
**Dentistry — Chairside denture base
relining materials —**

**Part 1:
Hard type materials**

*Médecine bucco-dentaire — Matériaux de rebasage pour base de
prothèses dentaires —*

Partie 1: Matériaux durs

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Published in Switzerland

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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.

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 of 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 www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthetic materials*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

A list of all parts in the ISO 23401 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

The purpose of denture base relining materials is to improve the fit of dentures to the oral mucosa. The materials can reline the denture the same day. Thus, they can be a useful material for the general denture patients and especially for bedridden patients who may have no access to dental surgery.

Requirements and test methods for the soft type materials are defined in detail by ISO 10139-1 and ISO 10139-2, but it is extremely difficult to incorporate the hard type materials in these International Standards of soft lining materials because of the differences in the main components, curing mechanisms and physical properties.

Also, chairside denture base relining materials and denture base materials covered by ISO 20795-1 and ISO 20795-2 differ in terms of polymerization method and required properties. As chairside denture base relining materials are partially or even mainly handled intraorally, properties such as consistency and exothermicity during intra-oral polymerization are quite important.

Specific qualitative and quantitative requirements for freedom from biological hazard are not included in this document, but it is recommended that, in assessing possible biological or toxicological hazards, reference be made to ISO 10993-1 and ISO 7405.

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Dentistry — Chairside denture base relining materials —

Part 1: Hard type materials

1 Scope

This document specifies the requirements for acrylic hard type materials used as chairside denture base relining materials and the test methods to determine compliance with these requirements. This document also specifies requirements for packaging and marking the products and for the instructions for use to be supplied by the manufacturer.

Dentures which are relined by chairside denture base relining materials specified by this document are limited to those of acrylic.

This document is not applicable to either denture base relining materials that are for laboratory use or soft lining materials.

NOTE 1 Acrylic hard type materials contain acrylic and methacrylic monomers such as acrylic acid esters and substituted (meth)acrylic acid esters and their polymers.

NOTE 2 Acrylic dentures are made of polymers such as poly (acrylic acid esters), poly (substituted acrylic acid esters) and rubber-modified poly (methacrylic acid esters).

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 1942, *Dentistry — Vocabulary*

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

ISO 4545-1, *Metallic materials — Knoop hardness test — Part 1: Test method*

ISO 6344-3, *Coated abrasives — Determination and designation of grain size distribution — Part 3: Microgrit sizes P240 to P5000*

ISO 8601-1, *Date and time — Representations for information interchange — Part 1: Basic rules*

ISO 20795-1, *Dentistry — Base polymers — Part 1: Denture base polymers*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942, ISO 20795-1 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

3.1 chairside denture base relining
denture base relining where the relining material is moulded and partially or completely polymerized intraorally

3.2 peak temperature
maximum temperature during polymerization

4 Classification

4.1 Types

The chairside denture base relining materials are classified into the following types in accordance with their methods of polymerization.

- Type 1: materials whose setting is affected by mixing initiator(s) and activator(s) (“self-curing” materials);
- Type 2: materials whose setting is affected by the application of light from an external source (“light-curing” materials);
- Type 3: materials whose setting is affected by mixing initiator(s) and activator(s) and also by the application of light from an external source (“dual-curing” materials).

4.2 Classes

The chairside denture base relining materials are classified into the following classes in accordance with material form.

- Class 1: powder and liquid;
- Class 2: paste;
- Class 3: sheet.

5 Requirements

5.1 Appearance

5.1.1 Liquid

The liquid shall be homogeneous when tested in accordance with [6.4.1](#). The liquid shall be free of deposits or sediment.

5.1.2 Powder, paste and sheet

The powder, paste and sheet shall not contain extraneous materials when tested in accordance with [6.4.1](#). Separation of liquid (e.g. monomer) shall not be observed in the paste or sheet when tested in accordance with [6.4](#).

5.2 Consistency

The diameter of the compressed mixture of Class 1 or Class 2 materials shall be from 30 mm to 60 mm when tested in accordance with [6.5](#).

5.3 Peak temperature

The peak temperature of the Type 1 and Type 3 materials shall not be more than 60 °C when tested in accordance with [6.6](#).

5.4 Porosity and defects

The cured chairside denture base relining materials shall not have porosities or defects that can be easily identified when tested in accordance with [6.4.2](#).

5.5 Surface finish

The cured chairside denture base relining materials shall have a glossy surface when tested in accordance with [6.4.3](#).

5.6 Water sorption

The water sorption shall not be more than 32 µg/mm³ when the cured chairside denture base relining material is tested in accordance with [6.7](#).

5.7 Water solubility

The water solubility shall not be more than 8,0 µg/mm³ when the cured chairside denture base relining material is tested in accordance with [6.7](#).

5.8 Knoop hardness

The Knoop hardness of the cured chairside denture base relining materials shall not be less than 7 HK 0,1 /20 (load / dwell time) when tested in accordance with [6.8](#).

6 Test methods

6.1 Sampling

The test sample shall consist of a retail package, or packages, from the same batch and enough amount of the material to carry out the specified tests with an allowance for any repeat tests (approximately 60 ml).

