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

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

STANDARDSISO.COM : Click to view the full PDF of ISO 20126:2012



STANDARDSISO.COM : Click to view the full PDF of ISO 20126:2012



COPYRIGHT PROTECTED DOCUMENT

© ISO 2012

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Requirements	3
4.1 Pass-fail criteria	3
4.2 Physical inspection	3
4.3 Tuft retention	3
4.4 Fatigue resistance	3
4.5 Chemical challenge	3
4.6 Handle impact strength	3
5 Test method	3
5.1 Sampling	3
5.2 General test conditions	3
5.3 Physical inspection	3
5.4 Tuft-retention test	4
5.5 Fatigue resistance test	5
5.6 Resistance to chemical challenge	6
5.7 Handle impact test	6
6 Test report	9
7 Marking and labelling	10
8 Packaging	10
Bibliography	11

STANDARDSISO.COM : Click to view the full PDF of ISO 20126:2012

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.

STANDARDSISO.COM : Click to view the full PDF of ISO 20126:2012

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.

STANDARDSISO.COM : Click to view the full PDF of ISO 20126:2012

STANDARDSISO.COM : Click to view the full PDF of ISO 20126:2012

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

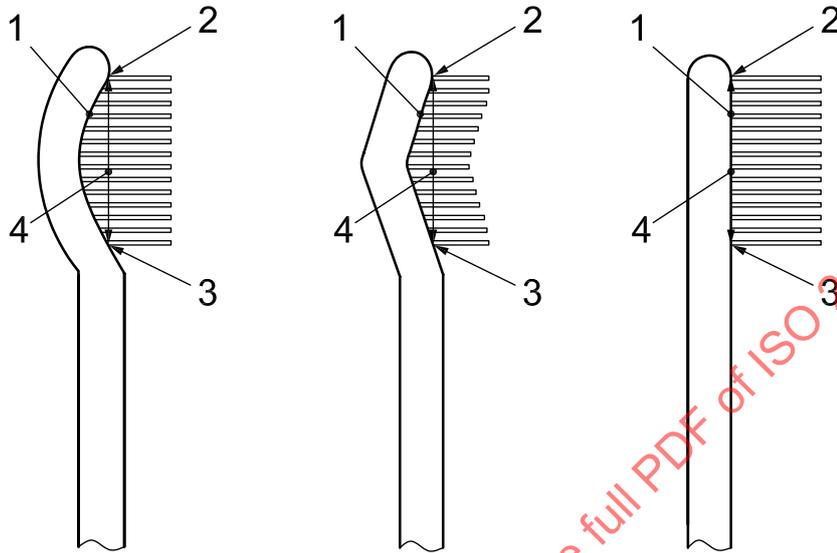
force required to remove one tuft from the brush head

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.



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 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 complete 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.

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 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 it and the shell.

5.4.1.3 Apparatus for applying, measuring and indicating the removal force, e.g. digital force gauge or 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).

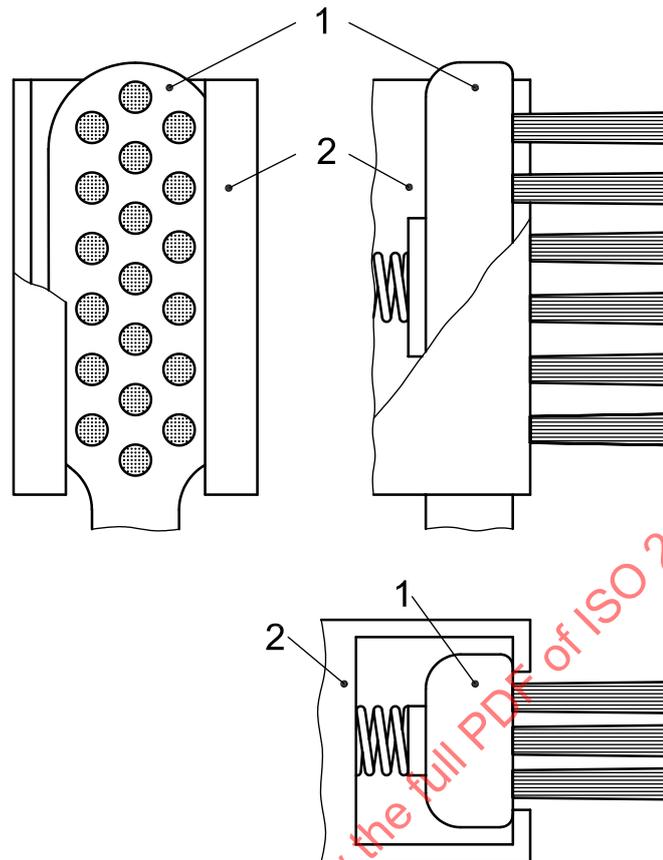
5.4.2 Procedure

Place the toothbrush in the gripping unit (5.4.1.1) and lock it into place so that the clamp (5.4.1.2) pulls the tuft along the long axis of the tuft, without any twisting. Do not compress the tufts during or after placement.

