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Dentistry — Denture adhesives

National foreword

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Foreword

This document (EN ISO 10873:2010) has been prepared by Technical Committee ISO/TC 106 "Dentistry" in collaboration with Technical Committee CEN/TC 55 “Dentistry” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2011, and conflicting national standards shall be withdrawn at the latest by March 2011.

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Foreword

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ISO 10873 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 7, *Oral care products*.

INTERNATIONAL STANDARD ISO 10873:2010(E)

Dentistry — Denture adhesives

1 Scope

This International Standard classifies denture adhesives used by wearers of removable dentures; it also specifies requirements, test methods and instructions to be supplied for the use of such products.

This International Standard is applicable to denture adhesives for use by the public and excludes the dental lining materials prescribed or applied by dental professionals.

This International Standard does not specify qualitative or quantitative requirements for freedom from biological hazards. For assessing possible biological hazards, see ISO 7405 and ISO 10993-1.

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, *Dentistry — Vocabulary*

ISO 3696, *Water for analytical laboratory use — Specification and test methods*

ISO 7823-2, *Plastics — Poly(methyl methacrylate) sheets — Types, dimensions and characteristics — Part 2 Extruded sheets*

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 and the following apply.

3.1
denture adhesives
dental product placed on the intaglio surface (fitting surface) of a removable denture to temporarily improve its retention to soft supporting tissues

3.2
glue type
denture adhesive in powder, cream, sheet or tape form with water-soluble polymer as adhesive constituent

3.3
liner type
denture adhesive in non-aqueous paste form

4 Classification

For the purposes of this International Standard, denture adhesives are categorized as one of the following types:

a) **Type 1**: glue type:

— Class 1: powder form;

— Class 2: cream form;

— Class 3: sheet or tape form.

b) **Type 2**: liner type.

5 Requirements

5.1 General

5.1.1 Biocompatibility

Particular attention should be given to assessing the effects on biocompatibility from the release of metallic ions from the denture adhesive.

5.1.2 pH value

Denture adhesives shall have a pH value within the range of 4 to 10 when tested in accordance with 7.2.

5.1.3 Microbiology

Testing for microbiological contamination shall be carried out according to appropriate methods such as those listed in References [11] to [14] or those specified in ISO 16212, ISO 18416, ISO 21148, ISO 21149, ISO 21150, ISO 22717, ISO 22718 and ISO 29621.

5.1.4 Stability

The denture adhesive shall show no signs of deterioration which may affect compliance with this International Standard after being subjected to one of the aging procedures specified in 7.3.

5.2 Specific requirements for Type 1 adhesives

5.2.1 Washability

There shall be no residual lump when tested in accordance with 7.4.

5.2.2 Strength of the adhesion to the prosthesis

Adhesion strength shall not be less than 5 kPa when tested in accordance with 7.5 and 7.6.

5.3 Specific requirements for Type 2 adhesives

5.3.1 Adhesion strength

Adhesion strength shall not be less than 5 kPa when tested in accordance with 7.7.

5.3.2 Peeling property

There shall be no residual lump when tested in accordance with 7.8.

5.3.3 Consistency

Consistency shall not be less than 15 mm when tested in accordance with 7.9.

6 Sampling

The sample shall be taken from one lot and shall be sufficient to complete all tests specified in Clause 7.

7 Test methods

7.1 Test conditions

All tests shall be conducted at a temperature of (23 ± 3) °C.

7.2 pH value measurement

7.2.1 Apparatus and material

7.2.1.1 **pH meter**, with a glass and comparison electrode assembly with an accuracy of ±0,02.

7.2.1.2 **Glass container**, of 500 ml capacity.

7.2.1.3 **Circular filter paper**, used to separate fine precipitates for chemical analysis.

7.2.2 Reagents

7.2.2.1 **Propylene glycol**, analytical grade.

7.2.2.2 **Water**, grade 3 in accordance with ISO 3696.

7.2.3 Procedure

7.2.3.1 Type 1 adhesives

7.2.3.1.1 Class 1 and Class 2

Take (1,0 ± 0,1) g of a Class 1 or Class 2 denture adhesive, add 5 g of propylene glycol (7.2.2.1) to disperse it, and while stirring, add 300 ml of water (7.2.2.2) and mix them sufficiently. Insert the electrode of the pH meter (7.2.1.1) into the dispersion and take the pH meter reading 3 min after the insertion.

