INTERNATIONAL STANDARD

ISO 1561

Second edition
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Dental casting wax

Cires dentaires

Reference number
ISO 1561:1995(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 1561 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthodontic materials*.

This second edition cancels and replaces the first edition (ISO 1561:1975), which has been technically revised.

Annex A of this International Standard is for information only.

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Dental casting wax

1 Scope

This international Standard specifies the classification of and requirements for dental casting wax, together with the test methods to be employed to determine compliance with these requirements.

This International Standard is applicable to dental casting wax used in making patterns in the production of fixed prostheses restorations by the "lost-wax" casting technique.

NOTE 1 Specific qualitative and quantitative requirements for freedom from biological hazard are not included in this International Standard. In assessing possible biological or toxicological hazards, reference should be made to ISO 10993-1 and ISO/TR 7405.

2 Definition

For the purposes of this International Standard, the following definition applies.

2.1 casting wax: Compound consisting essentially of natural waxes, resins and hydrocarbons of the paraffin and microcrystalline series.

3 Classification

Dental casting waxes are classified according to the flow characteristics that define their hardness as follows:

Type 1:	Soft
Type 2:	Hard

4 Requirements

4.1 Uniformity and purity

The wax shall be uniform and free from visible foreign materials.

4.2 Size and shape

The size and shape of the wax shall be as stated by the manufacturer.

4.3 Colour

The colour of the wax shall be as stated by the manufacturer.

4.4 Softening characteristics

The wax shall soften uniformly when heated, without becoming flaky. It shall not laminate when formed into a working mass.

4.5 Chipping

The wax shall not show appreciable chipping or flaking when trimmed to a fine margin at (23 ± 2) °C.

4.6 Flow behaviour

When tested in accordance with 6.2, the sample of the wax shall produce flow results complying with the requirements in table 1 for different types of wax at the three applicable test temperatures.

Table 1 — Wax flow behaviour (% change in specimen length)

Test temperatures	Type 1		Type 2	
	Minimum	Maximum	Minimum	Maximum
°C	%	%	%	%
30	—	1,0	—	—
37	—	—	—	1,0
40	50,0	—	—	20,0
45	70,0	90,0	70,0	90,0

4.7 Residue on ignition

The melted wax when ignited at 500 °C shall leave no residue in excess of 0,1 % of the original mass of the specimen, as tested in accordance with 6.3.

For wax having residue exceeding 0,1 % original mass at 500 °C ignition and designed for use with investments formulated for a burnout temperature higher than 700 °C, the manufacturer shall indicate on the label the amount of residue at 500 °C. When the wax is ignited at 500 °C, the residue shall be within 20 % of the manufacturer's stated value. Such wax shall not leave more than 0,1 % residue when ignited at 700 °C.

5 Sampling

The method of procurement and the amount of wax needed for testing shall be the subject of agreement between the interested parties.

6 Test methods

6.1 Visual inspection

Use visual inspection in determining compliance with the requirements as specified in 4.1 to 4.5 and in clause 7.

6.2 Evaluation of flow characteristics

6.2.1 Apparatus

6.2.1.1 Metric micrometer.

6.2.1.2 Flow-testing instrument (see figure 1), consisting of the following parts:

— a metallic cylinder (A);

— a shaft having low thermal conductivity (B);

— a brass plate (C);

— a measuring dial gauge (D) with scale graduated in 0,005 mm;

— a lock-nut screw (E).

The total mass of the components A, B, C and D shall be 2 kg. 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 heat loss from the specimen. The diameter of the brass plate (C) shall be not less than 51 mm and thickness not greater than 6,35 mm.

