INTERNATIONAL STANDARD

ISO 15854

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2005-07-15

Dentistry — Casting and baseplate waxes

Art dentaire — Cires pour coulée et pour plaque de base

Reference number
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Foreword

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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 15854 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthodontic materials*.

This first edition cancels and replaces ISO 1561:1995 and ISO 12163:1999, which have been technically revised.

Introduction

This International Standard does not include specific and quantitative requirements for freedom from biological hazards. It is recommended that, in assessing possible biological or toxicological hazards, reference be made to ISO 7405 and ISO 10993-1 (see Bibliography).

Dentistry — Casting and baseplate waxes

1 Scope

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

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

ISO 3336, *Dentistry — Synthetic polymer teeth*[1)]

ISO 4824, *Dentistry — Ceramic denture teeth*[1)]

ISO 6873, *Dental gypsum products*

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942-2 and the following apply.

3.1
casting wax
mouldable material primarily for shaping patterns in the production of fixed cast restorations using the “lost-wax” procedure

3.2
baseplate wax
mouldable material primarily for shaping patterns that will be duplicated in denture base polymers, and for forming occlusion rims and other patterns

1) ISO 3336 and ISO 4824 are to be combined and revised as ISO 22112, *Dentistry — Artificial teeth for dental prostheses.*

4 Classification

Dental waxes covered by this International Standard are classified according to the flow characteristics that represent their hardness, as follows:

a) **Type 1** (casting wax):

   1) **Class 1** Soft

   2) **Class 2** Hard

b) **Type 2** (baseplate wax):

   1) **Class 1** Soft

   2) **Class 2** Hard

   3) **Class 3** Extra hard

5 Requirements

5.1 Appearance

The wax shall be uniform in colour, supplied in pieces of uniform size, of smooth texture and free of foreign materials. Test in accordance with 8.1.

5.2 Flow

The samples of the wax when tested in accordance with 8.2 shall have flow properties complying with the requirements in Table 1.

Table 1 — Flow requirements

Temperature	Type 1 Casting wax				Type 2 Baseplate wax					
	Class 1		Class 2		Class 1		Class 2		Class 3	
	Min.	Max.	Min.	Max.	Min.	Max.	Min.	Max.	Min.	Max.
°C	%	%	%	%	%	%	%	%	%	%
23,0 ± 0,1	—	—	—	—	—	1,0	—	0,6	—	0,2
30,0 ± 0,1	—	1,0	—	—	—	—	—	—	—	—
37,0 ± 0,1	—	—	—	1,0	5,0	90,0	—	10,0	—	1,2
40,0 ± 0,1	50,0	—	—	20,0	—	—	—	—	—	—
45,0 ± 0,1	70,0	90,0	70,0	90,0	—	—	50,0	90,0	5,0	50,0
— Undefined.										

5.3 Behaviour on trimming

The wax shall be capable of being trimmed without chipping, flaking or tearing when tested in accordance with 8.3.

5.4 Behaviour on softening (Type 1)

The wax shall soften without flaking or crumbling and shall cohere readily when tested in accordance with 8.4.

5.5 Appearance after flaming (Type 2)

The wax shall present a smooth glossy surface when tested in accordance with 8.5.

5.6 Behaviour on softening (Type 2)

The wax shall soften without becoming sticky or crumbly and shall be mouldable without breaking or laminating when tested in accordance with 8.6.

5.7 Residue on artificial teeth (Type 2)

The wax shall not leave a residue on either ceramic or plastic teeth when tested in accordance with 8.7.

5.8 Behaviour of colouring material (Type 2)

The colouring material shall neither separate from the wax nor impregnate the gypsum mould when tested in accordance with 8.7.

5.9 Adhesion on storage (Type 2)

Self-adhesion during storage of the wax shall be such that when tested in accordance with 8.8, there shall be no evidence of damage to wax surfaces that have been in contact with either wax or paper. Where separating paper is used, the wax and paper surfaces shall separate cleanly and readily.

5.10 Residue on ignition (Type 1)

If the manufacturer does not state a value for the residue on ignition, the solid residue of the wax, as determined in accordance with 8.9, shall be no greater than 0,1 %.

If the manufacturer states a value for the residue on ignition, the solid residue of the wax, as determined in accordance with 8.9, shall not differ by more than 20 % from that value.

5.11 Biocompatibility

See ISO 7405 and ISO 10993-1 for guidance on compatibility.

