

DRAFT INTERNATIONAL STANDARD

ISO/DIS 20126

ISO/TC 106/SC 7

Secretariat: JISC

Voting begins on:
2021-03-08

Voting terminates on:
2021-05-31

Dentistry — Manual toothbrushes — General requirements and test methods

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

ICS: 97.170

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Reference number
ISO/DIS 20126:2021(E)

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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

Published in Switzerland

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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 <http://www.iso.org/directives>).

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

For an explanation on 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 WTO principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

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

ISO/DIS 20126

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;
- To exclude specific types of manual toothbrushes from the application of this document, the scope has been contracted.

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

Manual toothbrushes are used for the removal of dental plaque and oral debris in order to facilitate oral hygiene. This document is intended to determine the physical properties of manual toothbrushes. This document does not specify the physical properties of toothbrushes with injection moulded filaments. It will be developed as another part of this document after a methodology can be evaluated by the working group.

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, powered oral hygiene devices, and non-flat trim profile tufts (e.g. dual textured, bi-level, multi-level, rippled, or angled in opposing directions). These types of oral hygiene products should be evaluated for their safety in-use by appropriate test methods or clinical trials.

In addition, this document does not apply to particular designs of filament ends (e.g. tapered, feathered, with split tips, or spherical cap) or filament types (e.g. non-synthetic filaments, very thin, spiral or twisted) for the filaments end-rounding requirements. These types of manual toothbrushes should be evaluated for their safety in-use by appropriate test methods or clinical trials appropriately.

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2 Normative references (standards.iteh.ai)

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 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

manual toothbrush

hand-powered device, the working end of which carries filaments primarily for cleaning surfaces within the oral cavity

Note 1 to entry: Adapted from ISO 22254.

3.2

brush head

working end of a manual toothbrush to which the filaments are attached

Note 1 to entry: Adapted from ISO 22254.

3.3

filament

single strand within the brush head

[SOURCE: ISO 22254:2005, definition 3,3]

3.4

tuft

group of filaments gathered together and attached to the brush head

[SOURCE: ISO 22254:2005, definition 3.4]

3.5

tuft removal force

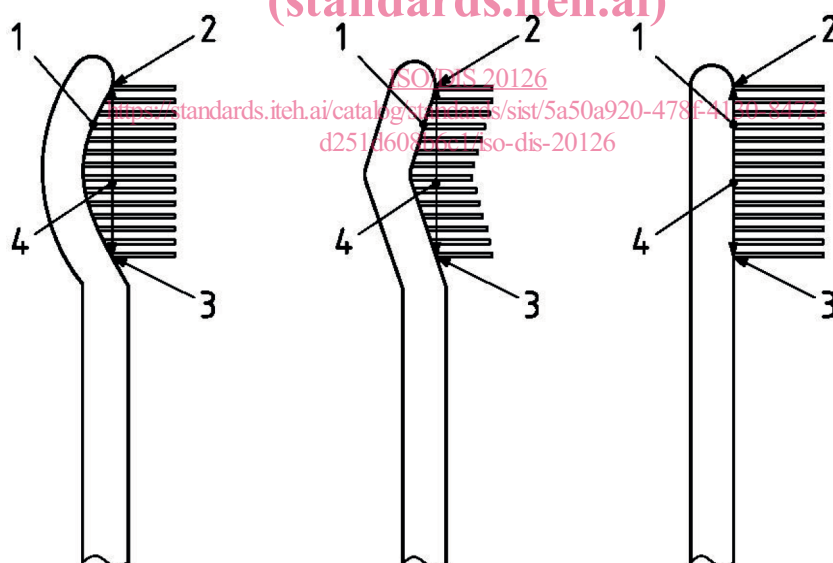
force required to remove one tuft from the brush head

3.6

tuft hole plane

plane between the bases of the tufts (where they meet the tufted hole surface) at the top of the brush head and the base of the tufts at the bottom of the brush head. See [Figure 1](#)

Note 1 to entry: Adapted from ISO 22254.



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**period of oscillation of the pendulum** **T_p**

period, expressed in seconds, of a single complete oscillation (to and from) of the pendulum, oscillating at angles of oscillation of less than 5 ° to each side of the vertical

[SOURCE: ISO 13802:1999, definition 3.3]

3.8**centre of percussion**

point on 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 13802:1999, definition 3.4]

3.9**pendulum length** **L_p**

distance, expressed in metres, 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: Adapted from ISO 13802:1999, definition 3.5.

3.10**impact length**

distance between the axis of rotation of the pendulum and the pendulum striking edge

Note 1 to entry: Adapted from ISO 13802:1999, definition 3.8.

3.11**end-rounding**

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

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.