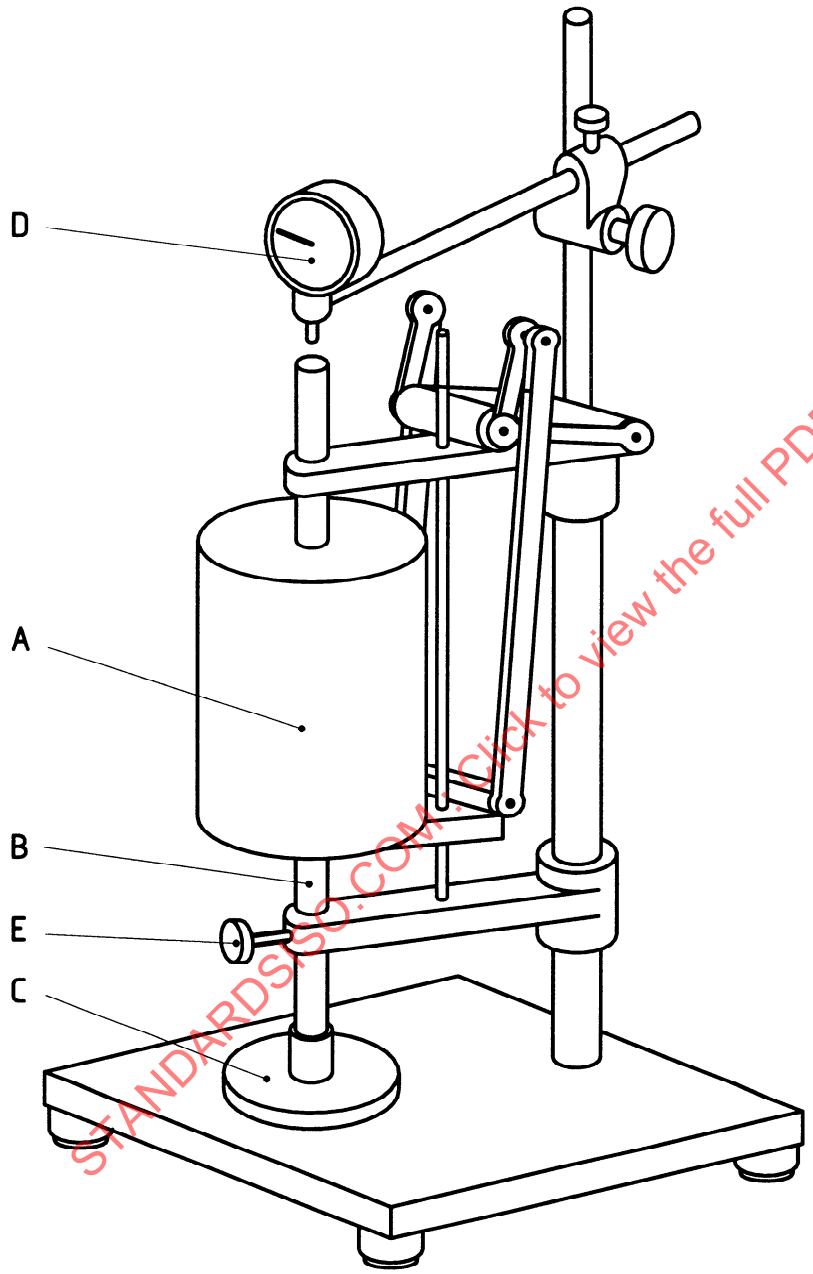
NOTE 2 If the flow-testing instrument is robust enough to support a measuring dial gauge and a lock-nut screw rigidly, or the instrument is built with them incorporated (see D and E in figure 1), then a measuring dial gauge accurate to 0,005 mm with a range of at least 10 mm may replace the micrometer for direct measurement.

6.2.1.3 Mould (see figure 2), consisting of a stainless steel plate 6 mm thick, having parallel flat top and bottom surfaces, and containing four holes each 10 mm in diameter. The axes of the holes shall be perpendicular to the surface of the plate. The sides of the holes shall be finished smooth.