6.2 Preparation of test specimens

Prepare the test specimens in accordance with the manufacturer's instructions for use. For Class 1 materials, vibration may be applied for 15 s or less to remove porosity immediately after mixing, if necessary.

6.3 Conditions for testing

Unless specified otherwise by the manufacturer or in this document, prepare and test all specimens at a temperature of (23 ± 2) °C and a relative humidity of (50 ± 20) %. Leave the chairside denture base relining material and test apparatus at a temperature of (23 ± 2) °C for 2 h or longer before testing, unless specified otherwise.

Leave the accessories used for fabrication of the test specimens under the same conditions for 30 min or longer before use.

6.4 Visual inspection

6.4.1 Appearance

Visually inspect the test sample of the liquid, powder, paste or sheet without magnification to determine compliance with the requirements (5.1.1 and 5.1.2).

6.4.2 Porosity and defects

Visually inspect the test specimen prepared in accordance with 6.7.3 without magnification to determine compliance with the requirements (5.4).

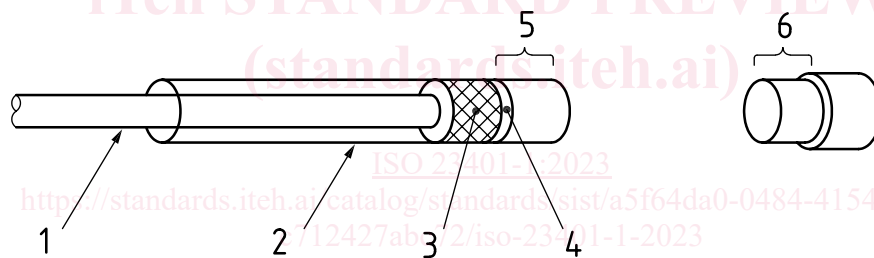
6.4.3 Surface finish

Visually inspect the test specimen prepared in accordance with 6.8.2 to determine compliance with the requirements (5.5).

6.5 Consistency

6.5.1 Apparatus

6.5.1.1 Sampling instrument, capable of measuring and collecting 0,5 ml of uncured material in a mixture of an appropriate amount (e.g. Figure 1).



Key

- 1 plunger
- 2 plastic (polyethylene or polypropylene) or glass tube
- 3 rubber plug
- 4 plastic (polyethylene or polypropylene) film
- 5 (0,5 ± 0,05) ml volume
- 6 plug gauge of (0,5 ± 0,05) ml volume

Figure 1 — Apparatus for measuring consistency

6.5.1.2 Unplasticized sheets (polyester, polyethylene, or polypropylene), having a thickness of (50 ± 25) μm.

6.5.1.3 Glass plate, with dimensions of approximately 70 mm × 70 mm and a thickness of 1 mm.

6.5.1.4 Plate for pressure, with dimensions of approximately 70 mm × 70 mm and made of glass or metal.

6.5.1.5 Weight, with a mass of 750 g including the plate for pressure.

6.5.2 Procedure

Prepare enough amount of material using the method specified by the manufacturer, collect $(0,5 \pm 0,05)$ ml using the sampling instrument (6.5.1.1) and place it on the central part of the lower glass plate (6.5.1.3) covered with an unplasticized sheet (6.5.1.2).

After 2 min from the start of mixing, gently place another unplasticized sheet and the plate for pressure (6.5.1.4) on top of the sample, then place the weight (6.5.1.5) centrally on the plate for a total mass of 750 g and apply for 5 min.

After removing the weight, measure the diameter values of the obtained disc-like sample in four directions at intervals of approximately 45° and calculate the mean of these values and make it the sample diameter.

Perform this test three times. When the consistency of at least two specimens fulfil the requirement (5.2), the material complies.

6.6 Peak temperature

6.6.1 Apparatus

6.6.1.1 Unplasticized sheet (polyester, polyethylene, or polypropylene), having a thickness of (50 ± 25) μm .

6.6.1.2 Two glass plates, with dimensions of approximately $100 \text{ mm} \times 80 \text{ mm} \times 6 \text{ mm}$.

6.6.1.3 Temperature measuring equipment, using a calibrated thermocouple and potentiometer for monitoring the temperature.

6.6.1.4 Circular stainless steel ring, with a notch in which a thermocouple can be placed, with an inner diameter of $(60 \pm 0,1)$ mm, an outer diameter of $(67 \pm 0,1)$ mm, a height of $(2 \pm 0,1)$ mm, and a notch depth of $(1 \pm 0,1)$ mm.

6.6.1.5 Thermocouple, consist of wires 0,1 mm to 1,0 mm in diameter, made of a material (e.g. copper/copper-nickel alloy) capable of registering temperature changes in a specimen of setting material to an accuracy of 0,1 $^\circ\text{C}$.

6.6.2 Procedure

Place one of the glass plates (6.6.1.2) in an oven at (37 ± 2) $^\circ\text{C}$ at least 2 h before the start of testing.

Place the unplasticized sheet (6.6.1.1) on the first glass plate (6.6.1.2) that has been kept at (23 ± 2) $^\circ\text{C}$ and place the ring (6.6.1.4) in the centre of it. Place the thermocouple (6.6.1.3) so that it is positioned in the centre of the ring (see Figure 2).