6 Sampling

The amount of material procured for testing shall be at least 250 g for Type 1, or 500 g for Type 2, and from one batch.

7 Test methods — General

7.1 Ambient temperature

Unless otherwise specified in this International Standard, all specimen preparation and testing shall be conducted at an ambient temperature of (23 ± 2) °C.

7.2 Apparatus function verification

All accessories, instruments and equipment shall be examined before use to ensure that they are in acceptable working order, appropriately calibrated and complying with specifications stated for them in this International Standard.

8 Test methods — Specific

8.1 Visual inspection

Carry out visual inspection at nominally normal visual acuity and without magnification.

8.2 Flow

8.2.1 Apparatus

8.2.1.1 Micrometer screw gauge

For measuring specimen length, use a micrometer screw gauge with a range of at least 10 mm, being accurate to 0,005 mm or better.

8.2.1.2 Flow-testing instrument

Use a flow-testing instrument, such as the one shown in Figure 1, consisting of the following components:

— metallic cylindrical weight (item 1 in Figure 1);

— plastic or hard rubber shaft (item 2 in Figure 1);

— brass plate (item 3 in Figure 1);

— measuring dial gauge (item 4 in Figure 1), with a range of at least 10 mm, accurate to 0,005 mm or better, and rigidly supported (optional);

— locking screw (item 5 in Figure 1) (optional).

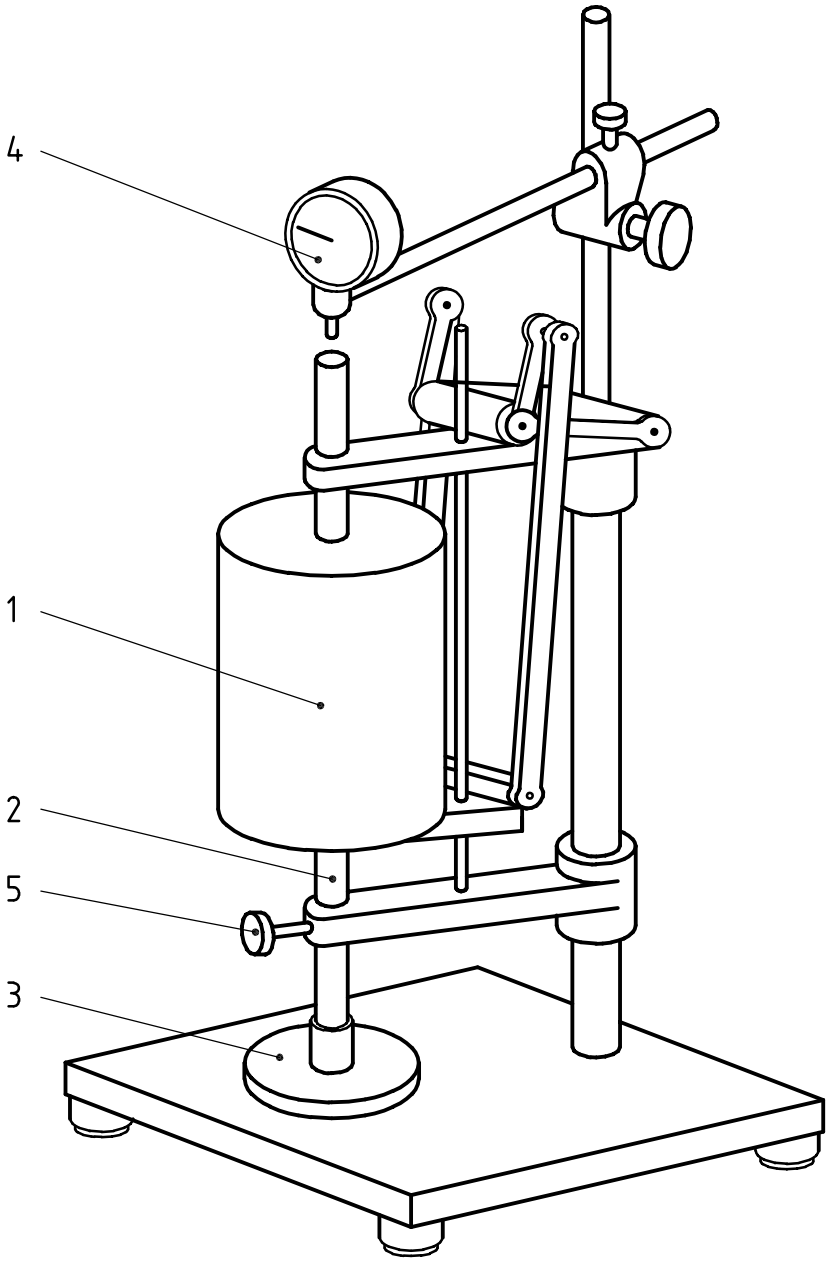
The total mass of the components of items 1, 2 and 3 shall be such as to provide an axial compressive force of (19,6 $\pm$ 0,1) N. The weight (1) shall be separated a minimum distance of 76 mm from the brass plate (3) by the shaft (2). The diameter of the brass plate (3) shall be no less than 50 mm and the thickness no greater than 6,5 mm. The optional dial gauge (4) and locking screw (5) may replace the micrometer screw gauge for direct measurement (8.2.3).

