
Dentistry — Physical properties of powered toothbrushes

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

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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 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.

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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.

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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]

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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

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6.1 General test conditions

All tests shall be conducted using dry brushes at (23 ± 5) °C and relative humidity (50 ± 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	CAS number	Synonyms
	%	g		
Ethanol	96	100	64-17-5	Ethyl alcohol
<i>L</i> -carvone	98	1,5	6485-40-1	
<i>L</i> -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.