Place the clamp on the filament tuft, ensuring that all the filaments from one tuft only are clamped; do not include filaments from the surrounding tufts. Secure the filaments from the tuft at approximately the mid-point of the tuft length. Record the force required to pull out the tuft using the testing apparatus (5.4.1.3).

Test two non-adjacent tufts of each type (if available).

STANDARDSISO.COM : Click to view the full PDF of ISO 20126:2012

**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 the 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 has 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 that 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
<i>L</i> -carvone	98,0
<i>L</i> -menthol	98,0
Sodium lauryl sulfate	95,0
Glycerine	98,0
Water	ISO 3696, Grade 3

5.6.2 Procedure

Add 1,5 g of *L*-carvone, 1,5 g of *L*-menthol and 15 g of sodium lauryl sulfate to 100 g of ethanol in the container (5.6.1.2) and stir well using the mixing apparatus (5.6.1.1). Add 250 ml of Grade 3 water in accordance with ISO 3696 and stir well to obtain a clear solution. Add 200 g of glycerine and 432 ml of Grade 3 water in accordance with ISO 3696 and stir to obtain a 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 Grade 3 water in accordance ISO 3696 and shake off excess water. Perform the test as required in 5.5 (fatigue resistance test).

5.7 Handle impact test

5.7.1 Apparatus

5.7.1.1 Clamping unit, to hold the toothbrush handle (see Figure 3). The clamping unit consists of the main block (key item 4) and the holding blocks (key items 6 and 7) as shown in Figure 3. The holding blocks can be moved by screws. The radius of the internal edges of the main block and the holding blocks should be $(4,0 \pm 0,1)$ mm.

5.7.1.2 Impact tester, with the striker for the pendulum

5.7.1.3 Striker for pendulum, made of hardened steel, with a cylindrical surface having a radius of curvature of $(0,80 \pm 0,20)$ mm, with its axis horizontal and perpendicular to the plane of swing of the pendulum.

5.7.2 Procedure

Hold the toothbrush handle using the clamping unit (5.7.1.1) with a clamping torque of $(0,70 \pm 0,03)$ N·m. Ensure that the tuft-hole plane (key item 1) is perpendicular to the bottom plane of the clamping unit (key item 5). The metal plate(s) can be used as the spacer to adjust the angle. Set the clamping unit on the impact tester so that the striker edge can hit the toothbrush handle at the centre of the tuft-hole area (key item 8) from the opposite side of the tuft-hole surface (key item 2).

The length, L_1 , between the top plane of the clamping unit (key item 3) and the centre of the tuft-hole area (key item 8) is 55 mm. Any curvature of the corners of the clamping unit shall not be taken into account for L_1 .

NOTE 1 The impact velocity of the striker is dependent on the height of the striker at the beginning of the test, or the vertical distance of fall of the pendulum striking edge. This height is a function of the length of the pendulum arm and the angle of the arm at the beginning of the test. The velocity of the striker edge at impact can be calculated by the following equation:

$$V = (2gh)^{0,5}$$

where

V is the velocity of the striker at the moment of impact, in metres per second;

g is the local gravitational acceleration, in metres per second squared;

h is the vertical distance of fall of the pendulum striking edge, in metres.

NOTE 2 ASTM D256-06 sets the vertical distance of the pendulum striking edge to be $(610 \pm 2,0)$ mm, which will produce a velocity of the striking edge at the moment of impact of approximately 3,5 m/s.

Ensure that the distance between the line of contact of the pendulum striking edge and the centre of percussion of the pendulum is less than 2,54 mm

NOTE 3 ISO 13802 states that the impact length shall be within 1 % of the pendulum length. Since the pendulum length may vary with machines, the ASTM D256-06 value of $\pm 2,54$ mm was chosen to be consistent across laboratories instead of the 1 % value specified in ISO 13802.

Determine the pendulum length, L_p (3.9), in metres, from the period of the oscillation, T_p , in seconds, using the following equation:

$$L_p = (g/4\pi^2)T_p^2$$

where

g is the local gravitational acceleration, in metres per second squared;

$4\pi^2$ equals 39,48.

Apply an energy (initial potential energy) of $(2,75 \pm 0,10)$ J.

The test result is divided into fractured (F) or not fractured (NF). When the toothbrush is fractured, measure the angle of the pendulum and calculate the absorbed energy, E_a , from the following equation:

$$E_a = WR(\cos \beta - \cos \alpha)$$

where

W is the striker weight, in newtons;

R is the distance between the axis of rotation and the centre of gravity, in metres;

α is the angle at the test starting position, in degrees;

β is the angle after breakage of the specimen, in degrees.

STANDARDSISO.COM : Click to view the full PDF of ISO 20126:2012