



SLOVENSKI STANDARD
oSIST prEN ISO 14356:2022
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Zobozdravstvo - Duplikacijski material (ISO/DIS 14356:2022)

Dentistry - Duplicating material (ISO/DIS 14356:2022)

Zahnheilkunde – Dublierwerkstoffe (ISO/DIS 14356:2022)

Médecine bucco-dentaire - Produits pour duplication (ISO/DIS 14356:2022)

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ISO/DIS 14356:2022(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.

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 14356 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthetic materials*.

This second edition cancels and replaces the first edition (ISO 14356:2003), which has been technically revised. This revision updates figures to be consistent with other impression material related standards.

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Dentistry — Duplicating material

1 Scope

This International Standard specifies requirements and tests for the duplicating materials used in dentistry which are primarily intended for forming flexible moulds needed to produce positive refractory investment copies of properly blocked-out master models.

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 (all parts), *Dentistry — Vocabulary*

ISO 6873, *Dentistry — Gypsum products*

ISO 7490, *Dental gypsum-bonded casting investments*

ISO 9694, *Dental phosphate-bonded casting investments*

ISO 11245, *Dental restorations — Phosphate-bonded refractory die materials*

ISO 11246, *Dental ethyl silicate bonded casting investments*

3 Terms and definitions

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

3.1

block out

to flow or mould waxes and/or materials such as cements, clays and polymeric materials into undercut areas on a master model, and then shape them so as to leave only those undercuts that are essential to the subsequent steps in producing a prosthesis that will fit and function optimally

Note 1 to entry: A blocked-out master model may also include other surface modifications needed relative to construction of a prosthesis.

3.2

double boiler

container system, usually in three parts, in which the upper container fits into the lower container such that boiling water in the lower container heats the contents of the lid-covered upper container

3.3

duplicating material

elastic material used to make flexible negative copy impressions or moulds of objects (models or casts) into which a mix of a refractory investment, or another mixture intended for a similar purpose, can be poured to produce a positive copy of the original object

3.4

non-reversible duplicating material

material which converts from a pourable consistency to a gel or rubber-like state and which thereafter cannot be returned to the pourable consistency for repeated use

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3.5

reversible duplicating material

material which can be recycled for more than one use by changing it, by means of heating, from an elastic gel state to a pourable consistency, and then returning it to the gel state by cooling

3.6

duplicating process

(for making metal and ceramic objects) method for making positive copies of master models from a negative mould

Note 1 to entry: The process is carried out according to the following steps:

- master model is blocked out,
- duplicating material is poured around blocked-out master model and allowed to gel or set,
- master model is separated from the duplicating material, leaving a flexible mould having surfaces that constitute a negative copy of the surfaces of the master model,
- an investment mixture is poured into the mould to form a refractory model on which polymeric or wax patterns, or both, can be laid down to form the shapes desired in metal or ceramic castings or on which slurries of porcelain can be applied for forming desired shapes.

Note 2 to entry: Gypsum product mixtures or other mixtures may be poured into the moulds to form copies of master models needed for other purposes.

3.7

effective setting time

(for materials setting at or near oral or room temperature) time measured from the commencement of mixing components of a material together, or otherwise activating the chemistry involved, to the time at which the activated material has developed the properties (elasticity, hardness, etc.) that will permit it to be used with optimal effectiveness in a subsequent step or for its intended purpose

3.8

functional life

(reversible duplicating material) number of times a material can be recycled for use, if handled and used according to the manufacturer's instructions, without loss of the properties required to ensure that the material is fit for the purpose intended

3.9

gelation

(agar duplicating material) transition of a material from a relatively fluid consistency to a gel state in which the material has developed the elastic properties needed for its intended purpose

3.10

immediate container

packaging component having internal surfaces in direct contact with the material contained

Note 1 to entry: An immediate container may be an unlabelled container protected by more durable outer packaging, such as a can, carton or drum. If strong enough to protect its contents without outer packaging, an immediate container can serve as a primary container on which labelling may be required.