7.2.3.1.2 Class 3

Take (1,0 ± 0,1) g of a Class 3 denture adhesive, add 300 ml of water and mix them sufficiently. Insert the electrode of the pH meter and take the pH meter reading 3 min after the insertion.

7.2.3.2 Type 2

Take (1,0 ± 0,1) g of denture adhesive, spread evenly over a radius of approximately 40 mm on a piece of filter paper (7.2.1.3). Place the filter paper in a glass container (7.2.1.2) and add 300 ml of water to it. After immersing in water for 1 h, insert the electrode of the pH meter into water and take the pH meter reading 3 min after the insertion.

7.3 Determination of stability — Aging procedure

Store the denture adhesives in their original containers at (40 ± 2) °C at (75 ± 5) % relative humidity for 3 months or at such conditions of time and temperature as will simulate storage at room temperature for 30 months[15].

7.4 Test of washability (for Type 1 adhesives)

7.4.1 Apparatus and materials

7.4.1.1 Water bath, capable of being maintained at a temperature of (37 ± 2) °C.

7.4.1.2 Poly(methyl methacrylate) plate (PMMA), approximately 50 mm × 50 mm, in accordance with ISO 7823-2.

7.4.2 Reagent

7.4.2.1 Water, in accordance with 7.2.2.2.

7.4.3 Procedure

Apply the denture adhesive on the PMMA plate (7.4.1.2) evenly following the manufacturer's instructions for use and immerse the plate in water for 1 h in the water bath (7.4.1.1) maintained at (37 ± 2) °C.

Wash the PMMA plate following the manufacturer's instructions for use and inspect the PMMA plate surface with the naked eye, without magnification. Repeat the tests to obtain five test results.

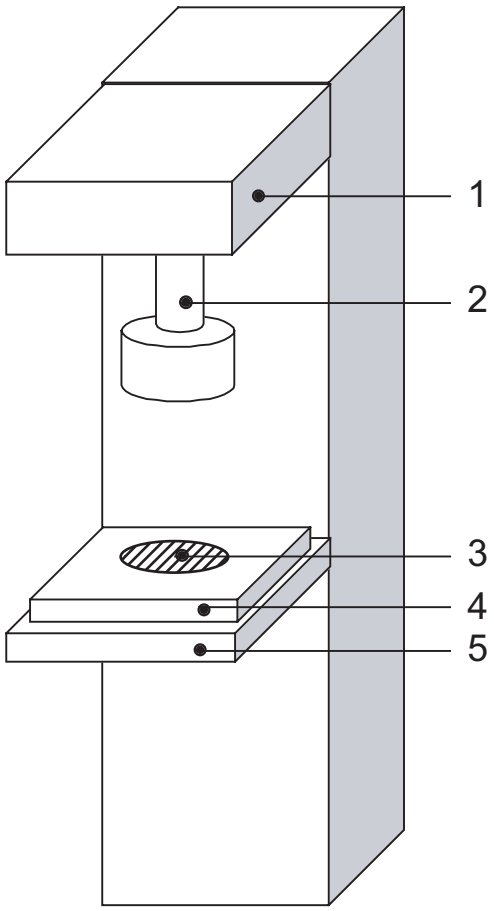
7.5 Adhesion strength test I (for Type 1 adhesives)

7.5.1 General

Conduct the following adhesion strength test within 3 min after removal from the water bath.

7.5.2 Apparatus

7.5.2.1 Adhesion test instrument, having a sample stand, of capacity up to 10 N (for both frame and load cell), with a cross-head speed up to 5 mm/min. See Figure 1.



Key

1 load detecting part
2 pressure sensitive shaft
3 denture adhesive
4 sample holder
5 sample stand

NOTE This is an example of a test instrument.

