

INTERNATIONAL
STANDARD

ISO
20127

Second edition
2020-08

**Dentistry — Physical properties of
powered toothbrushes**

*Médecine bucco-dentaire — Caractéristiques physiques des brosses à
dents électriques*



Reference number
ISO 20127:2020(E)

© ISO 2020



COPYRIGHT PROTECTED DOCUMENT

© ISO 2020

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

	Page
Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Requirements	2
4.1 Physical inspection	2
4.2 Electrical safety	2
4.3 Tuft retention	2
4.4 Mechanical strength	2
4.5 Resistance to chemical degradation	3
5 Sampling and pass-fail criteria	3
5.1 Sampling	3
5.2 Pass-fail criteria	3
6 Test methods	3
6.1 General test conditions	3
6.2 Visual inspection	3
6.3 Tactile inspection	3
6.4 Tuft retention	3
6.4.1 Apparatus	3
6.4.2 Procedure	4
6.5 Brush head plate retention	4
6.5.1 Apparatus	4
6.5.2 Procedure	4
6.6 Resistance to chemical degradation	5
6.6.1 Apparatus and chemicals	5
6.6.2 Procedure	5
7 Test report	6
8 Marking and labelling	6
8.1 Powered toothbrush components	6
8.2 Instructions for use	6
8.3 Marking and labelling	6
9 Packaging	6
Annex A (informative) Gripping device for tuft retention test	7
Annex B (informative) Gripping device for brush head plate retention test	9
Bibliography	17

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.

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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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 7, *Oral care products*, 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 20127:2005), which has been technically revised.

The main changes to the previous edition are as follows:

- a requirement and a test method for brush head plate retention have been added;
- clarification in scope to include all types of powered toothbrushes.

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.

Introduction

Powered toothbrushes are used for the removal of dental plaque and oral debris in order to facilitate oral hygiene.

Dentistry — Physical properties of powered toothbrushes

1 Scope

This document specifies requirements and test methods for the physical properties of powered toothbrushes in order to promote the safety of these products for their intended use.

There are different technologies of powered toothbrushes. Common features of those powered toothbrushes to which this document applies are:

- a battery;
- a motor;
- a mechanical or magnetic drive system;
- a moving brush head with tufted filaments.

Powered toothbrushes can have a moving brush head with different motions (e.g. oscillating-rotating, side-by-side), frequencies and velocities.

The requirements listed in this document apply to all types of powered toothbrushes. However, there is a possibility that some requirements are not applicable for all types, for example brush head plate retention can only be applied if the brush has a head portion that might get detached from the brush shaft.

This document is not applicable to other types of powered oral hygiene devices (such as powered interdental brushes) or manual toothbrushes.

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

IEC 60068-2-75, *Environmental testing — Part 2-75: Tests — Test Eh: Hammer tests*

IEC 60335-1, *Household and similar electrical appliances — Safety — Part 1: General requirements*

IEC 60335-2-52, *Household and similar electrical appliances — Safety — Part 2-52: Particular requirements for oral hygiene appliances*

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 terminological databases for use in standardization at the following addresses:

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

3.1

brush head

working end of an electrically powered toothbrush to which the filaments are attached

[SOURCE: ISO 22254:2005, 3.2, modified – adapted to an electrically powered toothbrush]

3.2

filament

single strand within the brush head

[SOURCE: ISO 22254:2005, 3.3]

3.3

powered toothbrush

hand-held electrically powered appliance, the brush head of which carries filaments, used primarily for cleaning surfaces within the oral cavity

3.4

brush head removal force

force required to remove the toothbrush tuft plate from the toothbrush shaft

3.5

tuft

group of filaments gathered together and attached to the brush head

[SOURCE: ISO 22254:2005, 3.4]

3.6

tuft removal force

force required to remove one tuft from the brush head

[SOURCE: ISO 20126:2012, 3.5]

4 Requirements

4.1 Physical inspection

The powered toothbrush, its components and all accessories shall be intact and free of visible contamination and sharp or rough surfaces when examined according to [6.2](#) and [6.3](#).

4.2 Electrical safety

The powered toothbrush and related accessories shall conform to the requirements described in IEC 60335-1 and IEC 60335-2-52.

4.3 Tuft retention

The tuft removal force shall not be less than 15 N when tested according to [6.4](#).

4.4 Mechanical strength

The powered toothbrush and related accessories shall conform to the requirements described in IEC 60335-1 and IEC 60335-2-52.

The retention force of the brush head plate shall not be lower than 50 N for each individual sample when tested according to [6.5](#).

4.5 Resistance to chemical degradation

Subject the brush head to a chemical degradation test according to [6.6](#). After this test, the brush head shall conform to the requirements of the spring-operated impact test as described in IEC 60335-1 and IEC 60068-2-75, and the brush head shall be operational and free of sharp or rough surfaces when examined.

