
**Dentistry — Manual toothbrushes —
General requirements and test methods**

*Médecine bucco-dentaire — Broses 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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 20126 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 7, *Oral care products*.

This second edition cancels and replaces the first edition (ISO 20126:2005), which has been technically revised.

The significant difference between this second edition and the first edition is:

- a requirement (4.6) and a test (5.7) for handle impact resistance have been added.

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Introduction

Manual toothbrushes are used for the removal of dental plaque and oral debris in order to facilitate oral hygiene. This International Standard is intended to determine the physical properties of manual toothbrushes, including impact resistance.

Specific qualitative and quantitative requirements for freedom from biological hazards are not included in this International Standard. 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 International Standard 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 International Standard does not apply to manual interdental brushes and powered oral hygiene devices, as these instruments are covered by separate International Standards.

2 Normative references

The following referenced documents are indispensable for the application 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*

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.

3.1

manual toothbrush

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

NOTE Adapted from ISO 22254:2005, definition 3.1.

3.2

brush head

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

NOTE Adapted from ISO 22254:2005, definition 3.2.

3.3

filament

single strand within the brush head

[ISO 22254:2005, definition 3.3]

3.4

tuft

group of filaments gathered together and attached to the brush head

[ISO 22254:2005, definition 3.4]

3.5

tuft-removal force

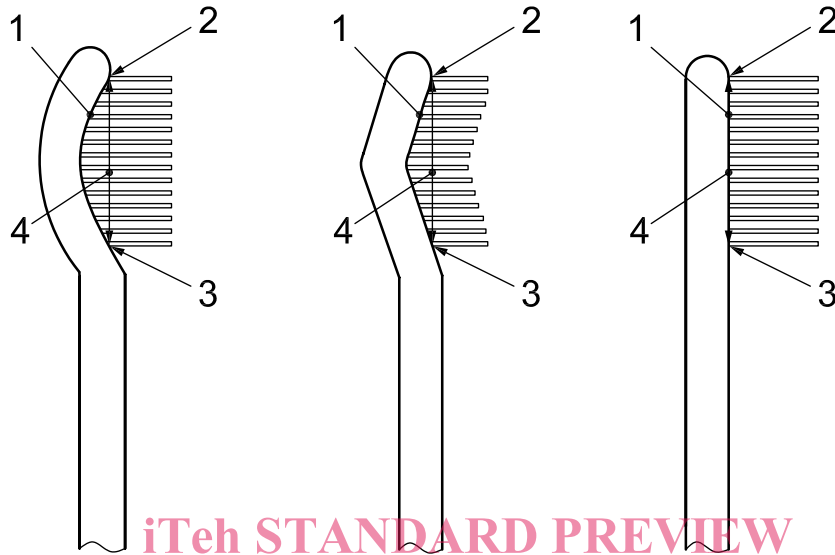
force required to remove one tuft from the brush head

3.6
tuft-hole plane

plane between the bases of the tufts (where they meet the tuft-hole surface) at the top of the brush head and at the base of the tufts at the bottom of the brush head

See Figure 1.

NOTE Adapted from ISO 22254:2005, definition 3.6.



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Key

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

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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 fro) of the pendulum, oscillating at angles of oscillation of less than 5° to each side of the vertical

[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

[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 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 Adapted from ISO 13802:1999, definition 3.8.

4 Requirements**4.1 Pass-fail criteria**

Test eight samples of each type. If none of the eight samples of each type fail, the sample set passes. If one sample does not meet the minimum requirement, test another eight samples. If no more samples fail, the toothbrush passes. If two or more samples out of the sixteen 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 Fatigue resistance

The toothbrush shall compete 75 000 cycles without breaking when tested according to 5.5.

NOTE A cycle is one application of force followed by removal of the force.

4.5 Chemical challenge

The toothbrush shall comply with 4.4 after being subjected to a chemical challenge according to 5.6.

4.6 Handle impact strength

When tested in accordance with 5.7, the handle should not fracture. If the handle does fracture, however, the minimum absorbed energy at fracture shall be 0,8 J.

5 Test method**5.1 Sampling**

Obtain the toothbrushes for testing as manufactured and not modified in any way, except as specified in this International Standard.

5.2 General test conditions

Conduct the tests using dry toothbrushes at a temperature of (23 ± 5) °C and a relative humidity of (50 ± 10) %.

5.3 Physical inspection

Inspect the toothbrush and related accessories using normal acuity without magnification. Use tactile inspection to detect sharp or rough surfaces.