

International Standard

ISO 14356

Dentistry — **Duplicating material**

Médecine bucco-dentaire — Produits pour duplication

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthodontic materials*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 14356:2003), which has been technically revised.

The main changes are as follows: standards/iso/fe339bc4-795a-4d72-8014-753459e487cb/iso-14356-2024

- figures have been updated to be consistent with other impression material related standards;
- terminology, references and document format have been updated.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Dentistry — **Duplicating material**

1 Scope

This document specifies the 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 documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 6873, Dentistry — Gypsum products

ISO 15912, Dentistry — Refractory investment and die material

ASTM D624-00, Standard test method for tear strength of conventional vulcanized rubber and thermoplastic elastomers

3 Terms and definitions

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

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at https://www.iso.org/obp
- IEC Electropedia: available at https://www.electropedia.org/

3.1

double boiler

container system 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

3.2

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

3.3

effective 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 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

Note 1 to entry: This applies to materials setting at or near oral or room temperature.

3.4

functional life

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

Note 1 to entry: This applies to reversible duplicating material.

3.5

gelation

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

Note 1 to entry: This applies to agar duplicating material.

3.6

immediate container

packaging component that has internal surfaces in direct contact with the material contained

Note 1 to entry: An immediate container can 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.

3.7

initial setting time

time measured from the commencement of mixing components of a material or otherwise activating the chemistry involved and ending at a time when results of a prescribed test, conducted at a specified temperature, show that the mixture has begun to set, thus indicating that the effective setting time is 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.

[SOURCE: ISO 1942:2020, 3.3.1.31, modified — Note to entry added.]

3.8

investment

powdered *refractory* (3.13) 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

Note 1 to entry: This applies to a casting material.

3.9

melt

change a material, by heating, from a gel state to a pourable fluid state

Note 1 to entry: This applies to agar hydrocolloid.

3.10

outer package

wrapping or carton, used to cover one or more *immediate containers* (3.6) or *primary containers* (3.12) in preparation for retail marketing

Note 1 to entry: Legislation or specific standards can apply.

[SOURCE: ISO 4823:2021, 3.8]

3.11

pouring temperature

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

Note 1 to entry: This applies to duplicating material.

3.12

primary container

packaging component for retail marketing which can be covered by an *outer package* (3.10)

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

Note 1 to entry: A primary package can be required to bear specific labelling information by legislation or specific standard.

Note 2 to entry: A primary container may also be an *immediate container* (3.6), and vice versa.

3.13

refractory

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

3.14

slurry

mixture, consisting of a powder and water, or a powder and another liquid, that has a consistency that allows 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

Note 1 to entry: This applies to ceramic, gypsum or investment materials.

3.15

storage

holding of a material in an *immediate container* (3.6) in a protected environment before the container is opened for the first use, and between subsequent openings of the container

3.16

store, verb

 $\langle agar\ hydrocolloid \rangle$ to hold a material at the temperature specified in the manufacturer's instructions to keep it at pouring consistency

Note 1 to entry: This applies to agar hydrocolloid.

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, <u>Clauses 9</u>, <u>10</u> and <u>11</u> shall be reviewed 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 be in accordance with Figure 1, line b scribed on the test block, 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, if applicable, gypsum

When tested in accordance with 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 be in accordance with Figure 1, line c for the full length of the distance between lines d_1 and d_2 (see Figure 1).

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5.7 Elastic recovery

When tested in accordance with 8.4, the elastic recovery shall be at least 96,50 %.

5.8 Tear strength

When tested in accordance with <u>8.5</u>, 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 can 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 conformity with the specifications stated for them in this document, 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 $\frac{11}{1}$ b), $\frac{11}{1}$ c) and $\frac{11}{1}$ 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 Standard Site 1.21

Use a double boiler 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, provided 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.

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 conform to the related requirement, the material passes. If none conforms, the material fails. If only one specimen conforms, make three additional specimens. If all three of the additional specimens conform, 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 conform to the related requirement, the material passes. If only one or two specimens conform, the material fails. If only three specimens conform, make a series of five additional specimens. If all five of the second series of specimens conform, the material passes; otherwise the material fails.