8.2.1.3 Pouring pan

For melting the wax, use a metal or porcelain pan with handle similar to the example shown in Figure 2.

8.2.1.4 Infrared lamp

For heating the wax, use an infrared lamp with nominal power of 250 W.



Key

1 weight
2 shaft
3 brass plate
4 gauge
5 locking screw

Figure 1 — Flow-testing instrument

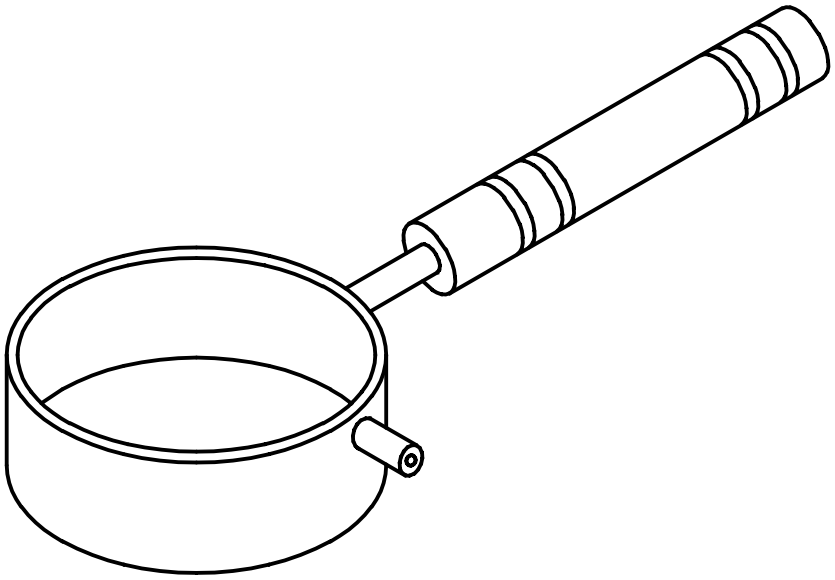


Figure 2 — Example of pouring pan

Dimensions in millimetres

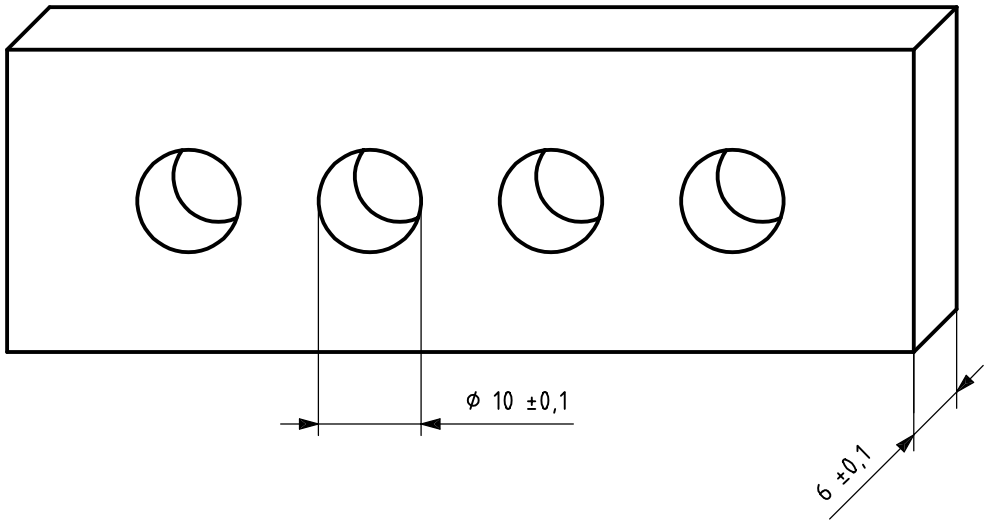


Figure 3 — Mould for forming flow specimens

8.2.1.5 Mould

For forming the specimens, use a mould as shown in Figure 3, consisting of a flat stainless steel plate, (6,0 ± 0,1) mm thick, with parallel top and bottom surfaces. The plate shall have four holes (10,0 ± 0,1) mm in diameter, with the axes of the holes perpendicular to the surface of the plate. The sides of the holes shall be polished such that the surface roughness (Ra) is less than 0,3 µm.