6.2.1.4 Pouring pan (see figure 3), of metal or conventional porcelain, with handle.

6.2.1.5 Cellophane or polyethylene film.

6.2.1.6 Calibrated thermometer.



Key

A Weight

B Shaft

C Brass plate

D Gauge

E Lock-nut screw

Figure 1 — Flow-testing instrument

Dimensions in millimetres

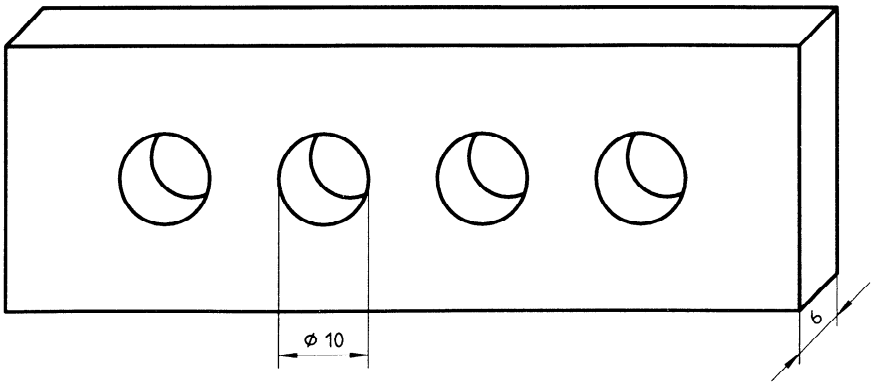


Figure 2 — Mould for forming flow specimens

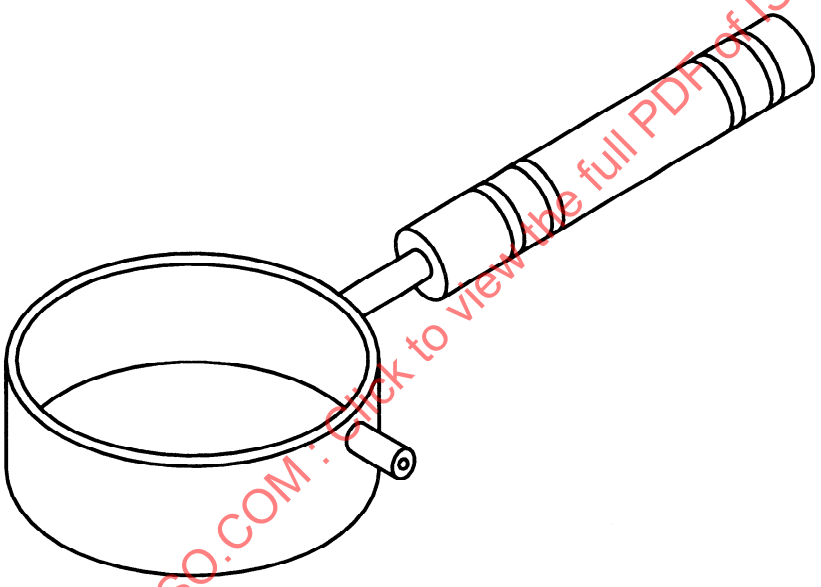


Figure 3 — Metal pouring pan

6.2.2 Preparation of test specimens

Break a quantity of wax into pieces and place in the metal or porcelain pouring pan (6.2.1.4). Place the pan on a surface which is 130 mm below a 250 W infrared lamp.

Heat the wax, and stir constantly as it melts, until the mass becomes a uniformly translucent liquid. Raise the temperature of the melt 0 to 15 °C above the melting point stated by the manufacturer (7.2.6). Use a thermometer or a solid thermocouple for measuring the temperature while stirring constantly.

Lubricate the mould (6.2.1.3) with a silicone grease whose melting point is higher than (75 ± 5) °C. Place the mould on a smooth glass slab 152 mm long, 76 mm wide and 19 mm thick, and pour the melted wax into the mould, both mould and slab being pre-heated to (55 ± 5) °C. As the wax solidifies and a shrinkage void appears, add more liquid wax.

When the wax has lost its mirror-like surface glaze, place a smooth, flat tin-foil- or aluminium-foil-covered glass plate, preheated to (55 ± 5) °C, on top of the mould. Apply a load of 90 N (mass of 9 kg) to the top of the foil-covered glass plate for 20 min. Remove the load and the glass plate, and trim the excess wax away by drawing a straight-edged metal scraper across the mould, thereby finishing the wax specimen flush with the surface.

Each specimen shall be smooth on both ends, and faces shall be parallel to each other; this can be

achieved by rubbing both ends on a clean piece of paper before removal from the mould. After chilling in water at 10 °C, remove the wax specimens from the mould by gently tapping the side of the mould. Store the specimens at (23 ± 2) °C for at least 24 h before testing.

6.2.3 Procedure

Place the wax specimen prepared in accordance with 6.2.2 in the flow-testing instrument (6.2.1.2) between two sheets of thin cellophane or polyethylene film (6.2.1.5) and apply a load of 19,6 N (mass of 2 kg) to the specimen at (23 ± 2) °C for 1 min. Remove the wax specimen for measurement.

Determine the initial length of the specimen, prepared in accordance with 6.2.2 at (23 ± 2) °C, using the micrometer (6.2.1.1). When using the micrometer, take four measurements at the periphery and one measurement in the centre of the specimen. Average the measurements and record to the nearest 0,005 mm.