5 Sampling and pass-fail criteria

5.1 Sampling

Eight powered toothbrushes of each type shall be tested.

The powered toothbrushes sampled for testing shall be as manufactured and not modified in any way except as specified for this document.

5.2 Pass-fail criteria

If none of the eight sampled powered toothbrushes fail, the powered toothbrush passes. If one toothbrush does not meet the minimum requirement, another eight powered toothbrushes shall be tested. If no more toothbrushes fail, the powered toothbrush passes. If a total of two or more powered toothbrushes of the 16 fail, the powered toothbrush fails.

6 Test methods

6.1 General test conditions

All tests shall be conducted using dry brushes at $(23 \pm 5)^\circ\text{C}$ and relative humidity $(50 \pm 10)\%$.

6.2 Visual inspection

Perform visual inspection of the powered toothbrush and related accessories using normal visual acuity without magnification.

6.3 Tactile inspection

Perform tactile inspection of the powered toothbrush and related accessories in order to detect sharp or rough surfaces.

6.4 Tuft retention

6.4.1 Apparatus

6.4.1.1 Gripping unit, to secure the brush head, having a structure such that compressive force is not induced on the brush head (see [Annex A, Figure A.1](#)).

6.4.1.2 Clamp for securely holding all of the filaments in one tuft, for example a tuft gripping clamp (see [Annex A, Figure A.2](#)) or a collet chuck.

6.4.1.3 Apparatus for applying, measuring and indicating the removal force, a digital force gauge or a universal testing machine (force range from 5 N to 50 N, accurate to 0,1 N and a range of pulling speed from 20 mm/min to 100 mm/min).

6.4.2 Procedure

Place the powered toothbrush in the gripping unit (6.4.1.1) and lock into place so that the clamp (6.4.1.2) pulls the tuft along the long axis of the tuft without any twisting. The brush head shall not be compressed during or after the placement.

Place the clamp on the filament tuft. Be sure to clamp all of the filaments from one tuft only; do not include filaments from the surrounding tufts. The filaments from one tuft should be secured at approximately the midpoint of the tuft length. Record the force required to pull out the tuft using the testing apparatus (6.4.1.3). Test two tufts of each tuft type (if available). The tufts should be non-adjacent.

NOTE The different types of tuft are determined in view of properties such as filaments having different materials, length and diameters, or different shapes and diameters of the hole.

6.5 Brush head plate retention

6.5.1 Apparatus

6.5.1.1 Brush head holder, to hold the shaft of the brush head. This is a universal spring-loaded holder designed to accommodate a variety of different brush heads. The top vice is moveable and can slide back and forth on the brush head holder, and the bottom vice is locked onto a mounting base (6.5.1.2) with clamps (6.5.1.3). Swivel headgrips, adjusted with set screws, hold onto the shaft at different points and angles to accommodate different shaft designs. See [Figure B.1](#).

NOTE The brush head refers to the removable working end (i.e. refill) of the powered toothbrush.

6.5.1.2 Mounting base, to mount the brush head holder (6.5.1.1) to a mechanical test apparatus (6.5.1.5). See [Figure B.2](#).

6.5.1.3 Clamps, to attach the brush head holder (6.5.1.1) to the mounting base (6.5.1.2).

6.5.1.4 Gripping unit, to securely grip the tuft plate of the brush head, without inducing forces in the tuft plate that would lead to significant deformation. Examples of appropriate gripping units are the following: a U-shaped fixture, with a collar large enough to grip behind the tuft plate (see [Figure B.3](#)); an embedding rod, which accommodates all circular tuft plate designs and secures the tufts of the brush head with dental resin material to minimize any compressive forces on the tuft plate (see [Figure B.4](#)).

6.5.1.5 Mechanical test apparatus for applying, measuring and indicating the brush head removal force, a digital force gauge or a universal testing machine with sufficient force capacity, an appropriate accuracy and a cross-head speed at least up to 50 mm/min.

6.5.2 Procedure

Adjust the socket head screws on the brush head holder (6.5.1.1) to open the fixture and slide the brush head in between the top and bottom vice. When positioning the brush head between the top and bottom vice, leave only enough space between the brush head holder and the tuft plate for clearance of the gripping unit (6.5.1.4) to be attached to the tuft plate (see [Figure B.5](#)).

NOTE 1 Inter-laboratory testing has shown that the position of the brush head in the brush holder can have a significant effect on the measured head-retention force.

With the brush head holder (6.5.1.1) placed on the flat surface of a table, adjust the setscrews on the swivel head grips for both the top and bottom vice of the brush head holder until the tuft plate of the brush head is parallel with the table surface.