8.2.1.6 Glass slab

As a base for the mould, use a glass slab, approximately 152 mm long, 76 mm wide and 19 mm thick.

8.2.1.7 Thin glass plate

For covering the mould, use a thin glass plate large enough for the purpose and covered with thin tin or aluminium foil.

8.2.1.8 Test environment

Use a temperature-controlled water bath of sufficiently large volume, equipped with a temperature control device accurate to 0,1 °C and a stirring device that ensures homogeneity of temperature over the test volume.

8.2.2 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 the infrared lamp. Heat the wax, stirring constantly until completely melted.

Immediately afterwards, pour the melted wax into the mould which is placed on a smooth glass slab, heated to (55 ± 5) °C and lubricated with a very thin film of silicone grease as release agent. 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 or aluminium foil-covered glass plate, heated to (55 ± 5) °C and lubricated as above, on top of the mould. For 30 min, apply a force of approximately 90 N to the top of the foil-covered glass plate. Remove force and glass plate, and remove excess wax by drawing a straight-edged metal scraper across the mould, finishing the specimens flush with the mould's top face.

Chill the mould containing the specimens in water at approximately 10 °C and remove from the glass plate. The end faces of the specimens should be smooth and parallel. If necessary, they may be smoothed by rubbing on paper or very fine abrasive paper whilst still in the mould. Remove the specimens from the mould and store them at ambient temperature for at least 24 h before testing.

8.2.3 Procedure

Place one specimen between two sheets of polyethylene film under the brass plate of the flow-testing instrument. Apply an axial compressive force of (19,6 ± 0,1) N to the specimen at ambient temperature for 1 min, and then remove the specimen for measurement. Using the micrometer screw gauge, determine the length of the specimen. Record this as the initial length, to the nearest 0,005 mm.

Place the specimen between two sheets of polyethylene film under the brass plate again. Place the flow-testing instrument in the water bath such that the specimen is immersed to a depth of about 50 mm. Allow the system to equilibrate at the test temperature 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 ambient temperature for 30 min. Strip off the polyethylene films, and determine the final length in the same way as the initial length.

Alternatively, if the flow-testing instrument is equipped with a measuring dial gauge and a locking screw, 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 locking screw and apply the axial force to the specimen at ambient temperature for 1 min. Tighten the locking screw and record the initial length. Place the flow-testing instrument 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 locking screw to apply the axial force to the specimen for 10 min. Tighten the locking screw again, then remove the flow-testing instrument from the water bath. Cool the entire system in air to ambient temperature for 30 min with the locking screw tight. Release the locking screw for 30 s and record the final length.

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

8.2.4 Expression of results and evaluation

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

If both results meet the requirement listed in Table 1, the product complies with this requirement. If one result meets the requirement and one fails, two additional specimens shall be tested. If both additional results meet the requirement, the product complies with this requirement. In any other case, it fails to comply.

8.3 Behaviour on trimming

Apply a dental wax carver to a stick or sheet of the wax to pare off a section. Visually inspect the cut surface for signs of chipping, flaking and tearing.

8.4 Behaviour on softening (Type 1)

8.4.1 Apparatus

8.4.1.1 Glass plate, approximately 50 mm long and 50 mm wide

8.4.1.2 Dental wax knife

8.4.2 Procedure

With a hot wax knife, soften a small amount of wax and place it onto the glass plate. Visually observe the state of the wax during the softening process for any signs of crumbling or flaking.

Repeat the procedure with three further amounts of wax, adding each one immediately to the mass of wax on the glass plate. Allow to cool to ambient temperature and visually assess whether the wax has developed into a cohesive mass without signs of separation or delamination.

8.5 Appearance after flaming (Type 2)

Cut a square sheet of wax, with side lengths of approximately 80 mm, and pass it quickly over the lambent flame of a Bunsen burner or equivalent flame device, repeating until the surface has been superficially melted. Allow to cool and visually inspect the wax surface for smoothness and gloss.