Figure 1 — Adhesion test instrument

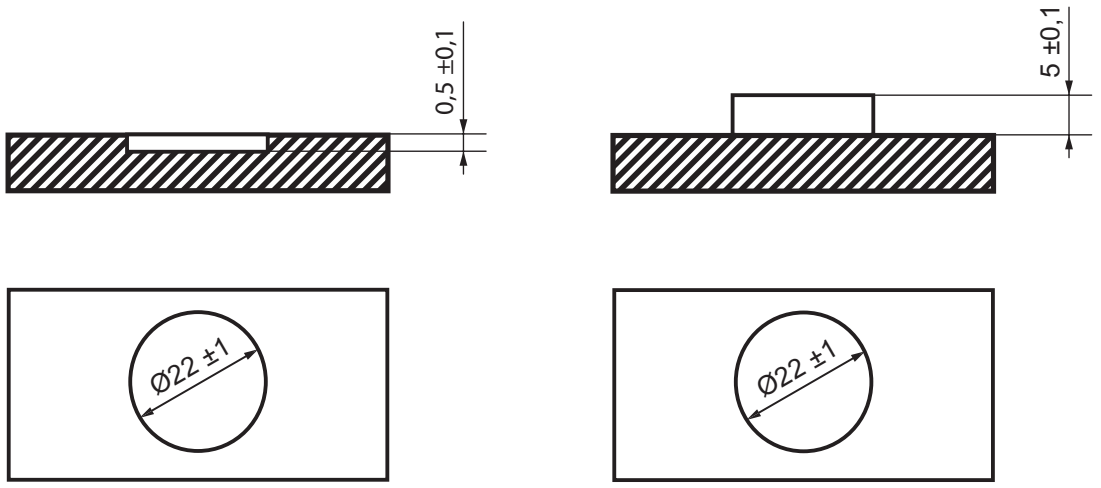
7.5.2.2 **Sample holder I**, having a hole with a diameter of (22 ± 1) mm and a depth of (0,5 ± 0,1) mm, made of poly(methyl methacrylate) complying with ISO 7823-2. See Figure 2 a).

7.5.2.3 **Sample holder II**, having a raised circular part with a diameter of (22 ± 1) mm and a height of (5,0 ± 0,1) mm made of poly(methyl methacrylate) complying with ISO 7823-2. See Figure 2 b).

7.5.2.4 **Pressure sensitive shaft**, having a circular base with a diameter of (20,0 ± 0,5) mm, made of poly(methyl methacrylate) complying with ISO 7823-2. See Figure 3.

7.5.2.5 **Water bath**, in accordance with 7.4.1.1.

Dimensions in millimetres



a) Sample holder I **b) Sample holder II**

Figure 2 — Sample holders

7.5.3 Reagent

7.5.3.1 **Water**, in accordance with 7.2.2.2.

7.5.4 Procedure

7.5.4.1 Class 1 denture adhesive

Add water (7.2.2.2) to 1 g to 3 g of a Class 1 denture adhesive powder in a powder/water mass ratio of 4 and mix them homogeneously. Leave the mixture in a sealed container for 5 min before using it as a sample.

Slightly overfill the hole of holder I (7.5.2.2) with the mixture, flatten the surface, and then immerse the sample/sample holder I assembly in water for 1 min in the water bath (7.4.1.1) maintained at (37 ± 2) °C. Take out the sample/sample holder I assembly from the water bath and shake it once to remove water from the surface. Set the sample/sample holder I assembly on the sample stand of the adhesion test instrument (7.5.2.1) so that the load is applied to the centre of the sample.

Apply a load up to (9,8 ± 0,2) N at cross-head speed of 5 mm/min by the pressure sensitive shaft (7.5.2.4) to the sample, maintain the load in the position for 30 s and pull it toward the opposite direction at cross-head speed of 5 mm/min. Record the maximum force measured by the pressure sensitive shaft and calculate the force per unit area as the adhesion strength. See Figure 3 a). Repeat the test four times to obtain five results.

7.5.4.2 Class 2 denture adhesive

Slightly overfill the hole of the sample holder I with a Class 2 denture adhesive, flatten the surface, and then immerse the sample/sample holder I assembly in water for 1 min in the water bath maintained at (37 ± 2) °C. Take out the sample/sample holder I assembly and shake it once to remove water from the surface. Set the sample/sample holder I assembly on the sample stand of the adhesion test instrument (7.5.2.1) so that the load is applied to the centre of the sample.

