

INTERNATIONAL STANDARD

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10139-1

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Dentistry — Resilient lining materials for removable dentures —

Part 1:

Short-term materials

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*Produits et matériel pour l'art dentaire — Produits souples pour intrados
de prothèses dentaires amovibles —*
Partie 1: Produits à court terme



Reference number
ISO 10139-1:1991(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.

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 10139-1 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Sub-Committee SC 2, *Prosthetic materials*.

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

- Part 1: *Short-term materials*
- Part 2: *Long-term materials*

Introduction

0.1 This part of ISO 10139 applies to denture lining materials commonly referred to as “tissue conditioners” and temporary lining materials. These materials are intended to be inserted into a denture at the chairside, to be used for a limited period or “short-term” of approximately seven days with the aim of assisting the tissues in contact with the prosthesis to return to a healthy condition, or to improve the fit of a denture for several weeks.

0.2 Specific qualitative and quantitative requirements for freedom from biological hazard are not included in this International Standard, but it is recommended that, in assessing possible biological or toxicological hazards, reference should be made to ISO/TR 7405:1984, *Biological evaluation of dental materials*.

0.3 Although this International Standard does not specify requirements for the composition of the lining materials, some national and international authorities do require details of composition to be provided by the manufacturer.

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Dentistry — Resilient lining materials for removable dentures —

Part 1: Short-term materials

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.

3.1.2 The consistency measured shall be within $\pm 15\%$ of the value stated by the manufacturer [see clause 8f)] and shall not exceed limits stated in 3.1.1.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 10139. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 10139 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 1563:1990, *Dental alginate impression material*.

ISO 4823:1991¹⁾, *Dental elastomeric impression materials*.

3 Requirements

3.1 Consistency

3.1.1 When determined according to 5.1, the consistency shall be between 25 mm and 75 mm. The higher the consistency the greater the initial flow.

3.2 Penetration (behaviour in water)

3.2.1 When tested according to 5.2, the material shall satisfy the following requirements:

- the 2 h penetration shall be not greater than 1,8 mm;
- the seven-day penetration shall be not less than 0,18 mm;
- the ratio A/B shall be not greater than 5.

3.2.2 When tested according to 5.2, the value obtained for the penetration ratio (ratio A/B) shall not vary from the value stated by the manufacturer [see clause 8g)] by more than 0,5 and shall not exceed the limit stated in 3.2.1.

4 Sampling

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

1) To be published.

5 Test methods

5.1 Consistency test

5.1.1 Apparatus

- a) **Delivery tube or syringe** of a suitable material, for example, glass or polytetrafluoroethylene (PTFE), having an internal diameter between 10 mm and 15 mm and capable of dispensing a volume in excess of the sample size (i.e. in excess of $2 \text{ ml} \pm 0,1 \text{ ml}$).
- b) **Two glass plates**, one of which (the "upper" plate) has a mass of $100 \text{ g} \pm 1 \text{ g}$ and a thickness of not less than 2 mm.

NOTE 1 This "upper" plate is referred to in the procedure as the minor load.

- c) A **weight** of $1\,000 \text{ g} \pm 5 \text{ g}$.

NOTE 2 This is referred to in the procedure as the major load.

- d) **Equipment** for applying loads vertically as shown in figure 1.
- e) **Equipment** capable of maintaining the test apparatus in an environment of $(37 \pm 1) \text{ }^\circ\text{C}$.

5.1.2 Conditioning

Allow all test apparatus to reach equilibrium in the environment of $(37 \pm 1) \text{ }^\circ\text{C}$ for at least 30 min before testing.

