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Dentistry — Water-based cements —

Part 2:

Resin-modified cements

Art dentaire — Ciments dentaires hydrauliques —

Partie 2: Ciments modifiés résineux

[Revision of first edition (ISO 9917-2:1998)]

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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 Electro technical Commission (IEC) on all matters of electro technical 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.

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ISO 9917-2 was prepared by Technical Committee ISO/TC 106, Dentistry, Subcommittee SC 1, Restorative Materials.

This edition cancels and replaces the first edition (ISO 9917-2:1998)

ISO 9917 consists of the following parts, under the general title **Water-based cements**:

- *Part 1: Powder/liquid acid-base cements*
- *Part 2: Resin–modified cements*

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Dentistry — Water-based cements —

Part 2:

Resin-modified cements

Introduction

This International Standard has been prepared in order to present the requirements and test methods for cements in which setting is achieved by a combination of an acid-base reaction and polymerization. The polymerization component of the reaction may be activated by mixing different components or through application of energy from an external source. As far as possible test methods employed within this standard have been harmonized with those used in ISO 4049 and ISO 9917-1.

Specific qualitative and quantitative requirements for freedom from biological hazard are not included in this International Standard but it is recommended that when assessing possible biological or toxicological hazards reference should be made to ISO 10993-1 and ISO 7405.

1 Scope

This International Standard specifies requirements and test methods for dental cements, which are intended for lining, luting or restoration purposes and for which the materials are water-based and set by multiple reactions in which setting is achieved by a combination of an acid-base reaction and polymerisation.

Example:

Conventional **glass polyalkenoate cements** are normally formed by reacting an ion-leachable aluminosilicate glass with a polyalkenoic acid in an aqueous environment. Materials which fall within the scope of this standard will **normally** be able to effect setting by such an aqueous acid-base type reaction but **in addition** will be able to undergo setting by polymerization

NOTE: Attention of manufacturers and test laboratories is drawn to the following closely related Standards. Consideration should be given as to which is the most appropriate Standard by which to evaluate any individual product.

ISO 4049:2000 Dentistry -- Polymer-based filling, restorative and luting materials

ISO 9917-1:2003 Dentistry – Water-based cements. Part 1: Powder/liquid acid-base cements

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 3665:1996, *Photography – Intra-oral dental radiographic film – Specification.*

ISO 3696:1987, *Water for analytical laboratory use – Specification and test methods.*

ISO 7491: *Dental materials – Determination of colour stability of dental polymeric materials.*

ISO 9917-1: 2003, *Dentistry -Water-based cements: Part 1 Powder/liquid acid-base cements.*

ISO 1942: 2007, *Dentistry – Vocabulary*

Informative Note: the preferred method for indicating dates and times is as specified in ISO 8601:2004, *Data elements and interchange formats – information exchange – Representation of dates and times.*

3 Terms and definitions

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

3.1 mixing time

For the purposes of this standard the mixing time shall be defined as that part of the working time required in order to obtain a satisfactory mix of the components.

NOTE: materials which fall within the scope of this International Standard include both materials which require mixing as well as single component no-mix materials.

3.2 working time

For the purposes of this standard the working time shall be defined as the period of time, measured from start of mixing (if required), during which it is possible to manipulate the material without an adverse effect on its properties.

NOTE: working time is determined in the absence of activating radiation, if required for activation for Class 3 materials (see 4).

3.3

setting time

For the purposes of this standard, the setting time shall be defined as the period of time, from start of mix, until the completion of set, as defined by the ability of the material to support an indenter under a known load.

3.4

outer pack

A form of packaging used to combine a number of single dose containers or capsules.

3.5

outermost packaging

A form of packaging used to combine material and additional items including instructions for use and any proportioning or mixing devices which are supplied with the material.

4 Classification and applications

4.1 Classification

For the purposes of this International Standard, materials are classified on the basis of their setting characteristics as follows:

Class 1

These are materials in which the setting reaction of the polymerizable component is activated chemically following mixing of components.

Class 2

These are materials in which the setting reaction of the polymerizable component is light-activated.

Class 3

These are materials in which the setting reaction of the polymerizable component is activated chemically following mixing of components and may also be light-activated.

4.2 Applications

For the purposes of this International Standard, the clinical application of these materials is signified as follows:

- a) Luting
- b) Base or Lining
- c) Restoration

5 Requirements

5.1

Materials

During the course of testing there shall be no visible signs of extraneous matter in any component; separately supplied liquid shall be free of any gelation.

5.2 Working time

When tested in accordance with Annex A the Working Time shall comply with the requirements given in Table 1 and shall be at least as long as the value given by the manufacturer (see 8.2).

5.3 Setting time – Class 1 and 3 materials only

When tested in accordance with Annex A the Setting Time of Class 1 and 3 materials shall comply with the requirements given in Table 1 and shall be no greater than the value given by the manufacturer (see 8.2).

5.4 Film thickness – luting cements only (see 4.2)

When tested in accordance with Annex B the film thickness of luting materials shall comply with the requirements given in Table 1.

5.5 Flexural Strength

When tested in accordance with Annex C the flexural strength shall comply with the requirements given in Table 1.

5.6 Radio-opacity

If the manufacturer claims that the material is radio-opaque (see 8.2) the radio-opacity, determined in accordance with Annex D shall be equal to or greater than that of the same thickness of aluminium. If greater radio-opacity is claimed, it shall not be less than 0.5 mm below the value claimed by the manufacturer (see 8.2).

5.7 Shade and Colour stability – (restorative materials only)

When tested in accordance with Annex E the set material shall match closely that of the shade guide specified by the manufacturer. When tested in accordance with Annex E and ISO 7491 there shall be no more than a slight change in colour after 7 days.

Table 1 — Requirements for dental cements

Application	Film thickness	Working time	Setting time*	Flexural Strength
	μm	min	min	MPa
	Max.	Min.	Max.	Min.
Luting	25	1.5	8	10
Base or lining		1.5	6	10
Restorative		1.5	6	25

*Class 1 and 3 materials only. Class 3 materials tested without activation by light.

6 Sampling

A sample drawn from one batch shall provide sufficient material to complete all the prescribed tests plus an allowance for any necessary repeat tests should they become necessary. The test sample shall consist of packages prepared for retail sale.

7 Test conditions and preparation of test specimens

7.1 Test Conditions

Prepare and test all specimens at an ambient temperature of (23 ± 2) °C. Control the relative humidity to ensure that it remains at (50 ± 20) RH% at all times. If the material was refrigerated for storage, allow it to attain (23 ± 2) °C. Test equipment should be maintained at the condition specified in individual tests.

For Class 2 and 3 materials, activating radiation shall be excluded during the determination of working time.

Water used in all tests specified in this standard shall be prepared in accordance with ISO 3696 Grade 2.

For Class 2 and 3 materials, reference shall be made to the manufacturer's instructions (see 8.2) which state the external energy source to be used. Care shall be taken to ensure that the source is in a satisfactory working condition.

7.2 Method of Mixing

The cement shall be prepared according to the manufacturer's instructions. Sufficient cement shall be mixed to ensure that the preparation of each specimen is completed from one mix. A fresh mix shall be prepared for each specimen.

NOTE: For encapsulated materials, more than one capsule, simultaneously mixed, may be required for certain specimens. Likewise, for materials supplied in single dose containers several containers may be required for each test specimen.

7.3 Inspection Requirements

Visual inspection shall be used in determining compliance with 5.1, and 8.