Attach the mounting base (6.5.1.2) to the base of the mechanical test apparatus (6.5.1.5).

Calibrate the mechanical test apparatus (6.5.1.5) with the gripping unit (6.5.1.4) attached to the moveable crosshead of the mechanical test apparatus.

NOTE 2 This step is for a mechanical test apparatus that has software with the ability to perform calibrations with test fixtures, such as the gripping unit, attached to it.

With the brush head mounted in the brush head holder (6.5.1.1), secure the gripping unit (6.5.1.4) on the tuft plate of the brush head.

NOTE 3 If using the embedding rod gripping unit, see [Annex B](#) for specific mounting instructions.

Position the brush head holder (6.5.1.1) on the mounting base (6.5.1.2), so that the tuft plate is perpendicular to the pull axis of the mechanical test apparatus (6.5.1.5) (see [Figure B.7](#)). The load sensor of the mechanical test apparatus (6.5.1.5) should read close to 0 N. If not, lower or raise the moveable crosshead of the mechanical test apparatus (6.5.1.5) until the load cell reads approximately 0 N, and then lock the brush head holder (6.5.1.1) on the mounting base (6.5.1.2) with two clamps (6.5.1.3).

Run the mechanical test apparatus (6.5.1.5) at a pull speed of (50 ± 10) mm/min until the tuft plate dislodges from the brush head. Record the maximum force required to remove the tuft plate as the head-retention force.

6.6 Resistance to chemical degradation

6.6.1 Apparatus and chemicals

6.6.1.1 Apparatus for mixing the chemical challenge, for example stirring bar or mixer.

6.6.1.2 Container which can be sealed and is chemically inert, for example a polypropylene bottle.

6.6.1.3 Chemical components, of minimum purity and of the amounts listed in [Table 1](#).

Table 1 — Quantity and purity of products used

Component	Minimum purity %	Amount g	CAS number	Synonyms
Ethanol	96	100	64-17-5	Ethyl alcohol
L-carvone	98	1,5	6485-40-1	
L-menthol	98	1,5	2216-51-5	
Sodium lauryl sulfate	95	15,0	151-21-3	
Glycerine	98	200	56-81-5	
Water	ISO 3696, Grade 3	682	7732-18-5	

6.6.2 Procedure

Add 1,5 g L-carvone, 1,5 g L-menthol and 15 g sodium lauryl sulfate to 100 g ethanol in the container and stir well. Add 250 g water (according to ISO 3696, Grade 3) and stir well to obtain a clear solution. Add 200 g glycerine and 432 g water (according to ISO 3696, Grade 3) and stir to obtain a clear solution.

Place the removable brush head in the chemical-challenge solution. Ensure that the portion of the head containing filaments and 100 % of the total length of the removable head is immersed. If the head is not removable, immerse the portion of the head containing filaments and an additional 80 % of the portion of the head exposed to a chemical challenge during normal toothbrushing. After immersion seal the container. After 24 h without agitation, remove the toothbrush, rinse with water (ISO 3696, Grade 3) and shake off excess water.

Perform the spring-operated impact test as described in IEC 60335-1 and in IEC 60068-2-75.

7 Test report

The test report shall contain at least the following information:

- a) identification of the powered toothbrush;
- b) results and the units of measure used;
- c) any unusual features noted during the test;
- d) reference to this document (i.e. ISO 20127:2020);
- e) statement of conformity with this document;
- f) date of the test.

8 Marking and labelling

8.1 Powered toothbrush components

The powered toothbrush, all components and related accessories shall be marked in accordance with IEC 60335-1 and IEC 60335-2-52. The powered toothbrush shall also be marked with a manufacturer's tracking code.

8.2 Instructions for use

The powered toothbrush shall be supplied with instructions for use, maintenance and disposal and information on electrical safety (including warnings).

8.3 Marking and labelling

The packaging of powered toothbrushes shall be marked or labelled with the following information:

- a) name and address of manufacturer and/or responsible distributor;
- b) trade name;
- c) list of contents;
- d) tracking code.