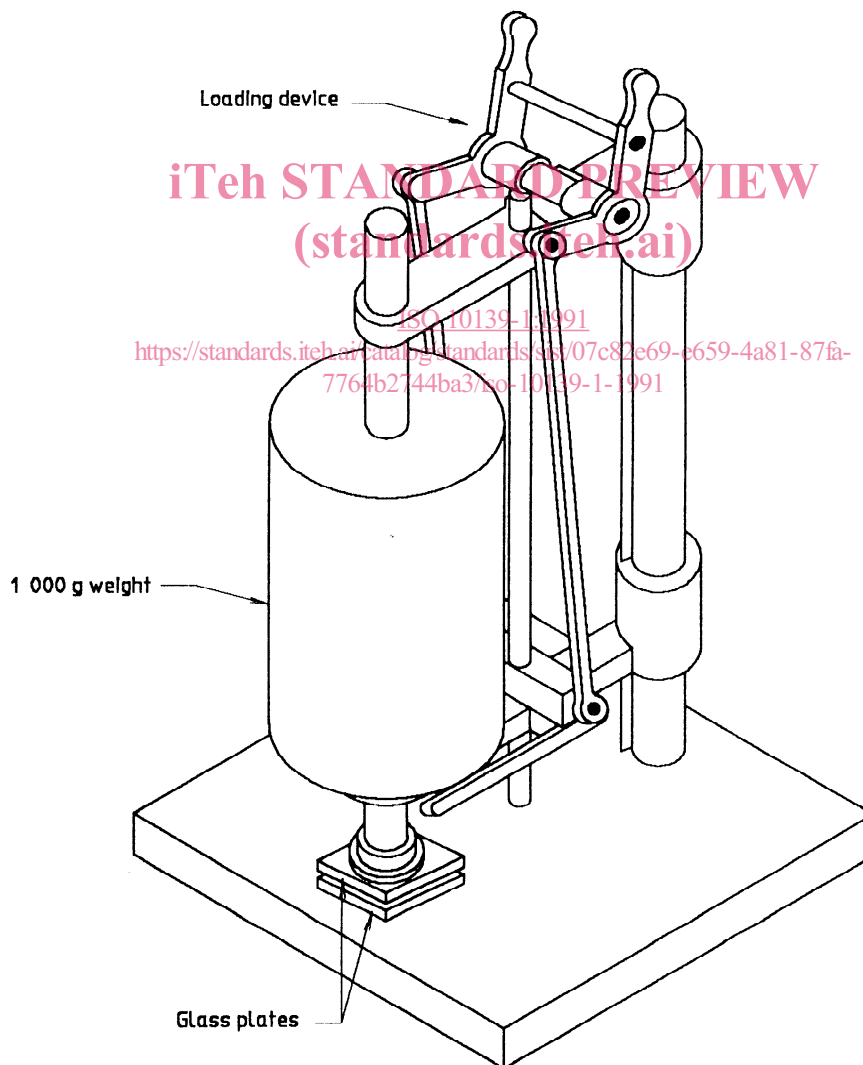


Figure 1 — Apparatus for determining consistency

5.1.3 Procedure

Prepare a sample using the manufacturer's recommended technique. Where a range of mixing times is given, use the mean time. Use the syringe [5.1.1a)] to dispense a sample of $2 \text{ ml} \pm 0,1 \text{ ml}$ onto one of the glass plates [5.1.1b)].

$30 \text{ s} \pm 1 \text{ s}$ after the end of mixing, compress the sample between the two glass plates by vertically applying the minor load [5.1.1b)] and immediately transfer the plates and the sample to the environment [5.1.1e)] maintained at $(37 \pm 1) ^\circ\text{C}$.

$120 \text{ s} \pm 1 \text{ s}$ after the end of mixing, vertically apply the major load [5.1.1c)] so that the total load (major and minor) becomes $1\ 100 \text{ g} \pm 6 \text{ g}$. Maintain this load for $60 \text{ s} \pm 1 \text{ s}$ and then remove the major load, leaving the minor load in place.

$8 \text{ min} \pm 0,5 \text{ min}$ after the end of the mixing, measure the maximum and minimum diameters of the disc through the glass plates to an accuracy of $\pm 0,5 \text{ mm}$ and calculate the average of the two measurements.

Repeat the test three more times and calculate the average of the four results.

5.2 Penetration test (behaviour in water)

5.2.1 Apparatus

- A **penetrometer instrument**, as shown in figure 2, equipped with a cylindrical penetrator, 1 mm in diameter, which is fixed on a vertical rod. The vertical rod plus the cylindrical penetrator shall have a total mass of $50 \text{ g} \pm 5 \text{ g}$. The penetrometer shall have a locking device which permits fixing the penetrator at any vertical position and a means of measuring the depth of penetration.
- A **water bath**, capable of being maintained at $(37 \pm 1) ^\circ\text{C}$ and large enough to carry three specimens below the water level.
- A **flat plate** of $50 \text{ mm} \times 50 \text{ mm} \times 4 \text{ mm}$ made of unplasticized poly(methyl methacrylate) (PMMA), such as Plexiglas or Perspex.²⁾
- A **metal ring** $30 \text{ mm} \pm 1 \text{ mm}$ internal diameter and $3 \text{ mm} \pm 0,1 \text{ mm}$ high.

