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Dentistry — Manual toothbrushes — General requirements and test methods

Médecine bucco-dentaire — Brosses à dents manuelles — Exigences générales et méthodes d'essai

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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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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 third edition cancels and replaces the second edition (ISO 20126:2012), which has been technically revised. It also incorporates the Amendment ISO 20126:2012/Amd.1:2018.

The main changes compared to the previous edition are as follows:

— a requirement (4.7) and a test method (5.8) for filament end-rounding have been added;

— the scope has been contracted to exclude specific types of manual toothbrushes from the application of this document.

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.

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Introduction

This document is intended to determine the physical properties of manual toothbrushes which are used for the removal of dental plaque and oral debris in order to facilitate oral hygiene.

Specific qualitative and quantitative requirements for freedom from biological hazards are not included in this document. It is recommended that, in assessing possible biological hazards, reference be made to ISO 7405 and ISO 10993-1.

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Dentistry — Manual toothbrushes — General requirements and test methods

1 Scope

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

This document does not specify any requirements and test methods for the physical properties of toothbrushes for which all the cleaning elements in the head are elastomer.

This document does not apply to manual single tuft toothbrushes, single use, interdental and powered oral hygiene devices. These types of oral hygiene products are evaluated for their safety in-use by appropriate test methods or clinical trials.

In addition, for the filaments end-rounding requirements, this document does not apply to particular filament types which 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 end-rounding process is inappropriate or impossible. These types of manual toothbrushes are evaluated for their safety in-use by appropriate test methods or clinical trials appropriately.

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*

ISO 22254, *Dentistry — Manual toothbrushes — Resistance of tufted portion to deflection*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 and ISO 22254 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
manual toothbrush
hand-powered device, the working end of which carries *filaments* (3.3) primarily for cleaning surfaces within the oral cavity

3.2
brush head
working end of a *manual toothbrush* (3.1) to which the *filaments* (3.3) are attached

[SOURCE: ISO 22254:2005, 3.2, modified — the word "manual" has been added.]

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3.3
filament
single strand within the *brush head* (3.2)

[SOURCE: ISO 22254:2005, 3.3]

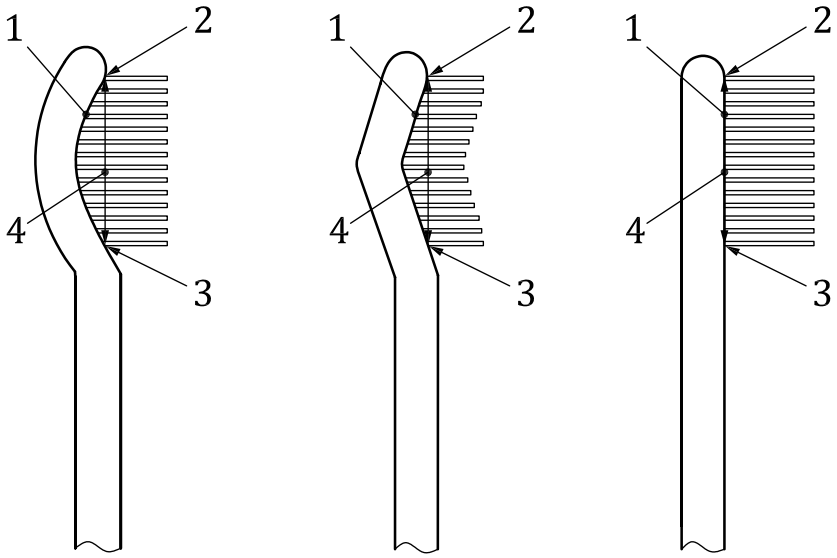
3.4
tuft
group of *filaments* (3.3) gathered together and attached to the *brush head* (3.2)

[SOURCE: ISO 22254:2005, 3.4]

3.5
tuft removal force
force required to remove one *tuft* (3.4) from the *brush head* (3.2)

3.6
tuft hole plane
plane between the base of the *tufts* (3.4) at the top of the *brush head* (3.2) and the base of the tufts at the bottom of the brush head (where they meet the tufted hole surface)

Note 1 to entry: See Figure 1.



Key
1 tuft hole surface
2 top of brush head
3 bottom of brush head
4 tuft hole plane

Figure 1 — Tuft hole plane

3.7
T_p
period of oscillation of the pendulum
period, expressed in seconds, s, of a single complete oscillation of the pendulum, oscillating at angles of oscillation of less than 5°, on average, to each side of the vertical

[SOURCE: ISO 13802:2015, 3.3]

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3.8
centre of percussion
point on a pendulum at which a perpendicular impact in the plane of swing does not cause reaction forces at the axis of rotation of the pendulum

[SOURCE: ISO 13802:2015, 3.4]

3.9
pendulum length
L_p
distance between the axis of rotation of the pendulum and the *centre of percussion* (3.8), equal to an equivalent theoretical pendulum mass concentrated at the point which gives the same period of oscillation, T_p (3.7), as the actual pendulum

Note 1 to entry: The pendulum length is expressed in metres.

3.10
impact length
distance between the axis of rotation of the pendulum and the pendulum striking edge

3.11
end-rounding
procedure of manufacturing toothbrushes to eliminate the sharp edge of the free end of *filaments* (3.3)

4 Requirements

4.1 Pass-fail criteria

4.1.1 Pass-fail criteria except for filament end-rounding

Eight manual toothbrushes shall be tested. If none of the eight manual toothbrushes fail, the sample set passes. If one sample does not meet the minimum requirement, test another eight manual toothbrushes. If no more samples fail, the toothbrush passes. If two or more samples out of the 16 fail, the toothbrush fails.

4.1.2 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.

4.2 Physical inspection

The toothbrush shall be intact and free of visible contamination and sharp or rough surfaces when examined according to 5.3.

4.3 Tuft retention

The tuft removal force shall be not less than 15 N when tested according to 5.4.

4.4 Handle impact strength

When tested in accordance with 5.5, the handle should not fracture. If the handle does fracture, however, the minimum absorbed energy at fracture shall be 0,8 J.

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