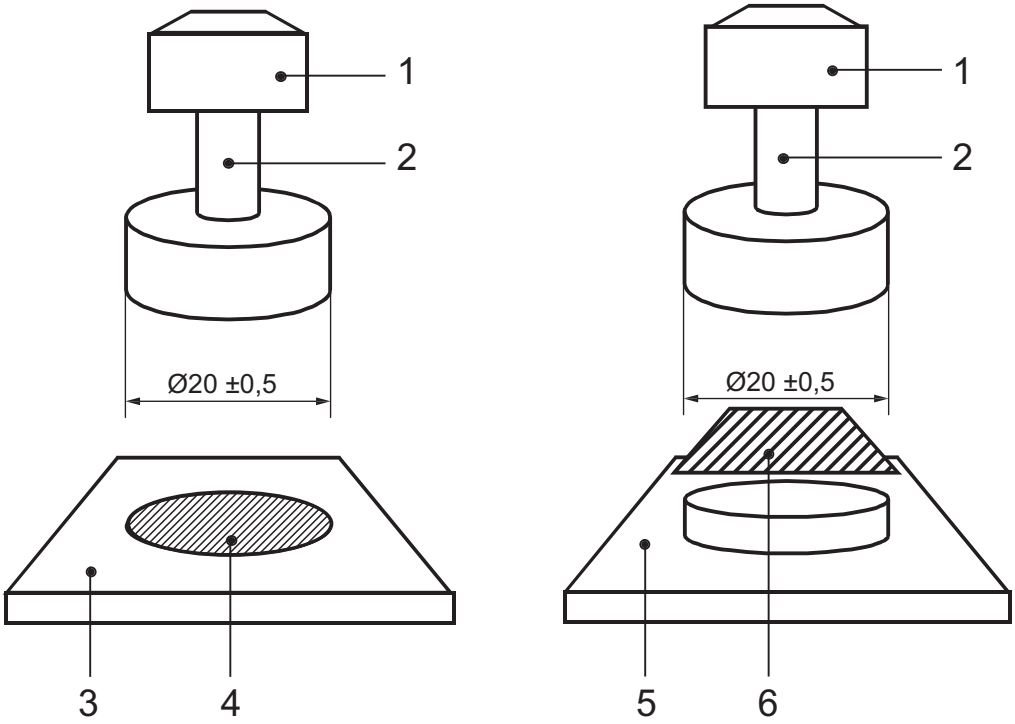
Apply a load up to (9,8 ± 0,2) N at cross-head speed of 5 mm/min by the pressure sensitive shaft to the sample, maintain the load in the position for 30 s and pull it toward the opposite direction at cross-head speed of 5 mm/min. Record the maximum force measured by the pressure sensitive shaft and calculate the force per unit area as the adhesion strength. See Figure 3 a). Repeat the test four times to obtain five results.

7.5.4.3 Class 3 denture adhesive

Take a Class 3 denture adhesive so that the minimum dimensions of its total area will be 21 mm × 21 mm and after immersing this in water for 5 s in the water bath maintained at (37 ± 2) °C, take out and shake it once to remove water from the surface. Place the sample immediately on the sample holder II (7.5.2.3) so that the sample evenly covers the raised circular part and set the sample/sample holder II assembly on the sample stand of the adhesion test instrument so that the load is applied to the centre of the sample.

Apply a load up to (9,8 ± 0,2) N at cross-head speed of 5 mm/min by the pressure sensitive shaft (7.5.2.4) to the sample, maintain the load in the position for 30 s and pull it toward the opposite direction at cross-head speed of 5 mm/min. Record the maximum force measured by the pressure sensitive shaft and calculate the force per unit area as the adhesion strength. See Figure 3 b). Repeat the test four times to obtain five results.

Dimensions in millimetres



a) Class 1 or Class 2 **b) Class 3**

Key

1 load detector
2 pressure sensitive shaft
3 sample holder I
4 Class 1 or Class 2 sample
5 sample holder II
6 Class 3 sample

Figure 3 — Layout for adhesion test instrument

7.6 Adhesion strength test II (for Type 1 adhesives)

7.6.1 General

Conduct the following adhesion strength test within 3 min after removal from the water bath.

7.6.2 Apparatus (see 7.5.2)

7.6.3 Reagent (see 7.5.3)

7.6.4 Procedure

7.6.4.1 Class 1 denture adhesive

Add water (7.2.2.2) to 1 g to 3 g of a Class 1 denture adhesive powder in a powder/water mass ratio of 4 and mix evenly. Leave the mixture in a sealed container for 5 min before using it as a sample.

