INTERNATIONAL STANDARD

ISO 20795-2

Second edition
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Dentistry — Base polymers —

Part 2: Orthodontic base polymers

Médecine bucco-dentaire — Polymères de base —

Partie 2: Polymères pour base orthodontique

Reference number
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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 20795-2 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthodontic materials*.

This second edition cancels and replaces the first edition (ISO 20795-2:2010), which has been technically revised.

ISO 20795 consists of the following parts, under the general title *Dentistry — Base polymers*:

— *Part 1: Denture base polymers*

— *Part 2: Orthodontic base polymers*

Introduction

Polymeric materials based on methacrylates have been widely used in the construction of both active and passive removable orthodontic appliances for many years. These removable appliances are mainly used in the orthodontic treatment of children. The method of preparing the polymeric part of the orthodontic appliance has several potential problems. Depending on the polymerization process and polymer/monomer mixing ratio, the polymer part of the removable orthodontic appliance may be weaker than if conventional flasking and heat systems of polymerization were used. There may be a greater risk that an appliance will have more residual substances such as monomers than a conventional heat-cured denture base polymer. In addition, a high monomer content of the polymer/monomer mix may cause increased contraction on polymerization.

Specific qualitative and quantitative requirements for freedom from biological hazard are not included in this part of ISO 20795, but it is recommended that, in assessing possible biological or toxicological hazards, reference be made to ISO 10993-1 and ISO 7405.

Dentistry — Base polymers —

Part 2:
Orthodontic base polymers

1 Scope

This part of ISO 20795 is applicable to orthodontic base polymers and copolymers used in the construction of both active and passive orthodontic appliances and specifies their requirements. It also specifies test methods to be used in determining compliance with these requirements. It further specifies requirements with respect to packaging and marking the products and to the instructions to be supplied for use of these materials.

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 1942, *Dentistry — Vocabulary*

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

ISO 7491, *Dental materials — Determination of colour stability*

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

ISO 20795-1:2008, *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 and the following apply.

3.1
autopolymerizable materials
products having polymerization initiated by chemical means and not requiring application of temperatures above 65 °C to complete the polymerization

3.2
build up technique
spray on technique
gradual addition of increments of powder and liquid on the master cast until the desired shape is attained

3.3
immediate container
container that is in direct contact with the ⟨orthodontic⟩ base materials

3.4
light activated polymers
products having polymerization initiated by the application of energy from an external radiation source, such as visible light

3.5
liquid
monomeric liquid to be mixed with polymeric particles to form a mouldable dough or fluid resin mixture used for forming ⟨orthodontic⟩ bases

3.6
orthodontic base
polymer part of the ⟨orthodontic⟩ appliance

3.7
outer packaging
labelled container or wrapping within which other containers are packed

3.8
powder
polymeric particles to be mixed with monomeric liquid to form a mouldable dough or fluid resin mixture used for forming ⟨orthodontic⟩ bases

3.9
processing
procedure of preparing a solid ⟨orthodontic⟩ base polymer plate and/or specimen by polymerization or injection

3.10
thermoplastic material
hard ⟨orthodontic⟩ polymeric material that can be softened by application of heat to make it mouldable, and then returned to the hardened state upon cooling

4 Classification

Orthodontic base polymers covered by this part of ISO 20795 are categorized into the following types:

— Type 1: autopolymerizable materials;

— Type 2: light-activated materials;

— Type 3: thermoplastic materials.

5 Requirements

5.1 Unpolymerized material

5.1.1 Liquid component

5.1.1.1 General

The liquid shall consist essentially of monomeric material compatible with the powder.

5.1.1.2 Homogeneity

The liquid shall be free of deposit or sediment that can be observed by visual inspection (see 8.1.1).

5.1.2 Solid components

The solid or semi-solid components shall be free of extraneous material that can be observed by visual inspection (see 8.1.1).

5.2 Polymerized material

5.2.1 Biocompatibility

Specific qualitative and quantitative requirements for freedom from biological hazard are not included in this part of ISO 20795, but it is recommended that, in assessing possible biological or toxicological hazards, reference be made to ISO 10993-1 and ISO 7405.

5.2.2 Surface characteristics

5.2.2.1 When processed in the manner recommended by the manufacturer and in contact with materials recommended by the manufacturer, orthodontic base polymer test specimens prepared in accordance with 8.5.2 and 8.6.3 shall have a smooth, hard, and glossy surface (see 8.1.1).