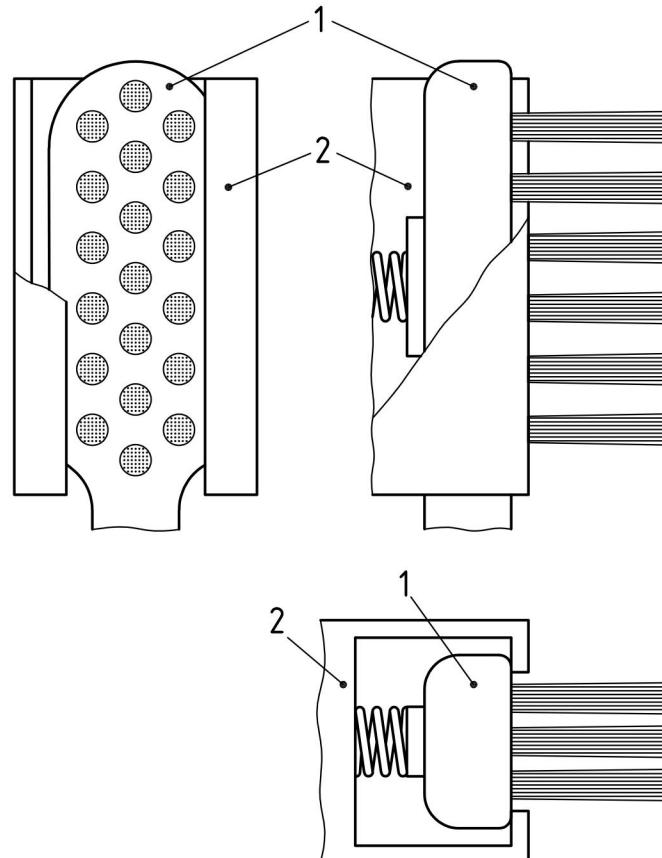
9 Packaging

The packaging shall be such that it will neither contaminate nor permit contamination of the powered toothbrush when examined in accordance with [6.2](#).

Annex A (informative)

Gripping device for tuft retention test

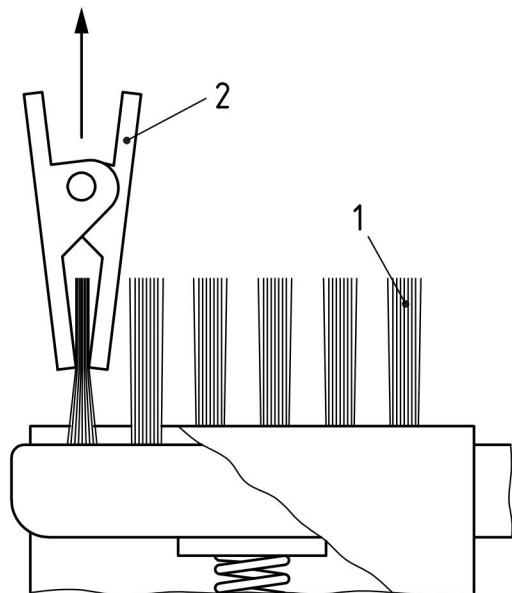
The items of the gripping device for tuft retention test are shown in [Figure A.1](#) and [Figure A.2](#).



Key

- 1 brush head
- 2 brush-head gripping device

Figure A.1 — Brush-head gripping unit



Key

- 1 tuft
- 2 tuft gripping clamp

Figure A.2 — Tuft gripping clamp

Annex B (informative)

Gripping device for brush head plate retention test

B.1 General

The items of the gripping device for brush head plate retention test are shown in [Figures B.1 to B.7](#).

B.2 Apparatus

B.2.1 Brush head holder. Swivelled head grips can accommodate different shaft designs. The top vice is moveable and can be slid back and forth to accommodate different shaft lengths and avoid clamping on manufacturing seams.

B.2.2 U-shaped fixture, with a collar large enough to grip behind the tufted plate.

B.2.3 Embedding rod, with dental resin and pin to hold onto the tuft plate.

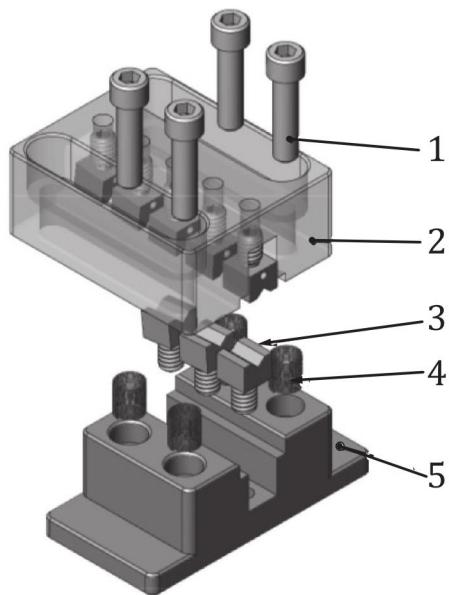
B.3 Mounting procedure

Use dental wax to seal the hole at the base of the cavity for the embedding rod. Insert a pin into the pin hole to keep the dental resin in place once it hardens.

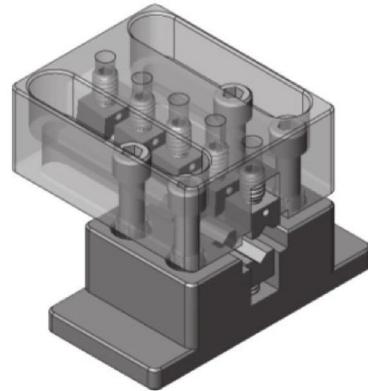
The brush head with the tuft plate is pushed into the dental resin material and held in place until it sets.