Slightly overfill the hole of holder I (7.5.2.2) with the mixture, flatten the surface, and then immerse the sample/sample holder I assembly in 300 ml of water (7.2.2.2) for 10 min in the water bath (7.4.1.1) maintained at (37 ± 2) °C. Take out the sample/sample holder I assembly from the water bath and shake it once to remove water from the surface. Set the sample/sample holder I assembly on the sample stand of the adhesion test instrument (7.5.2.1) so that the load is applied to the centre of the sample.

Apply a load up to (9,8 ± 0,2) N at cross-head speed of 5 mm/min by the pressure sensitive shaft (7.5.2.4) to the sample, maintain the load in the position for 30 s and pull it toward the opposite direction at cross-head speed of 5 mm/min. Record the maximum force measured by the pressure sensitive shaft and calculate the force per unit area as the adhesion strength. See Figure 3 a). Repeat the test four times to obtain five results.

7.6.4.2 Class 2 denture adhesive

Slightly overfill the hole of the sample holder I (7.5.2.2) with a Class 2 denture adhesive, flatten the surface, and then immerse the sample/sample holder I assembly in 300 ml of water (7.2.2.2) for 10 min in the water bath (7.5.2.5) maintained at (37 ± 2) °C. Take out the sample/sample holder I assembly and shake it once to remove water from the surface. Set the sample/sample holder I assembly on the sample stand of the adhesion test instrument (7.5.2.1) so that the load is applied to the centre of the sample.

Apply a load up to (9,8 ± 0,2) N at cross-head speed of 5 mm/min by the pressure sensitive shaft (7.5.2.4) to the sample, maintain the load in the position for 30 s and pull it toward the opposite direction at cross-head speed of 5 mm/min. Record the maximum force measured by the pressure sensitive shaft and calculate the force per unit area as the adhesion strength. See Figure 3 a). Repeat the test four times to obtain five results.

7.6.4.3 Class 3 denture adhesive

Take a Class 3 denture adhesive so that the minimum dimensions of its total area will be 21 mm × 21 mm and after immersing this in 300 ml of water (7.2.2.2) for 10 min in the water bath (7.5.2.5) maintained at (37 ± 2) °C, take it out and shake it once to remove water from the surface. Place the sample immediately on the sample holder II (7.5.2.3) so that the sample evenly covers the raised circular part and set the sample/sample holder II assembly on the sample stand of the adhesion test instrument (7.5.2.1) so that the load is applied to the centre of the sample.

Apply a load up to (9,8 ± 0,2) N at cross-head speed of 5 mm/min by the 20 ± 0,5 mm pressure sensitive shaft (7.5.2.4) to the sample, maintain the load in position for 30 s and pull it toward the opposite direction at cross-head speed of 5 mm/min. Record the maximum force measured by the pressure sensitive shaft and calculate the force per unit area as the adhesion strength. See Figure 3 b). Repeat the test four times to obtain five results.

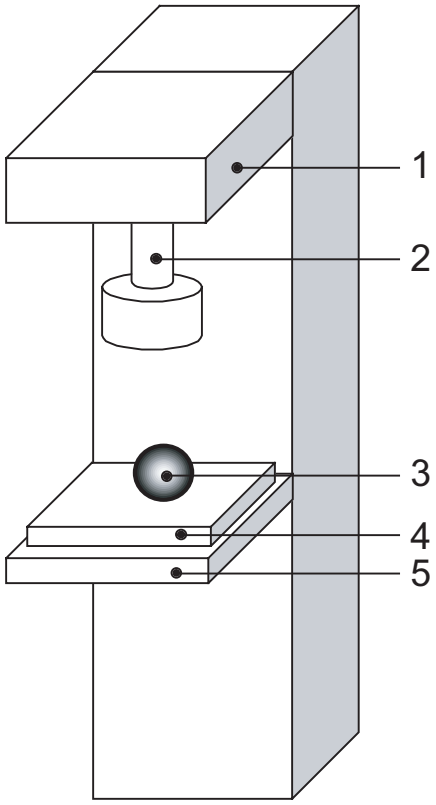
7.7 Adhesion strength test (for Type 2 adhesives)

7.7.1 Apparatus

7.7.1.1 Adhesion test instrument, having a sample stand, of capacity up to 10 N (for both frame and load cell), with a cross-head speed up to 5 mm/min. See Figure 4.