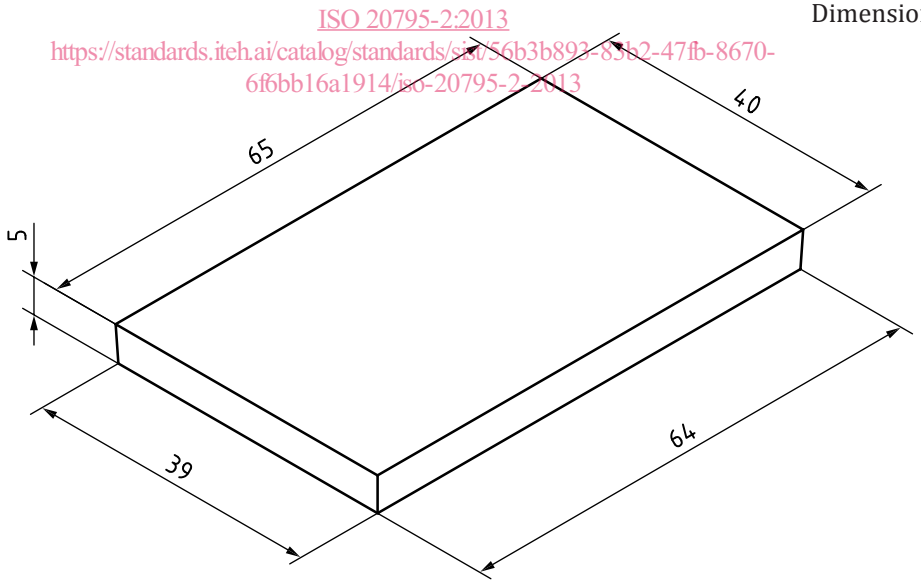
5.2.2.2 The test specimens for residual methyl methacrylate monomer (see 8.5) and the specimens for water sorption and solubility testing (see 8.7) shall retain their form without visible distortion after processing (see 8.1.1).

5.2.2.3 When polished in accordance with 8.3.1.4, the specimen plates shall present a smooth surface with a high gloss (see 8.1.1).

5.2.3 Shape capability

When prepared in accordance with the manufacturer's instructions, all types of orthodontic base polymers shall produce a test specimen plate (see 8.3.1.4) with defined edges and dimensions as given in Figure 1.

Dimensions in millimetres



NOTE Dimensional tolerance shall be ± 1 mm.

Figure 1 — Model of the specimen plate (see 8.3.1.2.1)

5.2.4 Colour

The colour of a test specimen strip prepared in accordance with 8.3.2.3 shall be as stated by the manufacturer when tested and inspected in accordance with 8.1.1 and 8.2.

Coloured orthodontic base polymers shall be evenly pigmented and/or coloured.

Transparent orthodontic base polymers shall be transparent or clear.

5.2.5 Freedom from porosity

When prepared in accordance with 8.3.2.3, the test specimen strips shall not show pores that can be observed by visual inspection (see 8.1.1).

5.2.6 Ultimate flexural strength

When determined in accordance with 8.3.2.5, the ultimate flexural strength shall be not less than 50 MPa (see Table 1).

5.2.7 Flexural modulus

When determined in accordance with 8.3.2.5, the flexural modulus of the processed orthodontic base polymer shall be at least 1 500 MPa (see Table 1).

5.2.8 Maximum stress intensity factor

When determined in accordance with 8.4, the maximum stress intensity factor shall be at least 1,1 MPa·$m^{1/2}$ (see Table 1).

5.2.9 Total fracture work

When determined in accordance with 8.4, the total fracture work shall be at least 250 J/m^2 (see Table 1).

5.2.10 Residual methyl methacrylate monomer

When orthodontic base polymers are prepared and tested in accordance with 8.5, the following shall apply (see Table 1).

The maximum mass fraction of residual methyl methacrylate is 5 % for all three types of orthodontic base polymers.

The residual methyl methacrylate content claimed by the manufacturer [see 9.3 b)] shall not exceed the stated value by more than 0,2 % mass fraction when tested in accordance with 8.5.

5.2.11 Plasticizers

If the orthodontic base polymer contains extractable phthalate plasticizer(s), identify and quantify the plasticizer(s) as percent mass fraction determined in accordance with 8.6. The content shall not exceed the stated value by more than 10 % (see Table 1).

5.2.12 Water sorption

When the processed polymer is tested in accordance with 8.7, the increase in mass per volume (water sorption) shall not exceed 32 µg/mm^3 (see Table 1).