- Unplasticized polyester film** of $50 \mu\text{m} \pm 30 \mu\text{m}$ thickness.
- A **glass plate** of $50 \text{ mm} \times 50 \text{ mm} \times 6 \text{ mm} \pm 0,5 \text{ mm}$.
- A **weight** of $2 \text{ kg} \pm 0,1 \text{ kg}$.

5.2.2 Procedure

Prepare a sample of approximately 20 ml using the manufacturer's recommended technique. When a range of mixing times is given, use the mean time.

Place the metal ring [5.2.1d)] on the PMMA plate [5.2.1c)] and fill it to a slight excess with the mixed material. Cover the material with the polyester film [5.2.1e)]. Place the glass plate [5.2.1f)] on top and apply the weight [5.2.1g)]. 10 min after the start of mixing, remove the load, the glass plate and the polyester film, and store the sample in the water bath at $(37 \pm 1) ^\circ\text{C}$.

$115 \text{ min} \pm 0,5 \text{ min}$ after the start of mixing, remove the specimen from the water bath. Place the specimen under the penetrometer instrument, bring the penetrator just into contact with the surface of the specimen and lock in position. Bring the rod from the dial gauge into contact with the vertical rod and adjust to zero.

$120 \text{ min} \pm 0,5 \text{ min}$ after the start of the mixing, release the vertical rod for $1,5 \text{ s} \pm 0,5 \text{ s}$, allowing the penetrator to penetrate the specimen and lock it in position. Bring the rod of the dial indicator into contact with the adjusted vertical rod again and record the depth of penetration, in millimetres. Bring the cylindrical penetrator into contact with a new area on the specimen and repeat this test two more times. Record the mean of the three measurements as value *A*.

Store the specimen again in water at $(37 \pm 1) ^\circ\text{C}$, repeat the test after seven days and record the mean value as *B*.

It is important to test three samples with three readings (penetrations) from each sample. The penetrations shall be 5 mm from the ring and from each of the other penetrations.

Calculate the penetration ratio as *A/B* and express the result to one decimal place.

2) Plexiglas and Perspex are trade-names. This information is given for the convenience of users of this International Standard and does not constitute an endorsement by ISO of the products named. Equivalent products may be used if they can be shown to lead to the same results.

