INTERNATIONAL STANDARD

ISO 12163

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Dental baseplate/modelling wax

Cires dentaires à modeler

Reference number
ISO 12163:1999(E)

Foreword

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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 12163 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthodontic materials.*

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Introduction

This International Standard does not specify the requirements for safety from biological or toxicological hazards. It is however recommended that reference be made to ISO 7405 and ISO 10993-1 for assessing possible biological or toxicological hazards.

Dental baseplate/modelling wax

1 Scope

This International Standard specifies the classification of, and requirements for, dental baseplate/modelling wax consisting of natural and synthetic waxes used principally in the construction of dentures, together with the test methods to be employed to determine compliance with those requirements.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents 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 1302, *Technical drawings — Method of indicating surface texture.*

ISO 1942-2, *Dental vocabulary — Part 2: Dental materials.*

ISO 3336:1993, *Dentistry — Synthetic resin teeth.*

ISO 4824:1993, *Dentistry — Ceramic denture teeth.*

ISO 6873:1998, *Dental gypsum products.*

3 Classification

Dental baseplate/modelling waxes are classified according to the flow characteristics that represent their hardness, as follows:

Type 1: Soft

Type 2: Hard

Type 3: Extra-hard

4 Requirements

4.1 Appearance

The sheet wax shall be uniform in colour and thickness, of smooth texture and free of foreign materials. Use visual inspection (6.1) to determine compliance with this requirement.

4.2 Colour

The colour of the wax shall be as stated by the manufacturer. Use visual inspection to determine compliance with this requirement (6.1).

4.3 Behaviour on softening

When heated, the wax shall soften without crumbling or becoming flaky, and shall cohere readily and not laminate when formed into a working mass (6.1).

4.4 Behaviour on trimming

The wax shall be trimmed easily and cleanly with a sharp instrument at (23,0 ± 2,0) °C without tearing, chipping or flaking (6.1).

4.5 Appearance after flaming

The wax shall have a smooth glossy surface after sufficient flame heating to melt the wax superficially (6.1).

4.6 Residue

The wax shall not leave a residue on ceramic or plastic teeth when tested as described in 6.2.1.

4.7 Behaviour of colouring material

The colouring material shall neither separate from the wax nor impregnate the gypsum mould when tested as described in 6.2.1.

4.8 Flow behaviour

The samples of wax, when tested in accordance with 6.2.2, shall have flow properties complying with the requirements in Table 1.

Table 1 — Flow at certain temperatures

Temperature °C	Type 1		Type 2		Type 3	
	Minimum (%)	Maximum (%)	Minimum (%)	Maximum (%)	Minimum (%)	Maximum (%)
(23,0 ± 0,1)	—	1,0	—	0,6	—	0,2
(37,0 ± 0,1)	5,0	90,0	—	10,0	—	1,2
(45,0 ± 0,1)	—	—	50,0	90,0	5,0	50,0

4.9 Adhesion on storage

Self-adhesion during storage of the wax shall be such that when tested as described in 6.2.3, there shall be no evidence of damage to wax surfaces that have been in contact with each other or with the paper. Where separating paper is used, the wax and paper surfaces shall separate cleanly and readily.

5 Sampling

The method of procurement and the amount of wax needed for testing shall be the subject of agreement between the interested parties. The material procured shall be from a single production batch.

6 Test methods

6.1 Visual inspection

Use visual inspection in determining compliance with requirements specified in 4.1, 4.2, 4.3, 4.4 and 4.5.

6.2 Physical tests

6.2.1 Residue and colouring material

6.2.1.1 Apparatus

6.2.1.1.1 Metal former, of design illustrated in Figure 1, which incorporates a trough 5 mm wide and at least 1,5 mm deep for use in mounting the teeth.