5.2.13 Water solubility

When the processed polymer is tested in accordance with 8.7, the loss in mass per volume (water solubility) shall not exceed 5 µg/mm^3 (see Table 1).

Table 1 — Summary of requirements described in 5.2.6 to 5.2.13

Requirements	Flexural properties		Fracture toughness		Residual methyl methacrylate monomer	Phthalate plasticizers	Water sorption	Water solubility
	Ultimate flexural strength	Flexural modulus	Maximum stress intensity factor	Total fracture work				
	σ	E	K_{max}	W_f			w_{sp}	w_{sl}
	MPa min.	MPa min.	MPa $m^{1/2}$ min.	J/m^2 min.	Percent mass fraction max.	Percent mass fraction max.	$\mu g/mm^3$ max.	$\mu g/mm^3$ max.
All types	50	1 500	1,1	250	5	Maximum 10 % above stated value[a]	32	5

[a] For example, if the manufacturer states a percent mass fraction of 5 % of phthalate plasticizers, the content shall not be more than 5,5 %.

6 Sampling

The test sample shall consist of a retail package, or packages, containing sufficient material to carry out the specified tests, plus an allowance for any necessary repetition of the tests. If more than one package is required, all material shall be of the same batch.

7 Preparation of specimen plates and test specimens

7.1 Laboratory environment

Prepare and test specimens and specimen plates at (23 ± 2) °C and (50 ± 10) % relative humidity, unless otherwise specified in this part of ISO 20795 or in the manufacturer's instructions.

7.2 Procedures

Prepare, manipulate, and process materials for making the test specimens and specimen plates using the equipment and procedures recommended in the manufacturer's instructions (see 9.3), unless otherwise specified in this part of ISO 20795.

From materials requiring a mixture of two or more ingredients, prepare separate mixes for each test specimen or specimen plate.

7.3 Special equipment

Any special equipment specified by the manufacturer for processing a material shall be made available by the manufacturer.

8 Test methods

8.1 Inspection for compliance determination

8.1.1 Visual inspection

Observe the test samples by visual inspection in order to determine compliance with the requirements laid down in 5.1.1.2 and 5.1.2.

Observe the test specimen(s) by visual inspection in order to determine compliance with the requirements laid down in 5.2.2.1, 5.2.2.2, and 5.2.5 and inspect for colour (see 5.2.4) in accordance with ISO 7491.

Observe the test specimen plate(s) by visual inspection in order to determine compliance with the requirements laid down in 5.2.2.3 and 5.2.3.

Inspect visually to determine compliance with Clause 9.

8.1.2 Expression of results

Report whether the liquid components pass or fail (see 5.1.1.2).

Report whether the solid components pass or fail (see 5.1.2).

Report whether the surfaces of the orthodontic base polymer specimens have a smooth, hard, and glossy surface (see 5.2.2.1) and whether the specimens pass or fail.

Report whether the form of specimens is retained without distortion and whether the specimens pass or fail (see 5.2.2.2).

Report whether the specimen plates have a smooth surface with a high gloss after polishing and whether the specimen plate passes or fails (see 5.2.2.3).

Report whether the specimen plate has defined edges and whether the specimen plate passes or fails (see 5.2.3).

Report whether the material passes or fails the requirements for labelling, marking, packaging, and instructions (see Clause 9).

8.2 Colour

8.2.1 General

Compare a specimen strip prepared in accordance with 8.3.2.3 for compliance with 5.2.4. Inspect its colour visually (see 8.1.1) for compliance with the manufacturer's statement [see 9.2.1 c) and 9.2.2 c)].

8.2.2 Expression of results

Report whether the material passes or fails (see 5.2.4) when tested in accordance with ISO 7491.

8.3 Polishability, freedom from porosity, ultimate flexural strength, and flexural modulus

8.3.1 Polishability

8.3.1.1 Materials

8.3.1.1.1 Wet pumice for polishing, having a grain size of approximately 10 µm to 20 µm.

8.3.1.2 Apparatus

8.3.1.2.1 Model of the specimen plate, in metal or polymer (see Figure 1).

8.3.1.2.2 Denture flask, capable of accommodating the test specimen plate so that the corners are not less than 5 mm from the walls of the flask.

8.3.1.2.3 Equipment for processing the orthodontic base resin, including gypsum or hydrocolloid investment system [see 9.3 j)].