Dimensions in millimetres
surface roughness values in micrometres

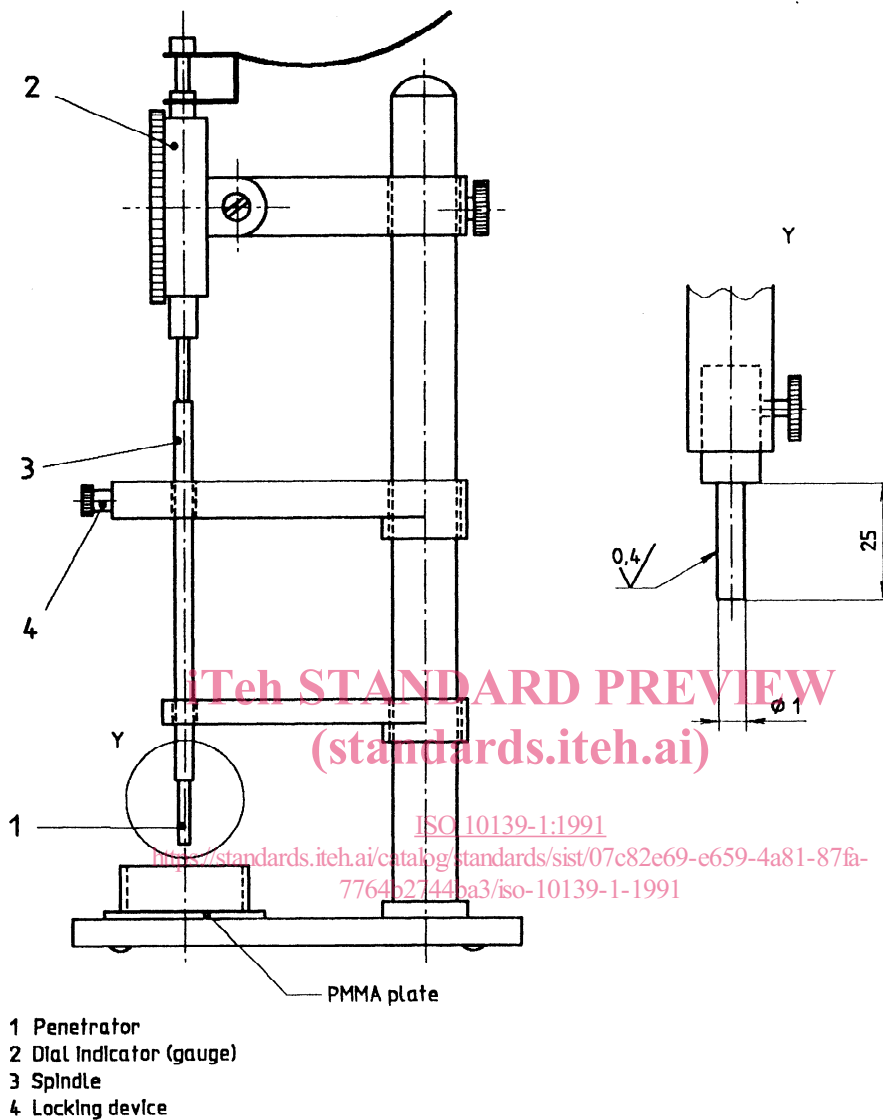


Figure 2 — Penetrometer

6 Packaging

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

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

For the purposes of this part of ISO 10139, the container is considered to be the immediate wrapping of the components.

7 Marking of packages and containers

7.1 Packages

Each outer package shall be clearly marked with the following information:

- trade-name of the product;
- the manufacturer's registered name or trademark;
- a statement that the product is intended for short-term use;

- d) the mass of solids (in grams) and/or volume of liquids (in millilitres);
- e) the date(s) of manufacture or dispatch (year and month) by the manufacturer;
- f) the recommended conditions of storage, and the shelf life or expiry date for the product under the conditions of storage;
- g) the flash-point of any liquid in the package;
- h) hazard warning, where appropriate, for toxic, hazardous, inflammable or irritating characteristics.

7.2 Individual containers

All containers shall be clearly marked with the required information. In those cases where the size of the container or package is too small to accept some of the details, reference may be made on the outside package to a leaflet inside where the additional information is available. Unless national legislation prohibits or provides for alternatives, the labelling shall include the following:

- a) trade-name of the product;
- b) the manufacturer's name and address, and/or agent in country of sale;
- c) a statement that the product is intended for short-term use;
- d) the USE BEFORE date, beyond which the material may not exhibit its best properties (expiry date);
- e) any special storage conditions;
- f) the mass of solids (in grams) and/or volume of liquids (in millilitres);
- g) the flash-point of any liquid in the package;
- h) any pharmaceutically active ingredients when present and referred to in the material claim or use;

- i) manufacturer's batch reference.

8 Information to be supplied by manufacturer

Adequate and accurate instructions for use shall accompany each package and shall include the information required for a), b), c) and f) in 7.2, plus the following information:

- a) the powder/liquid ratio where applicable, indicated by mass (in grams) and volume (in millilitres);
- b) the time, temperature and procedure to mix or prepare the material properly;
- c) the working time and where applicable, the recommended time of placement;
- d) the time at which the denture may be removed from the mouth;
- e) the method(s) for cleaning;

NOTE 3 Some cleaning agents are incompatible with some short-term resilient lining materials.

- f) the consistency (in millimetres) determined according to 5.1;
- g) the penetration ratio determined according to 5.2 and the following text:

The penetration ratio indicates the change in firmness of the material between 2 h and 7 days. Penetration ratios greater than 1 indicate increased firmness. Ratios less than 1 indicate that the material is softer at 7 days.

The closer the 2 h penetration value is to 1,8, the softer will be the material. The closer the 7 day penetration value is to 0,18, the harder will be the material.

- h) the recommended storage conditions and shelf life.