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Dentistry — Manual toothbrushes — General requirements and test methods

*Art dentaire — Broses à dents manuelles — Exigences générales et
méthodes d'essai*

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Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
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Foreword

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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 first edition of ISO 20126, together with ISO 22254, cancels and replaces ISO 8627:1987.

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 for the physical properties of manual toothbrushes, but the impact resistance is not included until such time that the test can be evaluated by the working group.

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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.

Specifically excluded are 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 3696:1987, *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.

3.1

manual toothbrush

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

3.2

brush head

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

3.3

filament

single strand within the brush head

3.4

tuft

group of filaments gathered together and attached to the brush head

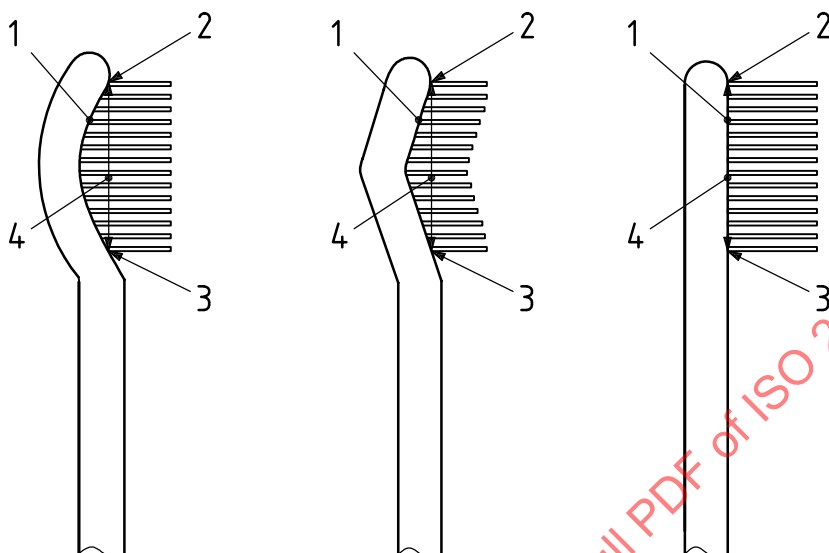
3.5

tuft removal force

force required to remove one tuft from the brush head

3.6 tuft hole plane
plane between the base 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.



Key

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

Figure 1 — Tuft hole plane

4 Requirements

4.1 Pass-fail criteria

A minimum of eight samples of each type shall be tested. If none fails, the sample set passes. If one sample does not meet the minimum requirement, another eight samples shall be tested. If no more samples fail, the toothbrush passes. If a total of two or more samples 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 complete 75 000 cycles without breaking when tested according to 5.5. 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.

5 Test methods

5.1 Sampling

The toothbrushes obtained for testing shall be as manufactured and not modified in any way except as specified in this International Standard. Eight toothbrushes shall be tested.

5.2 General test conditions

The tests shall be conducted using dry toothbrushes at $(23 \pm 5) ^\circ\text{C}$ and relative humidity $(50 \pm 10) \%$ unless otherwise noted.

5.3 Physical inspection

Visual inspection of the toothbrush and related accessories shall be performed using normal acuity without magnification. Tactile inspection shall also be performed to detect sharp or rough surfaces.

5.4 Tuft retention test

5.4.1 Apparatus

5.4.1.1 Gripping unit to secure the brush head, having a structure such that compressive force is not induced on the tufts. See Figure 2.

5.4.1.2 Clamp, for securely holding all of the filaments in one tuft; e.g. a tuft gripping clamp or a Collet chuck used to grip a tuft, and consisting of an outer shell that slips over the filaments and a probe which screws into the shell, pinching the filaments between itself and the shell.