7.7.1.2 **Pressure sensitive shaft**, having a circular base with a diameter of (20 ± 0,5) mm, made of poly(methyl methacrylate) complying with ISO 7823-2. See Figure 5.

7.7.1.3 **Poly(methyl methacrylate) plate (PMMA)**, in accordance with 7.4.1.2.

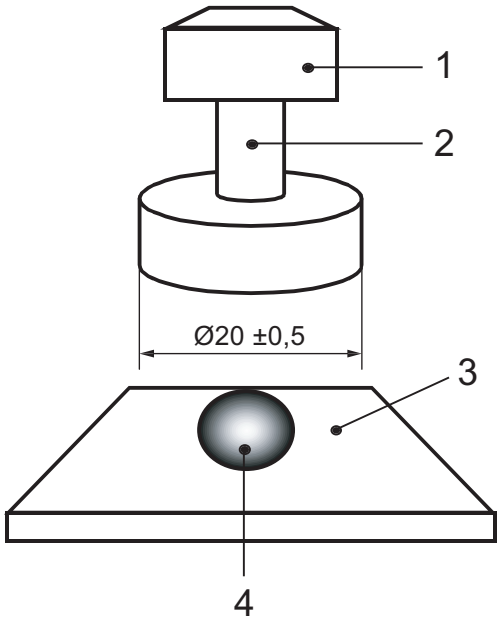


Key
1 load detecting part
2 pressure sensitive shaft
3 denture adhesive
4 sample holder
5 sample stand

NOTE This is an example of a test instrument.

Figure 4 — Adhesion strength test instrument for Type 2 adhesives

Dimensions in millimetres



Key
1 load detector
2 pressure sensitive shaft
3 PMMA plate
4 denture adhesive

Figure 5 — Layout for adhesion strength test for Type 2 adhesives

7.7.2 Reagent

7.7.2.1 Water, in accordance with 7.2.2.2.

7.7.3 Procedure

Immerse the pressure sensitive shaft (7.7.1.2) in water (7.2.2.2) for 12 h. After the shaft has fully absorbed the water, lightly wipe the moisture off the shaft.

Take $(0{,}8 \pm 0{,}1)$ g of a type 2 denture adhesive and shape into a sphere for use as a sample. Place the sample on the PMMA plate (7.7.1.3) and set the plate on the sample holder of the adhesion test instrument (7.7.1.1) so that the load is applied to the centre of the sample. Press the sample by the pressure sensitive shaft (7.7.1.2) at cross-head speed of 5 mm/min up to a load of $(9{,}8 \pm 0{,}2)$ N, and then immediately pull it toward the opposite direction at cross-head speed of 5 mm/min. Record the maximum force measured by the pressure sensitive shaft, and calculate the force per unit area as the adhesion strength. See Figure 5. Repeat the test four times to obtain five test results.

7.8 Peeling test (for Type 2 adhesives)

7.8.1 Apparatus and materials

7.8.1.1 Water bath (see 7.4.1.1).

7.8.1.2 Poly(methyl methacrylate) plate (PMMA), minimum dimensions of 20 mm $\times$ 30 mm, in accordance with ISO 7823-2.

7.8.1.3 Adhesive poly(vinyl chloride) tape (PVC), $(0{,}2 \pm 0{,}03)$ mm thick, at least 6 mm wide.

7.8.2 Reagents

7.8.2.1 Water, in accordance with 7.2.2.2.

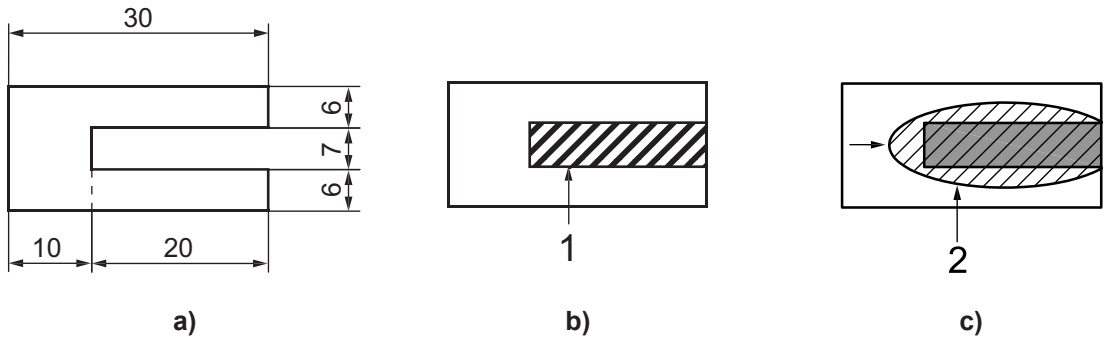
7.8.2.2 Diluted ethanol, reagent grade, diluted to 50 % (volume fraction) in the water (7.2.2.2).