6.2.1.1.2 Normal dental laboratory apparatus for denture flasking and processing, as shown in Figure 1.

6.2.1.2 Procedure

Place a strip of the test wax in the trough of the metal former. Mount three anterior synthetic polymer teeth conforming to ISO 3336 and three ceramic teeth conforming to ISO 4824 into the wax as shown in Figure 1 a). Invest the metal former and mounted teeth in a denture flask using dental plaster or dental stone, or both, conforming to ISO 6873 [see Figure 1b)]. Let the flask remain undisturbed for between 2 h and 3 h after pouring the plaster or stone in contact with the wax. Then immerse the flask in a water bath at (50 ± 2) °C for 10 min, remove and open immediately. Strip out the metal block and the bulk of the wax, and flush the flask with a continuous stream of boiling water for (60 ± 5) s.

6.2.1.3 Evaluation

When examined in accordance with 6.1, all exposed teeth and gypsum surfaces shall be free from wax residue.

6.2.2 Flow

6.2.2.1 Apparatus

6.2.2.1.1 Micrometer screw gauge, accurate to 0,005 mm or better.

6.2.2.1.2 Flow-testing instrument (see Figure 2),consisting of the following components:

a) **metallic cylinder (weight)** (A);

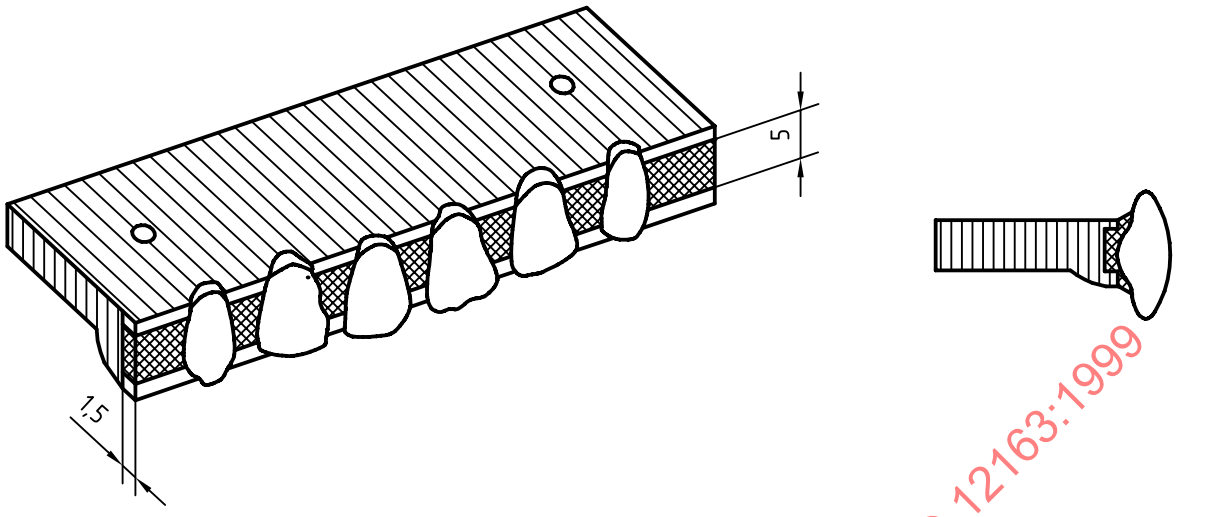
b) **shaft** having a low thermal conductivity (B);

c) **brass plate** (C);

