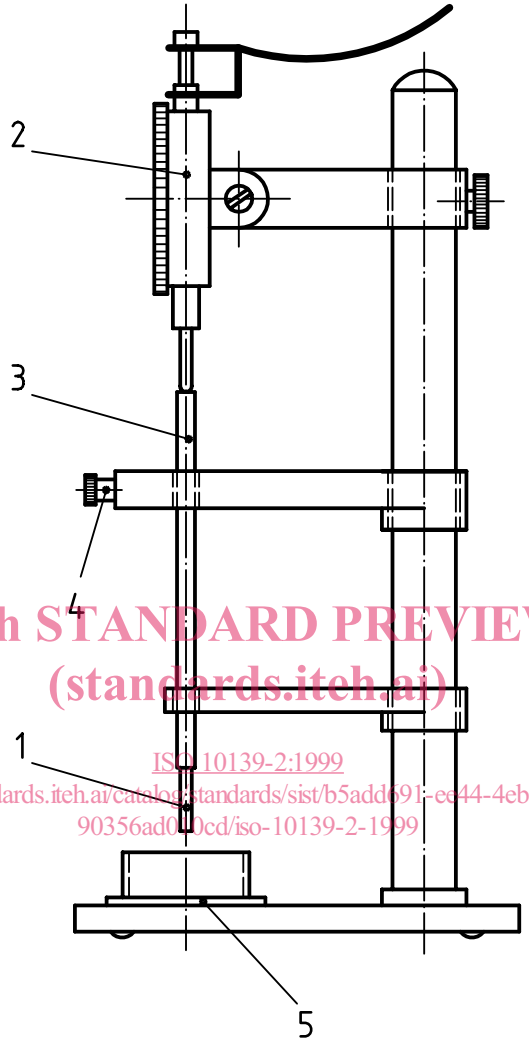
Class	Depth of penetration ratio R
I	$R \leqslant 1{,}10$
II	$1{,}10 < R \leqslant 1{,}75$

6 Test method

6.1 Apparatus

6.1.1 Penetrometer, as shown in Figure 1, equipped with a cylindrical penetrator, 1 mm in diameter, which is fixed on a spindle.

The spindle plus the cylindrical penetrator shall have a total mass of (100 ± 5) g. The penetrometer shall have a locking device which permits fixing of the penetrator at any vertical position, and a means of measuring the depth of penetration.



Key

1 Penetrator
2 Dial indicator (gauge)
3 Spindle
4 Locking device
5 PMMA plate

Figure 1 — Penetrometer

6.1.2 Water bath, capable of being maintained at (37 ± 1) °C, sufficiently large to hold three test specimens below the water level and filled with water in conformity to ISO 3696, Grade 3.

6.1.3 Mould, suitable for producing test specimens of (30 ± 1) mm diameter and (4 ± 0,5) mm thick, constructed using a smooth metal or polymer disc as a template.

6.2 Sampling and samples

6.2.1 Test sample

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

6.2.2 Preparation of test specimens

Each test specimen shall be prepared in the mould cavity in accordance with the manufacturer's instructions. The specimen shall be removed from the mould and stored in the water bath at (37 ± 1) °C for (24 ± 1) h.

6.3 Procedure

6.3.1 General

Carry out the test procedure in accordance with 6.3.2 to 6.3.4 on each of three test specimens.

6.3.2 Penetration test (5 s), 24-h specimen

After the 24-h interval, remove the specimen from the water bath and immediately place it under the penetrometer. Bring the penetrator just into contact with the surface of the specimen and lock it into position. Bring the rod from the dial gauge into contact with the spindle and adjust the dial gauge to zero.

Release the spindle for (5 ± 0,5) s, allowing the penetrator to penetrate the specimen and then lock it into position. Bring the rod from the dial gauge into contact with the spindle and record the depth of penetration in millimetres. Make five such measurements, one at each of the points shown in Figure 2 and all within 1 min after having removed the specimen from the water bath. Return the specimen to the water bath. Calculate the mean depth of penetration.

Dimensions in millimetres

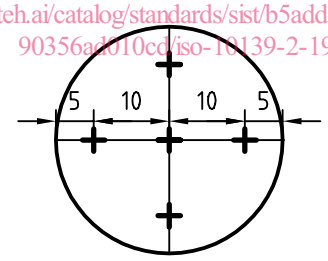


Figure 2 — Diagram to illustrate testing points for the penetrometer

6.3.3 Penetration test (30 s), 24-h specimen

Following completion of 6.3.2, after having kept the specimen in the water bath for (3 ± 2) min, remove it from the water bath and measure the depth of penetration after a loading time of (30 ± 0,5) s using the procedure described in 6.3.2.

Use fresh loading points and return the specimen to the water bath for (1,25 ± 0,25) min between each of the five measurements. Ensure that no measurement is made closer than 2 mm to a previous one. Calculate the mean depth of penetration.

After completion of the 30-s test on the 24-h specimen, immediately return the specimen to the water bath and maintain it in the water bath at (37 ± 1)°C for an additional 27 days. Change the water every 7 days.

NOTE Provided that the depth of penetration and time characteristics are recorded, it is permissible to obtain the 5-s and 30-s penetration values from a single test. If this procedure is adopted, return the specimen to the water bath for (1,25 ± 0,25) min between each test.

6.3.4 Penetration test (5 s), 28-day specimen

Twenty-eight days following specimen preparation, remove the specimen from the water bath and carry out the 5-s penetration test in accordance with 6.3.2. Ensure that no measurement is made closer than 2 mm to a previous one. Calculate the mean depth of penetration.

6.4 Expression of results

Record the test results (designated as a, b, c, d, e, f, x, y and z, expressed in mm) for each of the three specimens in the format illustrated in Table 3, and calculate the penetration ratio, R, for each specimen in accordance with Table 1.

Table 3 — Expression of results

Age of specimen	Loading time	Mean depth of penetration P			Penetration ratio R		
		Specimen 1	Specimen 2	Specimen 3	Specimen 1	Specimen 2	Specimen 3
	s	mm	mm	mm			
24 h	5	a	b	c	d/a	e/b	f/c
24 h	30	d	e	f			
28 days	5	x	y	z			

For each specimen calculate the percentage difference, D, between the mean depth of penetration in the 5-s penetration test at 24 h and at 28 days with respect to the depth of penetration at 24 h.

EXAMPLE For specimen 1, this would be calculated using the formula:

$$D = [(a - x)/a] \times 100$$

7 Requirements for labelling, marking and instructions supplied by manufacturer

7.1 Packaging

The components shall be supplied in sealed immediate containers made of materials which shall neither contaminate nor permit contamination of the contents. The immediate containers shall be packaged so as to prevent damage or leakage during transit and storage.

NOTE An outer package may also be used to present the immediate containers as a single unit.

7.2 Marking

The outer packages and the immediate containers or wrappings of the components shall be clearly marked with the following information:

a) the trade name of the product;

b) the manufacturer's name or trade mark and address, or those of the agent in the country of sale;

c) the description of the contents including the following:

1) the Type and Class of material, as determined in accordance with clause 5;

2) the number of this International Standard, i.e. ISO 10139-2:1999;

3) the chemical nature of the system, for example acrylic, polyphosphazene fluoroelastomer, silicone;

4) a statement that the product is a soft lining material for long-term use in removable dentures;