7.8.3 Procedure

Wash the surface of the PMMA plate (7.8.1.2) thoroughly and dry it. Paste the PVC tape (7.8.1.3) cut as shown in Figure 6 a) onto the washed PMMA plate.

Take $(0{,}5 \pm 0{,}1)$ g of a type 2 denture adhesive and apply it evenly to the top surface of the PMMA/PVC composite so as to cover the whole exposed part of the PMMA plate [the shaded part in Figure 6 b)] with it [see Figure 6 c)]. Immerse this sample in water (7.2.2.2) for 24 h in the water bath (7.4.1.1) maintained at (37 ± 2) °C and carefully peel off the denture adhesive with fingers so that it does not break. If any denture adhesive remains on the PMMA plate surface, wipe it off with a piece of gauze and inspect the surface with the naked eye, without magnification. If any residue still remains on the surface, wipe it off with a piece of gauze wetted with diluted ethanol (7.8.2.2) and inspect the surface again visually. Repeat the test four times to obtain five test results.

Dimensions in millimetres
Tolerance on dimensions: ±1



Key
1 exposed part of the PMMA plate
2 denture adhesive

Figure 6 — Procedure for the peeling test

7.9 Consistency test (for Type 2 adhesives)

7.9.1 Apparatus

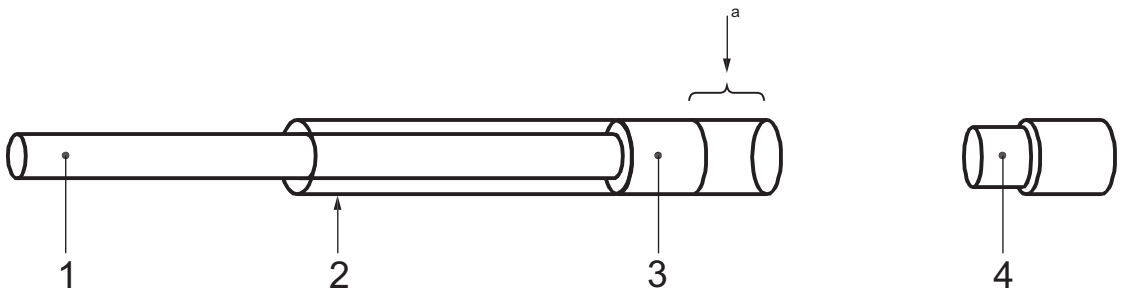
7.9.1.1 **Load applying apparatus**, in accordance with 7.7.1.1.

7.9.1.2 **Pressure sensitive shaft**, having a square base with minimum dimensions of 50 mm × 50 mm, made of metal or polymeric material. See Figure 8.

7.9.1.3 **Sampler**, capable of taking (0,5 ± 0,02) ml of a sample. See Figure 7.

7.9.1.4 **Poly(methyl methacrylate) plate (PMMA)**, in accordance with 7.4.1.2.

7.9.1.5 **Separating sheet**, transparent (e.g. polyethylene sheet), of a large enough size to cover the PMMA plate (7.9.1.4).



Key
1 pushing-out bar
2 glass or plastic tube
3 rubber stopper
4 capacity-setting gauge

[a] Capacity of 0,5 ml.