When testing is complete, remove the pin from the hole. Use a tool to push the dental wax and resin out of the rod.

Some brush heads have a manufacturing seam, as shown in the side view illustration in [Figure B.6 b\)](#), that if clamped by the bottom vice of the brush head holder can lead to artificially high head-retention forces. If possible, the brush head should be positioned in the brush head holder to avoid gripping this seam by sliding the top vice forward with respect to the bottom vice.



a) Exploded view



b) Assembled view

Key

- | | | | |
|---|-------------------|---|-------------|
| 1 | socket screws | 4 | springs |
| 2 | top vice | 5 | bottom vice |
| 3 | swivel head grips | | |

Figure B.1 — Brush head holder

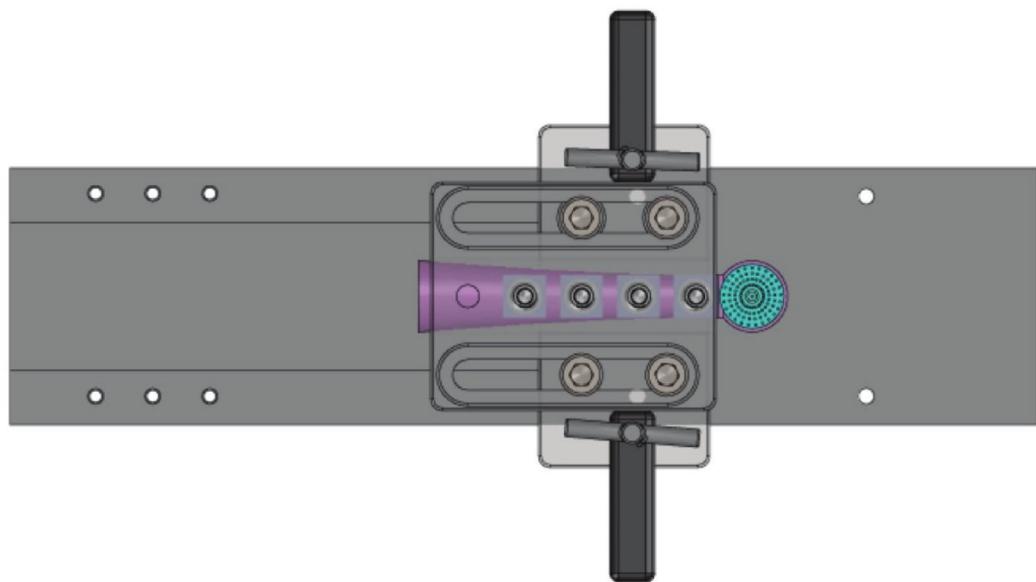


Figure B.2 — Brush head holder in mounting base

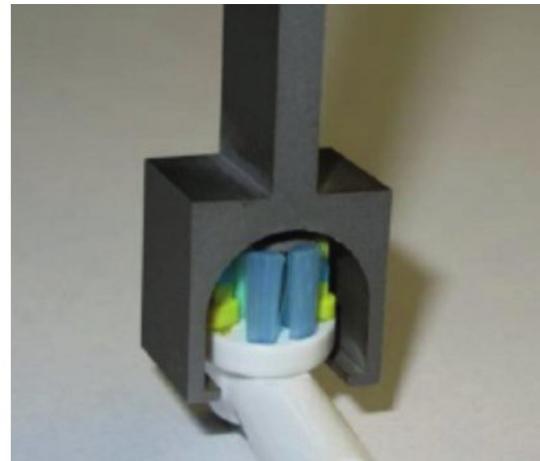
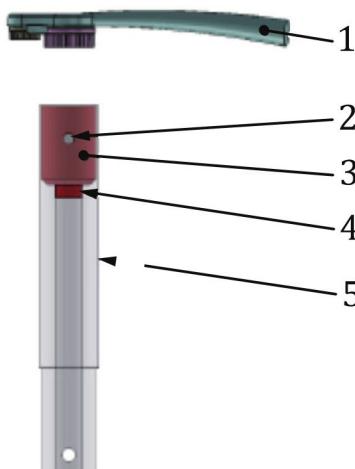