3.11

initial setting time

time measured from the commencement of mixing components of a material together, or otherwise activating the chemistry involved, to the time at which a test procedure, conducted at a specified temperature, indicates that the mixture has begun to set at a relatively rapid rate, thus indicating that the effective setting time will be reached at some predictable time thereafter

Note 1 to entry: Initial setting times stated in the manufacturer's instructions are useful to test operators, users, and standards developers because:

- they can often be used for determining whether a product is of a quality suitable for testing or use. For example, if the initial setting time found by the test operator or user corresponds closely to that stated in the instructions, it can usually be assumed that the product is suitable for testing or use.
- they can be helpful in the development of standards for certain materials if there is a need for a standard to identify a reference point in time that can be used as a basis for specifying when certain subsequent procedures should begin.

3.12

investment

(casting) powdered refractory material containing a binder, to be mixed with a specified liquid to form a slurry that can be poured into a mould made of duplicating material where it is allowed to harden to form a heat-resistant positive copy of a master model, or which can be poured around patterns to form a heat-resistant mould used for forming ceramic or metal objects

3.13

master model

definitive cast

(fixed and removable denture construction) positive copy of the hard and/or soft tissues of a dental arch, usually made by pouring a gypsum product slurry into an impression made of a dental arch

3.14

melt

(agar reversible duplicating material) change a material, by heating, from a gel state to a pourable fluid state

3.15

outer package

wrapping or carton which is used to cover one or more immediate or primary containers in preparation for retail marketing and which may be required by law or International Standard to bear specified labelling information

3.16

pouring temperature

(duplicating material) temperature of the material designated in the manufacturer's instructions for pouring the material around an object to be duplicated

3.17

primary container

retail marketing packaging component which may or may not be covered by an outer package and which may be required by law or International Standard to bear specified labelling information

EXAMPLE Bottle, carton, drum, jar, or tube, etc.

Note 1 to entry: A primary container may also be an immediate container, and vice versa.

3.18

refractory

material that retains its effective shape and composition when heated to the maximum temperature required for its use

3.19

slurry

(ceramic, gypsum or refractory investment) mixture, consisting of a powder and water, or a powder and another liquid, having a consistency that will allow it to be poured around patterns or into moulds, or to be otherwise applied, and then be allowed or caused to harden so as to form a desired shape

3.20

storage

holding of a material in an immediate container in a protected environment before the container is opened for the first use, and between subsequent openings of the container

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3.21

store, verb

(melted agar reversible duplicating material) to hold a material at the temperature specified in the manufacturer's instructions for keeping it at pouring consistency

4 Classification by types

There are two types of duplicating material:

- **Type 1:** Reversible duplicating materials
- **Type 2:** Non-reversible duplicating materials

5 Material characteristics and properties — Requirements

5.1 General

In order to arrive at an objective evaluation of a duplicating material, it is necessary to review [Clauses 9, 10 and 11](#) before any further steps in the evaluation are begun.

5.2 Melting temperature — Type 1 materials

When tested in accordance with [8.1](#), the melting temperature shall not exceed the maximum stated in the manufacturer's instructions [[11 c\) 2](#)].

5.3 Pouring temperature — Type 1 materials

The manufacturer's recommended maximum pouring temperature [[11 c\) 4](#)] shall not exceed 54 °C.

5.4 Component colours — Type 2 materials

Different components intended for use in the same mixture shall be supplied in contrasting colours in order to provide a means of determining when the components have been thoroughly mixed.

5.5 Detail reproduction

When tested according to [8.2](#), the duplicating material shall copy line b scribed on the test block ([Figure 1](#)), as a positive reproduction, for the full length of the distance between lines d_1 and d_2 , both of which shall also be completely reproduced.

5.6 Compatibility with refractory investment (and gypsum if applicable)

When tested according to [8.3](#), the duplicating materials shall impart a smooth surface to, and separate cleanly from, the investment or gypsum product poured against it. The investment and gypsum material poured against the lined surface of the duplicating material specimen shall copy line c for the full length of the distance between lines d_1 and d_2 ([Figure 1](#)).

5.7 Elastic recovery

When tested according to [8.4](#), the elastic recovery shall be at least 96,50 %.