8.6 Behaviour on softening (Type 2)

Take the specimen obtained in 8.5 and soften it evenly over the gas flame. Manually, roll it into a solid cylinder and mould it into a horseshoe shape. Visually check for breakage or delaminating and any wax sticking to the fingers during the test.

8.7 Residue on artificial teeth and behaviour of colouring material (Type 2)

8.7.1 Apparatus

8.7.1.1 Metal former

Use a metal former of design as illustrated in Figure 4 a), which incorporates a trough (6 ± 1) mm wide and ($2{,}0 \pm 0{,}5$) mm deep for use in mounting artificial teeth.

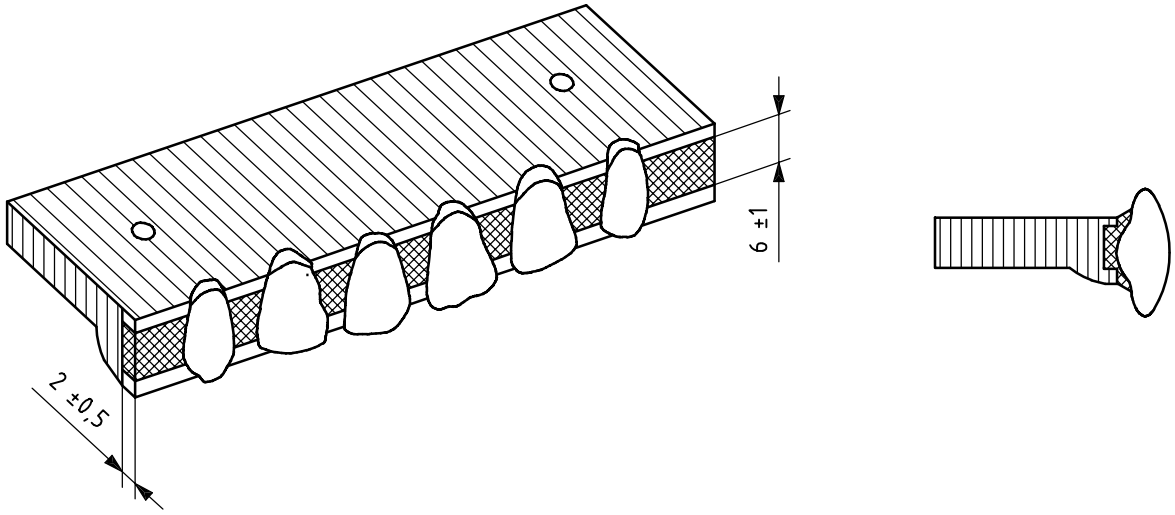
8.7.1.2 Processing equipment

Use normal dental laboratory apparatus for denture flasking and processing.