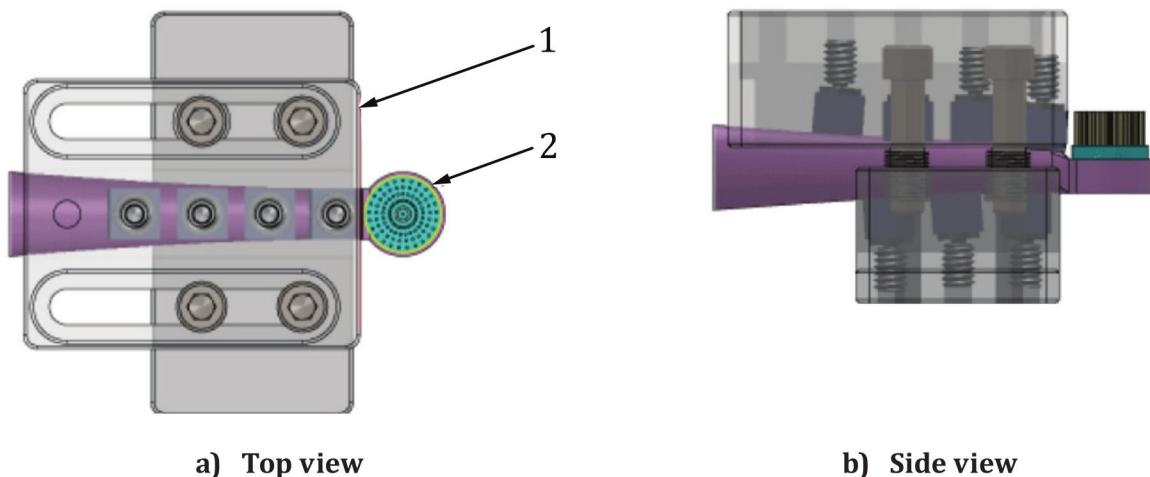
Figure B.3 — U-shaped fixture



Key

- | | | | |
|---|--------------|---|---------------|
| 1 | brush head | 4 | dental wax |
| 2 | pin | 5 | embedding rod |
| 3 | dental resin | | |

