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Dentistry — Physical properties of powered toothbrushes

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

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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

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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).

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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 third edition cancels and replaces the second edition (ISO 20127:2020), which has been technically revised.

The main changes are as follows:

- requirements and procedure for determining bristle end-rounding were added.

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.

These types of electric toothbrushes are tested for safety in use by means of appropriate test procedures or clinical studies

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 can detach from the brush shaft. In addition, for the filaments end-rounding requirements, this document does not apply to filament types that are very thin (less than 0,1 mm outside diameter) or have no sharp edges (e.g. tapered, feathered, with split tips or spherical cap) or non-synthetic filaments, where applying the end-rounding process is inappropriate or impossible.

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 3696:1987, *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 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

brush head

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

[SOURCE: ISO 22254:2005, 3.2, modified — Term "a toothbrush" changed 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]

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3.6

tuft removal force

force required to remove one tuft from the brush head

[SOURCE: ISO 20126:2022, 3.5]

3.7

end-rounding

procedure of manufacturing toothbrushes to eliminate the sharp edge of the free end of filaments

[SOURCE: ISO 20126:2022, 3.11]

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 meet 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 meet 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 meet the requirements of the spring-operated impact test described in IEC 60335-1 and IEC 60068-2-75. The brush head shall be operational and free of sharp or rough surfaces when examined.

4.6 Filament end-rounding

The percentage of filaments without sharp geometries at the tips shall be at least 50 % to provide a level of safety in-use for the oral soft tissues when tested according to [6.7](#).

This requirement does not apply to filament types that are very thin (less than 0,1 mm outside diameter) or have no sharp edges (e.g. tapered, feathered, with split tips or spherical cap) or to non-synthetic filaments, where applying an end-rounding process is inappropriate or impossible. These types of powered toothbrushes should be evaluated for safety in-use appropriately.

5 Sampling and pass-fail criteria

5.1 Sampling except for filament end-rounding

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 except for filament end-rounding

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.

5.3 Sampling and pass-fail criteria for filament end-rounding

All filaments from three tufts from three randomly selected toothbrushes shall be used for this test. If the brush head contains two or more types of filaments, test all the filaments from three tufts of each type. If none of the three toothbrushes fail, the sample set passes. If one sample does not meet the minimum requirement, test another three toothbrushes. If no more samples fail, the toothbrush passes. If two or more samples out of the six fail, the 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, which has a structure such that compressive force is not induced on the brush head (see [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 [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. 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 that have different materials, lengths 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 head grips, 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](#)).