5.8 Tear strength

When tested according to [8.5](#), the tear resistance shall be at least 0,3 N/mm for Type 1 materials and at least 1,0 N/mm for Type 2 materials.

5.9 Resistance to fungal growth — Type 1 materials only

When tested in accordance with 8.6, the specimens shall exhibit no fungal growth.

6 Sampling

Samples of material to be tested shall be procured from a single manufacturing batch as packaged for retail marketing.

NOTE Amounts of approximately 7,5 l of Type 1 materials and 3,7 l of Type 2 materials are usually enough for conducting all of the tests and for the considerable practice that may be necessary for the test operator to become proficient in specimen preparation and testing.

7 Test methods — General

7.1 Laboratory conditions

Unless otherwise specified in this document, all specimen preparation and testing shall be conducted under ambient laboratory conditions of (23 ± 2) °C and (50 ± 10) % relative humidity. Unless otherwise specified in this document, all equipment and materials used in the tests shall be brought to ambient temperature before use in specimen preparation and testing procedures.

7.2 Verification of apparatus function

Examine all accessories, instruments and equipment before they are used in order to determine whether they are in acceptable working order. Perform whatever calibration steps are necessary to ensure that the items are in compliance with the specifications stated for them in this International Standard, or in any related supporting standard.

7.3 Specimen preparation and testing

7.3.1 General

Unless otherwise specified, prepare and manipulate the materials to be used for forming the test specimens employing the equipment, and following the procedures, recommended in the manufacturer's instructions [see 11 b), 11 c) and 11 d)].

Time the schedules for specimen preparation and testing using a timing device such as a stopwatch accurate to ± 1 s over a 30 s period.

7.3.2 Preparation of Type 1 materials

Use the double-boiler method for melting Type 1 materials. The amount of melted material prepared for testing purposes at any one time shall be approximately 700 ml. Melted material remaining after the preparation of one set of specimens may be used for forming other sets of specimens to be formed and tested on the same day, providing that the material can be kept at the recommended temperature and consistency for pouring without re-melting.

7.3.3 Preparation of Type 2 materials

For Type 2 materials, use mass/mass proportioning of the components to be mixed. A volume of approximately 20 ml shall be prepared for each specimen tested.

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7.4 Pass/fail determinations

Unless otherwise specified in this document, the minimum number of specimens required for pass/fail determinations is either three or five, as indicated by an entry appearing beside the related specimen preparation or test procedure title.

Unless otherwise specified, the following rules apply.

- For a three-specimen minimum, make and test a series of three specimens initially. If at least two of the three specimens comply with the related requirement, the material passes. If none complies, the material fails. If only one specimen complies, make three additional specimens. If all three of the additional specimens comply, the material passes; otherwise the material fails.
- For a five-specimen minimum, make and test a series of five specimens initially. If at least four of the five specimens comply with the related requirement, the material passes. If only one or two specimens comply, the material fails. If only three specimens comply, make a series of five additional specimens. If all five of the second series of specimens comply, the material passes; otherwise the material fails.

7.5 Expression of test results

Report the number of specimens tested, the number complying with the specified requirement, and whether the material passes or fails.

8 Specific specimen preparation and test procedures

8.1 Melting temperature test — Type 1 materials only

8.1.1 Apparatus

8.1.1.1 Ceramic, glass or stainless steel double boiler system (3.2) having a component that will accommodate a volume of at least 700 ml of the melted duplicating material.

8.1.1.2 Temperature-measuring device, such as a calibrated 76 mm immersion thermometer having graduations of 0,1 °C, or equivalent.

8.1.1.3 Heat source, to provide the temperatures needed for the melting process.

8.1.2 Test procedure (one test)

Observe the rate of melting for the specified volume of material (7.3.2). When the material approaches the final stages of melting, use the device (8.1.1.2) to measure temperature of the material periodically until the moment at which the entire volume is free of lumps and granules. Record the temperature for this occurrence.

8.1.3 Pass/fail determination

Compare the melting temperature recorded according to 8.1.2 with the maximum temperature stated in the manufacturer's instructions [11 c) 2]]. Then record whether this temperature complies with the requirement stated in 5.2.