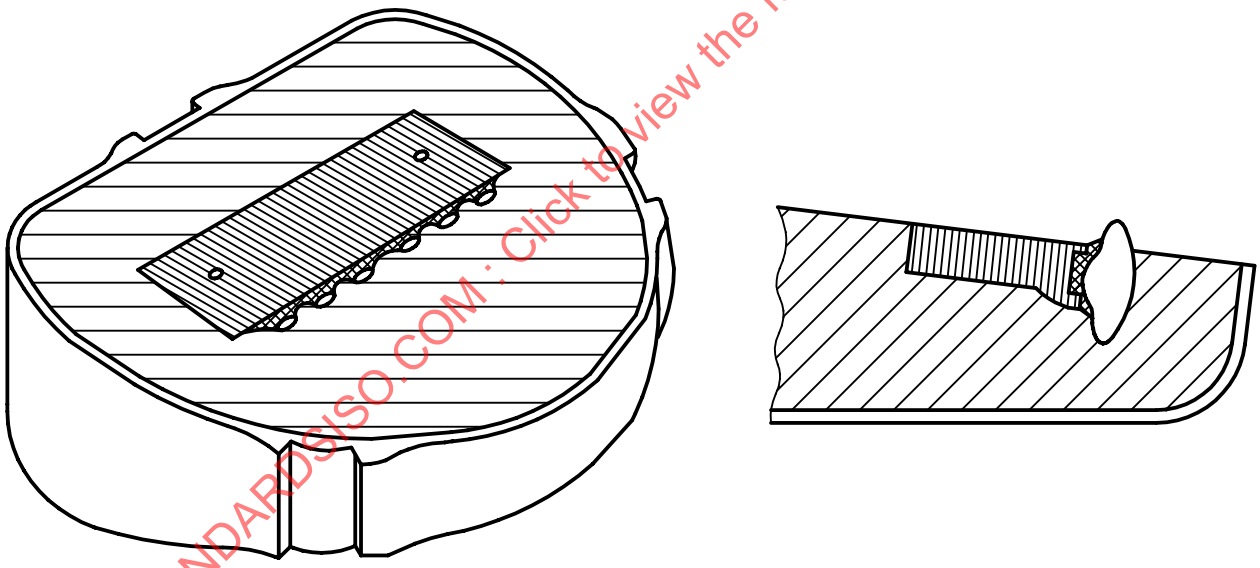
d) **measuring dial gauge** (D), accurate to 0,005 mm or better;

e) **lock-nut screw** (E).