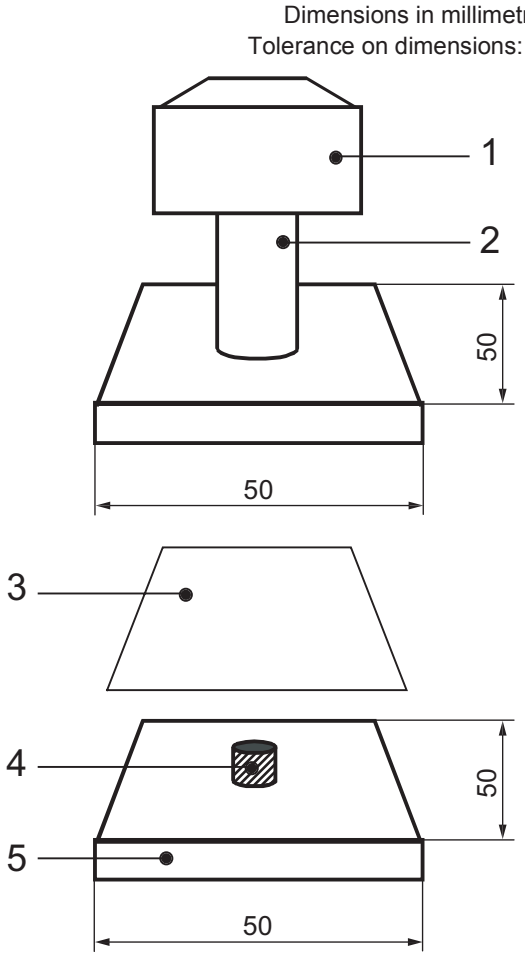
Figure 7 — Sampler

7.9.2 Procedure

Measure (0,5 ± 0,02) ml of a type 2 denture adhesive using the sampler (7.9.1.3). Place the sample in the centre of the PMMA plate (7.9.1.4), and cover it with the separating sheet (7.9.1.5). See Figure 8.

Set the PMMA plate with the sample on the sample stand of the load bearing apparatus (7.9.1.1) so that the load is applied to the centre of the sample. Press the sample by the pressure sensitive shaft (7.9.1.2) up to a load of (9,8 ± 0,2) N at cross-head speed of 5 mm/min and allow the cross-head to stay on the sample for 30 s.

After removing the load, measure the four diameters of the flattened sample at intervals of 45°. Calculate the average of the measured values and take it as the diameter to be considered when determining whether the sample complies with the requirement specified in 5.3.3. Repeat the test four times to obtain five test results.



Key

1 load detector
2 pressure sensitive shaft
3 separating sheet
4 sample
5 PMMA plate

Figure 8 — Layout for consistency test

7.10 Assessment

If four or more of five test results conform to the requirements in Table 1, it shall be assessed that the product has passed.

If three or more of five test results do not conform to the requirements in Table 1, it shall be assessed that the product has failed.

If only three of five test results conform to the requirements in Table 1, make an additional five samples for each test and if all the test results conform to the requirements in Table 1, it shall be assessed that the product has passed.

Table 1 — Requirements

Test methods	Requirements
7.2 pH value measurement	5.1.2 pH value
7.4 Test of washability (for Type 1 adhesives)	5.2.1 Washability
7.5 Adhesion strength test I (for Type 1 adhesives)	5.2.2 Strength of the adhesion to the prosthesis
7.6 Adhesion strength test II (for Type 1 adhesives)	5.2.2 Strength of the adhesion to the prosthesis
7.7 Adhesion strength test (for Type 2 adhesives)	5.3.1 Adhesion strength
7.8 Peeling test (for Type 2 adhesives)	5.3.2 Peeling property
7.9 Consistency test (for Type 2 adhesives)	5.3.3 Consistency

8 Accompanying information

8.1 Information to be included in the manufacturer's instructions

Each package shall be accompanied by instructions for use containing at least the following information:

a) instructions for application and removal;

b) ingredients; description of all principal ingredients;

c) cautions regarding usage:

- caution on the onset of the adhesive effect (for Type 1 adhesives),
- caution on washing after use (for Type 1 adhesives),
- caution on one dose duration (for Type 2 adhesives),
- caution on peeling after use (for Type 2 adhesives),
- other cautions on using methods;

d) safety precautions:

- caution on hypersensitivity,
- caution on extended use,
- recommendation to consult dentists,
- other cautions relative to usage,

e) cautions on storage and handling;

f) pH;

g) the package shall be secured for contamination.

8.2 Labelling on the package

The label on the package shall be marked with at least the following information:

a) the name or trademark of the manufacturer, or distributor and address;

b) the trade name;

c) a description of the product using the classification in Clause 4;

d) the lot number;

e) the minimum net mass or net contents;

f) the recommended storage conditions, if required;

g) the warnings on toxicity, danger or irritation, if required;

h) tracking code that includes an intelligible production date, expressed in accordance with ISO 8601, if the period of stability (shelf life) is less than 30 months.

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