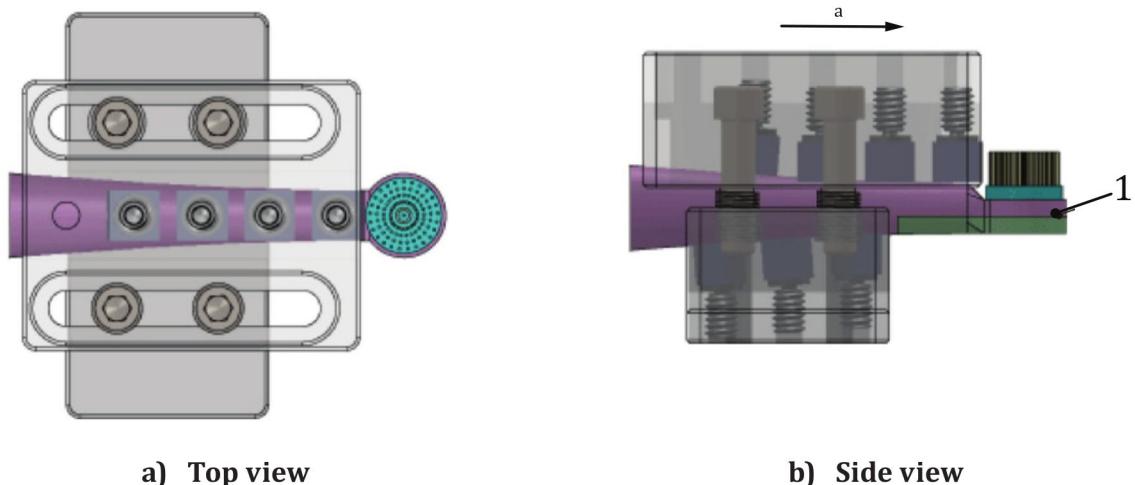
Figure B.4 — Embedding rod



Key

- 1 edge of brush head holder
- 2 tufted plate portion of brush head

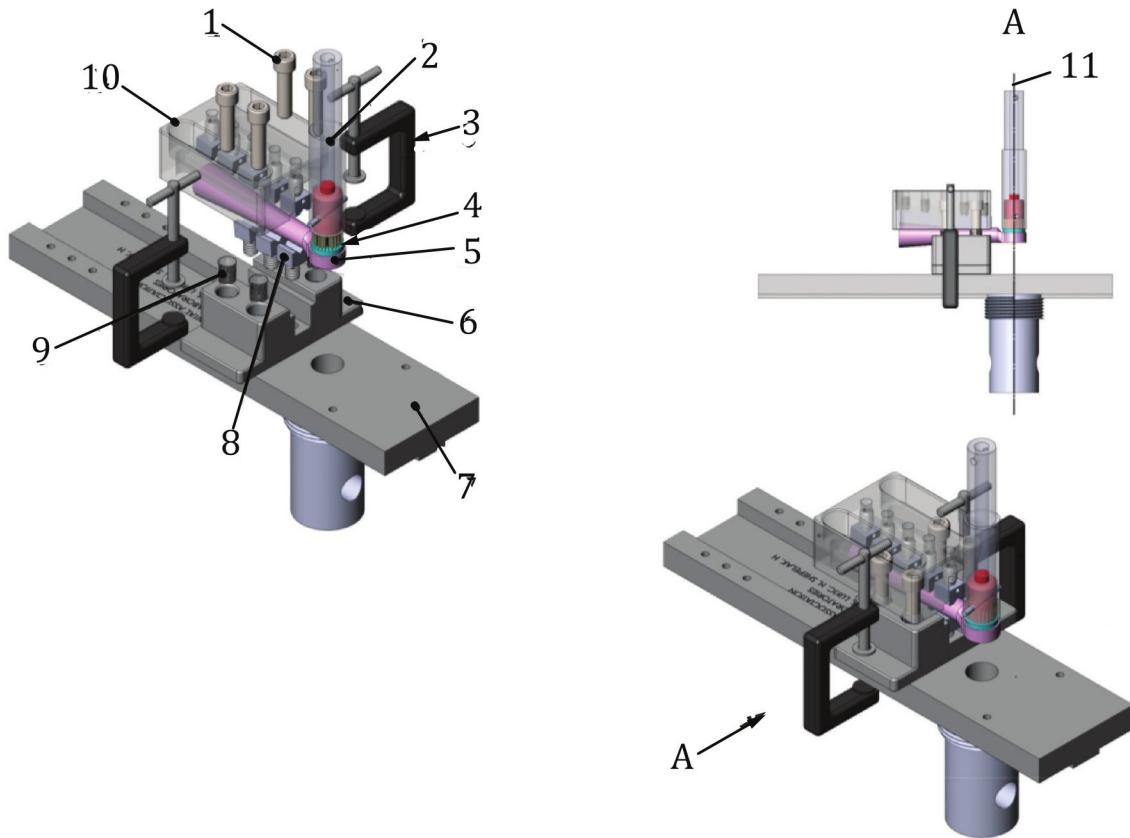
Figure B.5 — Toothbrush gripping



Key

- 1 split seam
- a Slide top vice of brush head holder.

Figure B.6 — Positioning of brush head holder



a) Exploded view

b) Assembled view

Key

1	socket head screws	7	mounting base
2	embedding rod	8	swivel head grips
3	table clamps	9	springs
4	tufted plate portion of brush head	10	top vice
5	brush head	11	pull axis
6	bottom vice	A	view A

NOTE This figure shows the test assembly using the embedding rod gripping unit. However, any other appropriate gripping unit can be used with this test assembly, such as the U-shaped gripping unit shown in [Figure B.3](#).

Figure B.7 — Setup for head plate retention force

B.4 Embedding rod mounting procedure

If an embedding rod ([Figure B.4](#)) is used as a gripping unit ([6.5.1.4](#)), the following instructions shall be used to load the head-retention force assembly in the mechanical test apparatus ([6.5.1.5](#)).

Attach the mounting base ([6.5.1.2](#)) to the base of the mechanical test apparatus ([6.5.1.5](#)).

Attach the embedding rod to the mechanical test apparatus ([6.5.1.5](#)) and calibrate the system. Then remove the embedding rod from the mechanical test apparatus ([6.5.1.5](#)).

NOTE 1 This step is for a mechanical test apparatus that has software with the ability to perform calibrations with test fixtures, such as the gripping unit, attached to it.

Seal the hole at the base of the cavity for the embedding rod with a piece of dental wax. Slide the pin through the pin hole on the cavity end. Mix the dental resin based on the manufacturer's instructions and fill the cavity of the embedding rod.

Centre the tuft plate over the cavity of the embedding rod and push the tufts into the dental resin such that the tuft plate is resting flat on the rim of the embedding rod. Hold the brush head firmly in place on the embedding rod until the dental resin sets.

NOTE 2 If the tuft plate of the brush head is smaller than the embedding rod cavity, a disposable Polytetrafluoroethylene (PTFE) washer can be used as an adapter to change the size of the cavity opening such that the tuft plate can rest on a flat surface over the rim (see [Figure B.8](#)).

Once the dental resin sets and the brush head is mounted in the embedding rod, adjust the socket head screws on the brush head holder ([6.5.1.1](#)) to open the jaws and slide the brush head in between the top and bottom vice. When positioning the brush head between the top and bottom vice, leave only enough space between the brush head holder and the tuft plate for clearance of the gripping unit ([6.5.1.4](#)) to be attached to the tuft plate (see [Figure B.5](#)).