Dimensions in millimetres

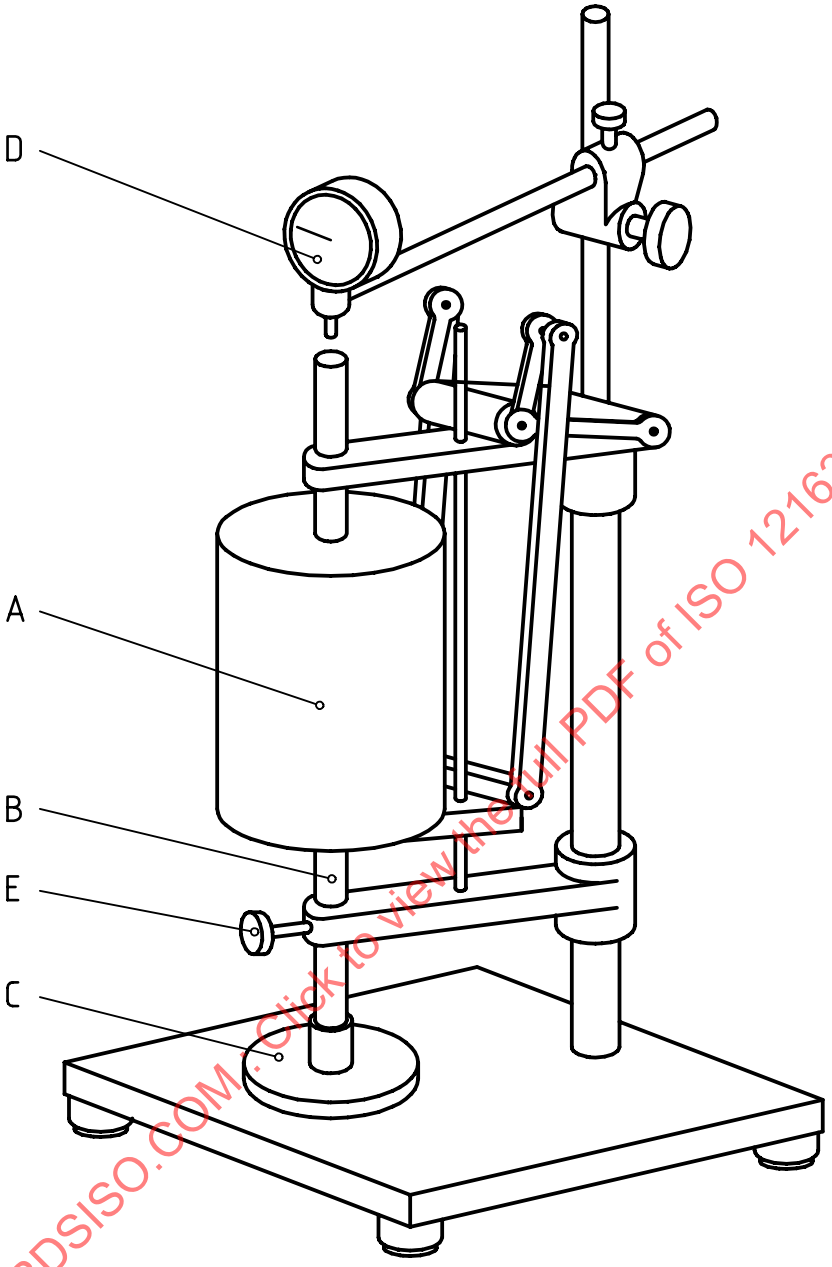


a)



b)

Figure 1 — Apparatus for test for residue and colouring material



Key

A Weight
B Shaft
C Brass plate
D Gauge
E Lock-nut screw

Figure 2 — Flow-testing instrument

The total mass of the components A, B and C shall be such as to provide an axial compressive force of (19,6 ± 0,1) N [(equivalent to a mass of (2 000 ± 10) g under standard gravity]. The cylinder (A) shall be separated a minimum distance of 76 mm from the brass plate (C) by the shaft (B). This shaft shall be of hard rubber or a similarly poor thermal conductor, to reduce loss of heat from the specimen. The diameter of the brass plate (C) shall be not less than 50 mm, and the thickness not greater than 6,5 mm.

6.2.2.1.3 Mould (see Figure 3), consisting of a flat stainless steel plate, 6 mm thick, with parallel top and bottom surfaces. The plate shall have four holes, 10 mm in diameter, with the axes of the holes perpendicular to the surface of the plate. The sides of the holes shall have a smooth finish.

6.2.2.1.4 Metal pouring pan (see Figure 4) or similar porcelain pan with handle.

6.2.2.1.5 Controlled-temperature water bath, consisting of a sufficiently large container equipped with a temperature control device that maintains a specific water temperature accurate to 0,1 °C and a stirring device that agitates the water continuously.

6.2.2.2 Preparation of test specimens

Break a sufficient quantity of wax into pieces and place in the pan. Place the pan on a surface which is approximately 130 mm below a nominal 250 W infrared lamp. Heat the wax, stirring until completely melted, ensuring that the temperature of the melt does not rise above 70 °C.

Pour the melted wax into the mould which is placed on a smooth glass slab 152 mm long, 76 mm wide and 19 mm thick, heated to (55 ± 5) °C and lubricated with silicone grease with a melting point higher than (75 ± 5) °C. As the wax solidifies and shrinkage voids appear, add more liquid wax.

When the wax has lost its surface glaze, place a smooth, flat tin-foil- or aluminium-foil-covered glass plate, heated to (55 ± 5) °C and lubricated as above, on the top of the mould. Apply a load of approximately 90 N to the top of the foil-covered glass plate for 30 min. Remove the force and glass plate and remove the excess wax by drawing a straight-edged metal scraper across the mould, finishing the specimen flush with the surface.