Place the specimen and flow-testing instrument in a water bath and hold at the desired test temperature (see table 1 in 4.6) for 30 min. Maintain the temperature of the bath to within 0,1 °C of the required temperature as measured using a calibrated thermometer (6.2.1.6). Agitate the water bath by means of a mechanical stirrer. While immersed, place the specimen in the instrument with a thin sheet of cellophane or polyethylene film between the instrument and each end of the specimen, with the bottom of the specimen 51 mm below the surface of the water in the bath.

Apply a constant axial load of 19,6 N (mass of 2 kg) 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. Strip off the waterproof cellophane or polyethylene films and determine the final length in the same manner as the original length.

All readings using the instrument dial gauge shall be made with the lock-nut tightened and at room temperature, specified as (23 ± 2) °C. Adjust the dial gauge to zero with two sheets of cellophane or polyethylene film in place, and the lock-nut tight at room temperature. During the test keep the lock-nut tight except during the flow time.

Repeat the test once at the same test temperature, using a second specimen.

Carry out the flow test at each of the three applicable test temperatures (depending on wax type) specified in table 1.

6.2.4 Expression of results and evaluation of flow

Calculate the flow, as evidenced by the change in measured length, as a percentage of the initial length to the nearest 0,1 % for each specimen.

If both specimens meet the requirement for flow listed in table 1, then report the value for flow at any temperature as the average value, to the nearest 0,1 %, for the two specimens. If one specimen meets the requirement and the other one fails, then three additional specimens shall be tested. If all of these specimens meet the requirement, then the material meets the requirement of this International Standard. If any of these additional specimens fails to meet the requirement, then the material fails to meet the requirements of this International Standard.

6.3 Determination of ignition residue

6.3.1 Procedure

Place approximately 1 g of wax, weighed accurately, in a crucible previously conditioned to constant mass by repeated heating to 500 °C and cooling to (23 ± 2) °C. Place the conditioned, tared crucible loaded with the wax sample in a furnace at (23 ± 2) °C. Increase the temperature of the furnace to 500 °C and maintain at this temperature for 1 h.

Then remove the crucible from the furnace, place in a desiccator, allow to cool to (23 ± 2) °C and then weigh.

Repeat the test once, using a second wax sample.

For wax with higher 500 °C ignition residue as stated by the manufacturer, i.e more than 0,1 % of original mass, an additional similar test shall be conducted at an ignition temperature of 700 °C.

6.3.2 Expression of results and evaluation of ignition residue

Report the value for ignition residue as the average value, to the nearest 0,02 %, of two determinations.

If both wax samples meet the requirement in 4.7, the material complies with the requirements of this International Standard. If neither meets the requirement, the material fails to meet the requirements of this International Standard. If one of the two samples meets the requirement, carry out the test on three additional samples. If all of these samples meet the requirement stated in 4.7, the material meets the requirements of this International Standard. If any one of these additional samples fails to meet the require-

ment, the material fails to meet the requirements of this International Standard.

If the test is also carried out at 700 °C, the results shall be expressed and evaluated similarly.

7 Packaging and marking

7.1 Packaging

The material shall be packaged in accordance with accepted commercial practice.

7.2 Marking

7.2.1 Lot number

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

7.2.2 Date of manufacture

Each container shall be marked with the date of manufacture (year and month) of the wax, either as a part of the lot number or as a separate item.

7.2.3 Net mass

Each container shall be marked with the minimum net mass, in grams, of the contents.

7.2.4 Type

Each container shall be marked with the type of wax, as designated in clause 3.

7.2.5 Ignition residue

Each container shall be marked with the amount of ignition residue of the wax, as determined in accordance with 6.3.

7.2.6 Melting point

The melting point shall be marked either on the package, in the instructions for use, or both.

Annex A
(informative)

Bibliography

[1] ISO/TR 7405:—[1], *Dentistry — Preclinical evaluation of biocompatibility of medical devices used in dentistry — Test methods.*

[2] IS0 10993-1:—[2], *Biological evaluation of medical devices — Part 1: Evaluation and testing.*

1) To be published. (Revision of ISO/TR 7405:1984)

2) To be published. (Revision of ISO 10993-1:1992)