With the brush holder ([6.5.1.1](#)) placed on the flat surface of a table, adjust the setscrews on the swivel head grips for both the top and bottom vice of the brush head holder ([6.5.1.1](#)) until the tuft plate of the brush head is perpendicular to the pull axis.

Attach the gripping unit ([6.5.1.4](#)) to the cross-head of the mechanical test apparatus ([6.5.1.5](#)) and lock it in place with a pin. Secure the brush head holder ([6.5.1.2](#)) with table clamps ([6.5.1.3](#)) on the mounting base ([6.5.1.2](#)). The load sensor should read close to 0 N. If not, move the cross-head of the mechanical test apparatus until the load cell reads approximately 0 N.

Run the mechanical test apparatus ([6.5.1.5](#)) at a pull speed of (50 ± 10) mm/min until the tuft plate dislodges from the brush head. Record the maximum force required to remove the tuft plate as the head-retention force.

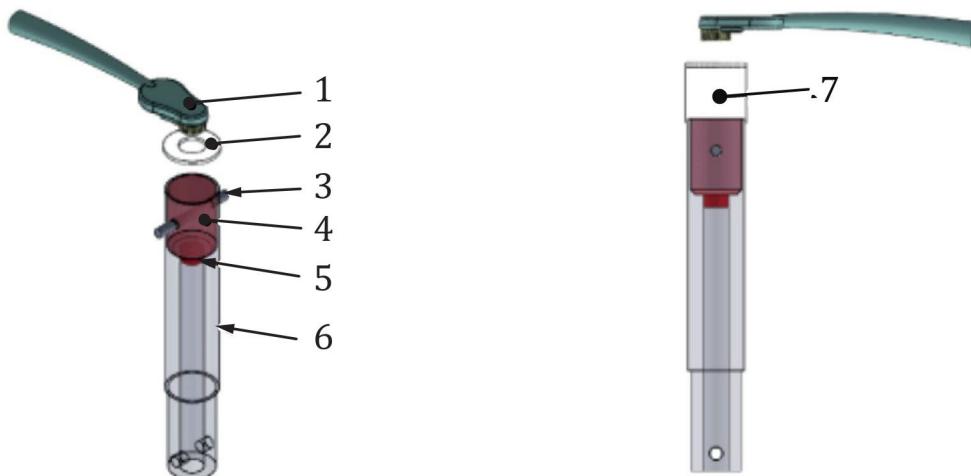
To remove the tuft plate from the embedding rod, slide the pin out of the pin hole on the cavity end. Use a rod or dowel to push the dental resin and tuft plate out of the embedding rod from the other end ([Figure B.9](#)).

B.5 Adaption of embedding rod to fit various sizes of brush heads

Use a flat custom machined washer to adapt the embedding rod to accommodate different sizes of the tuft plates on the brush head.

The washer shall be slightly larger than the embedding rod diameter.

The washer should have a large outer diameter to rest on top of the embedding rod opening (see [Figure B.8](#)).

**Key**

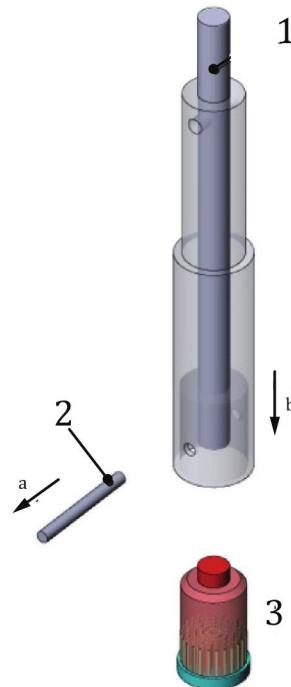
- | | | | |
|---|-----------------------|---|---|
| 1 | brush head | 5 | dental wax |
| 2 | washer, plastic, flat | 6 | embedding rod |
| 3 | pin | 7 | washer, slightly larger than embedding rod diameter |
| 4 | dental resin | | |

Figure B.8 — Example of adjusting the embedding rod cavity

B.6 Removal of the embedded tuft plate from the embedding rod gripping unit

The following steps shall be taken to remove the embedded tuft plate from the embedding rod gripping unit (see [Figure B.9](#)):

- remove pin;
- use a dowel/rod/screwdriver to push out the embedded tuft plate.



Key

- 1 rod
- 2 pin
- 3 embedded tuft plate
- a Direction of pin removal.
- b Direction of push out.

Figure B.9 — Removal of the embedded tuft plate

Bibliography

- [1] ISO 20126:2012, *Dentistry — Manual toothbrushes — General requirements and test methods*
- [2] ISO 22254:2005, *Dentistry — Manual toothbrushes — Resistance of tufted portion to deflection*

ICS 97.170

Price based on 17 pages