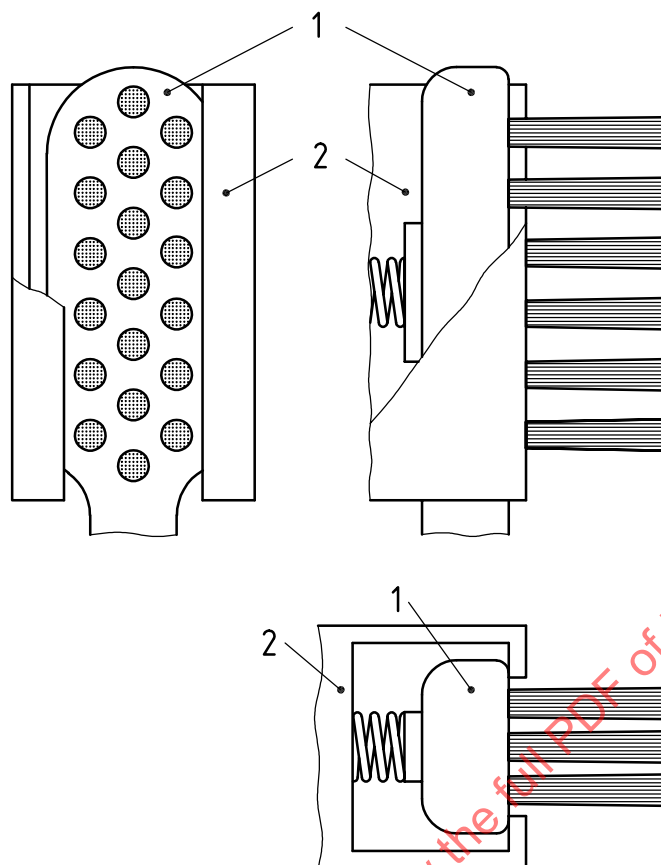
5.4.1.3 Apparatus for applying, measuring and indicating the removal force, e.g. digital force gauge or a universal testing machine (force range: 5 N to 50 N, accuracy: 0,1 N, range of pulling speed: 20 mm/min to 100 mm/min).

5.4.2 Procedure

Place the toothbrush in the gripping unit (5.4.1.1) and lock it into place so that the clamp (5.4.1.2) will pull the tuft along the long axis of the tuft without any twisting. The tufts shall not be compressed during and after being placed.

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 (5.4.1.3).

Test two tufts of each tuft type (if available). The tufts should be non-adjacent.



Key

- 1 brush head
- 2 brush-head gripping device

Figure 2 — Example of gripping unit for tuft retention test

5.5 Fatigue resistance test

5.5.1 Apparatus

5.5.1.1 Block for holding toothbrush body stationary, having a ridge for supporting the toothbrush at (55 ± 1) mm from the centre of the brush head and a gripping unit for locking the handle of the toothbrush in place.

5.5.1.2 Apparatus for applying a $(4,0 \pm 0,1)$ N force to the brush head and then fully relieving the force.

5.5.1.3 Apparatus for counting the number of cycles completed.

5.5.1.4 Apparatus for stopping the application of force when either of the following conditions have occurred:

- a) completion of the required number of cycles;
- b) handle breakage.

5.5.2 Procedure

Cut the filaments and any other attachments, flush to the brush head. Protect the brush head by covering the head with adhesive tape (thickness: less than 0,2 mm). Place the toothbrush against the block with the tuft hole plane perpendicularly facing the applied force. Lock the toothbrush in place ensuring that the ridge is at (55 ± 1) mm from the centre of the brush head.

NOTE If the test specimen cannot be locked in place due to its configuration, embed the specimen in epoxy resin or dental stone ensuring the surface level of epoxy resin or dental stone is at (55 ± 1) mm from the centre of the brush head.

Apply a $(4,0 \pm 0,1)$ N force to the centre of the brush head perpendicularly to the tuft hole plane with minimal impact and then fully relieve the force. Repeat a maximum of 75 000 cycles at (50 ± 10) cycles/min or until the handle breaks. Record the breakage if it is induced at less than 75 000 cycles.

5.6 Resistance to chemical challenge

5.6.1 Apparatus and chemicals

5.6.1.1 Apparatus for mixing the chemical-challenge solution, e.g. stirring bar or mixer.

5.6.1.2 Container, that can be sealed and is chemically inert, e.g. a glass bottle.

5.6.1.3 Chemicals, as listed in Table 1.

Table 1 — Components of chemical challenge solution

Chemical	Minimum purity
Ethanol	98,5 %
L-carvone	98,0 %
L-menthol	98,0 %
Sodium lauryl sulfate	95,0 %
Glycerine	98,0 %
Water	ISO 3696:1987, Grade 3

5.6.2 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 (5.6.1.2) and stir well using the mixing apparatus (5.6.1.1). Add 250 g water in accordance with ISO 3696:1987, Grade 3 and stir well to obtain a clear solution. Add 200 g glycerine and 432 g water in accordance with ISO 3696:1987, Grade 3 and stir to obtain clear solution.

Place the brush head and at least 80 % of a total length of the toothbrush in the chemical challenge solution. After 24 h without agitation remove the toothbrush, rinse with water in accordance with ISO 3696:1987, Grade 3 and shake off excess water. Perform the test as required in 5.5 (fatigue resistance test).

6 Test report

The test report shall contain the following information:

- the number of this International Standard, i.e. ISO 20126:2005;
- identification of the toothbrush;