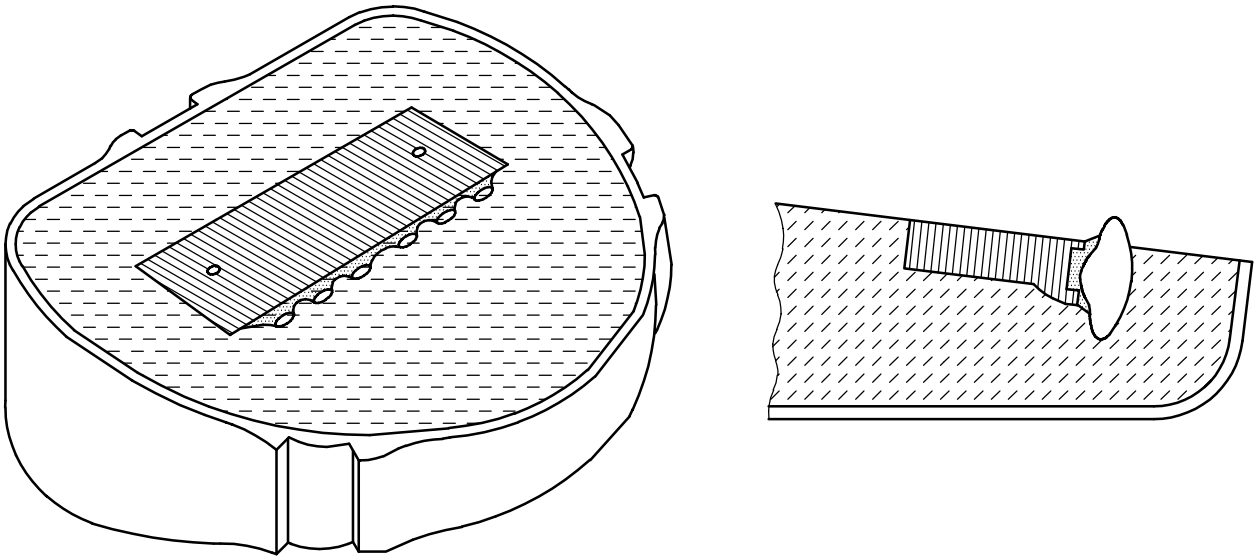
8.7.2 Procedure

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 4 a). Invest the metal former and mounted teeth in a denture flask using dental plaster or stone, or both, conforming to ISO 6873 [see Figure 4 b)]. Let the flask remain undisturbed for (2,5 ± 0,5) 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. Examine all exposed teeth and gypsum surfaces for evidence of wax residue.

Dimensions in millimetres



a) Metal former with teeth attached



b) Denture flask containing metal former with teeth attached

Figure 4 — Apparatus for test for residue on artificial teeth and behaviour of colouring material

8.8 Adhesion on storage (Type 2)

8.8.1 Apparatus

8.8.1.1 Platens

For encasing the assembled wax plates, use two platens (50 ± 1) mm wide, (60 ± 1) mm long and (5,0 ± 0,5) mm thick.

8.8.1.2 Oven

For storing the test assembly, use an oven or ovens capable of maintaining a temperature of 30 °C and 40 °C, respectively, to an accuracy of ± 1 °C.

8.8.1.3 Dead-weight

For loading the test assembly, use a deadweight exerting a force of (13,2 ± 0,1) N.

8.8.2 Procedure

Take three neighbouring wax sheets out of the package leaving the separating paper, if present, in place. Cut the assembly, if necessary, to a size of 50 mm × 75 mm. Place the test assembly between the two platens in such a manner that 15 mm of each wax sheet project from one end of the platens. Then place this test assembly horizontally on a flat rigid surface in the oven maintained at a temperature of (30 ± 1) °C for Class 1 wax and (40 ± 1) °C for Class 2 and Class 3 waxes. Place the deadweight onto the test assembly. After (24 ± 0,25) h remove the assembly from the oven and allow to cool to ambient temperature. At (120 ± 5) min after removal from the oven, separate the assembly by opening from the overlapping ends, and examine the surfaces in contact with each other for evidence of damage.

8.9 Residue on ignition (Type 1)

8.9.1 Apparatus

8.9.1.1 **Open crucible**, capable of holding approximately 1 g of wax.

8.9.1.2 **Balance**, capable of weighing approximately 50 g to an accuracy of ± 0,000 1 g.

8.9.1.3 **Furnace**, capable of maintaining a temperature of 700 °C with an accuracy of ± 20 °C.

8.9.2 Procedure

Condition the crucible to a constant mass (± 0,000 1 g) by sufficient repeated heating to 700 °C and cooling to ambient temperature in a desiccator.

Tare the conditioned crucible and add to it approximately 1 g of wax, weighed to an accuracy of 0,000 1 g. Place the crucible into the cold furnace (temperature less than 100 °C) and increase the temperature to 700 °C. Maintain that temperature for (60 ± 2) min. Immediately thereafter, remove the crucible and place in a desiccator. Allow to cool to ambient temperature and then reweigh.

Carry out two determinations.

8.9.3 Expression of results and evaluation

Express the residue on ignition as a percentage with respect to original mass of the specimen. Report the value as the average of the two determinations to the nearest 0,02 %.

If both results meet the requirement according to 5.10, the product complies. If both do not meet the requirement, the product fails. If one result only meets the requirement, repeat the test a further three times. To comply, all three additional results shall meet the requirement.

9 Marking and packaging

9.1 Marking

Each container shall be marked clearly with at least the following information:

a) trade or brand name of the product;

b) name and address of the manufacturer or agent of sale;

c) lot number;

d) minimum net mass or number of pieces for prefabricated patterns;

e) type, class and description of wax according to Clause 4;

f) residue on ignition as determined according to 8.9 (Type 1, only when required by 5.10);

g) recommended storage conditions;

h) expiry date in accordance with ISO 8601.

9.2 Packaging

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

Bibliography

[1] ISO 7405, *Dentistry — Preclinical evaluation of biocompatibility of medical devices used in dentistry — Test methods for dental materials*

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

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