Chill the mould with specimens in water at 10 °C and remove from the bath. The end faces should be smooth and parallel. If necessary, the end faces may be smoothed by rubbing on paper or very fine sandpaper while in the mould. Remove the specimens from the mould. Store the specimens at (23 ± 2) °C for at least 24 h before testing.

6.2.2.3 Procedure

Place each specimen, prepared in accordance with 6.2.2.2, between two sheets of thin polyethylene film under the brass plate of the flow-testing instrument. Apply an axial compressive force of (19,6 ± 0,1) N (see 6.2.2.1.2) to the specimen at (23 ± 2) °C for 1 min, and then remove the specimen for measurement of initial length.

Determine the initial length of the specimen at (23 ± 2) °C using the micrometer screw gauge. Record to the nearest 0,005 mm.

Again place the specimen between two sheets of polyethylene film under the brass plate. Place the flow-testing instrument in the water bath (6.2.2.1.5) at the chosen test temperature such that the specimen is immersed to a depth of about 50 mm. Allow the system to equilibrate for 20 min.

Apply the axial force to the specimen for 10 min, raise the load, and then remove the specimen from the water bath and cool in air to (23 ± 2) °C for 30 min. Strip off the polyethylene films and determine the final length in the same way as the initial length was determined.

Two such tests shall be performed at each of the temperatures specified in Table 1 (4.8).

Alternatively, a flow-testing instrument, equipped with a measuring dial gauge and a lock-nut screw- (6.2.2.1.2), may replace the micrometer for direct measurement. Set the dial gauge at zero with two sheets of polyethylene film in place. Place the specimen under the flow-testing instrument between the polyethylene films. Release the lock-nut

screw and apply the axial force to the specimen at (23 ± 2) °C for 1 min. Tighten the lock-nut screw and record the initial length. Place the flow-testing instrument, with the specimen and lock-nut screw tight, in the water bath at the test temperature so that the specimen is immersed to a depth of about 50 mm. Allow the system to equilibrate for 20 min. Release the lock-nut screw to apply the axial force to the specimen for 10 min. Tighten the lock-nut screw, then remove the flow-testing instrument from the water bath. Cool the entire system in air to (23 ± 2) °C for 30 min with the lock-nut screw tight. Release the lock-nut screw for 30 s, and record the final length.

6.2.2.4 Expression of results and evaluation

Report the flow, as determined by the change in specimen length, as a percentage of the initial length.

If either of the two results fails to meet the appropriate requirement for the flow listed in Table 1, then two additional specimens shall be tested. If either of these results fails to meet the requirement for the test, then the material fails to comply with this requirement of this International Standard.

6.2.3 Adhesion on storage

Prepare three wax specimens and, where used, two sheets of separating paper having nominal dimensions of 50 mm × 75 mm. Place the test assembly between two platens 50 mm wide, 60 mm long, and 5 mm thick in such a manner that 15 mm of each wax sheet projects from one end of the platens. Then place this test assembly horizontally on a flat rigid surface in an oven maintained at a temperature of (30,0 ± 1,0) °C for Type 1 wax and (40,0 ± 1,0) °C for Type 2 and Type 3 waxes. Apply a vertical compressive force of (13,2 ± 0,1) N to the test assembly. After 24 h remove the assembly from the oven and allow to cool to room temperature. After 2 h separate the assembly by opening from the overlapping ends, and examine the surfaces in contact with each other for evidence of damage.

7 Packaging and marking

7.1 Packaging

The wax packaging shall help to protect the wax against damage and contamination.

7.2 Marking

7.2.1 Lot number

Each container shall be marked with a serial number or a combination of letters and numbers which shall refer to the manufacturer's records for the particular lot or batch of the wax.

7.2.2 Net mass

The minimum net mass of the contents shall be marked on all containers.

7.2.3 Type

The type of wax in accordance with clause 3 shall be indicated on all containers.

7.2.4 Storage conditions

The storage conditions recommended by the manufacturer shall be marked on all containers.