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

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





COPYRIGHT PROTECTED DOCUMENT

© ISO 2022

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

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

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
4.1.1 Pass-fail criteria except for filament end-rounding.....	3
4.1.2 Pass-fail criteria for filament end-rounding.....	3
4.2 Physical inspection.....	3
4.3 Tuft retention.....	3
4.4 Handle impact strength.....	3
4.5 Fatigue resistance.....	4
4.6 Fatigue resistance after chemical challenge.....	4
4.7 Filament end-rounding.....	4
5 Test method	4
5.1 Sampling.....	4
5.2 General test conditions.....	4
5.3 Physical inspection.....	4
5.4 Tuft retention test.....	4
5.4.1 Apparatus.....	4
5.4.2 Procedure.....	4
5.5 Handle impact test.....	5
5.5.1 Apparatus.....	5
5.5.2 Procedure.....	6
5.6 Fatigue resistance test.....	7
5.6.1 Apparatus.....	7
5.6.2 Procedure.....	8
5.7 Fatigue resistance test after chemical challenge.....	8
5.7.1 Apparatus and chemicals.....	8
5.7.2 Procedure.....	8
5.8 Visual inspection for filament end-rounding.....	9
5.8.1 General.....	9
5.8.2 Apparatus.....	9
5.8.3 Procedure.....	9
6 Test report	10
7 Marking and labelling	10
8 Packaging	10
Bibliography	11

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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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

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.

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.

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.]

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.

4.5 Fatigue resistance

The toothbrush shall complete 75 000 cycles without breaking when tested according to [5.6](#).

4.6 Fatigue resistance after chemical challenge

The toothbrush shall comply with [4.5](#) after being subjected to a chemical challenge according to [5.7](#).

4.7 Filament end-rounding

The percentage of filaments without sharp geometries at the tips shall be at least 50 % to provide a level of safety in-use for the oral soft tissues when tested according to [5.8](#).

This requirement 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 to non-synthetic filaments, where applying an end-rounding process is inappropriate or impossible. These types of manual toothbrushes should be evaluated for safety in-use appropriately.

5 Test method

5.1 Sampling

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

5.2 General test conditions

Conduct the tests using dry toothbrushes at (23 ± 5) °C and 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 of the filaments in one tuft, for example, 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.

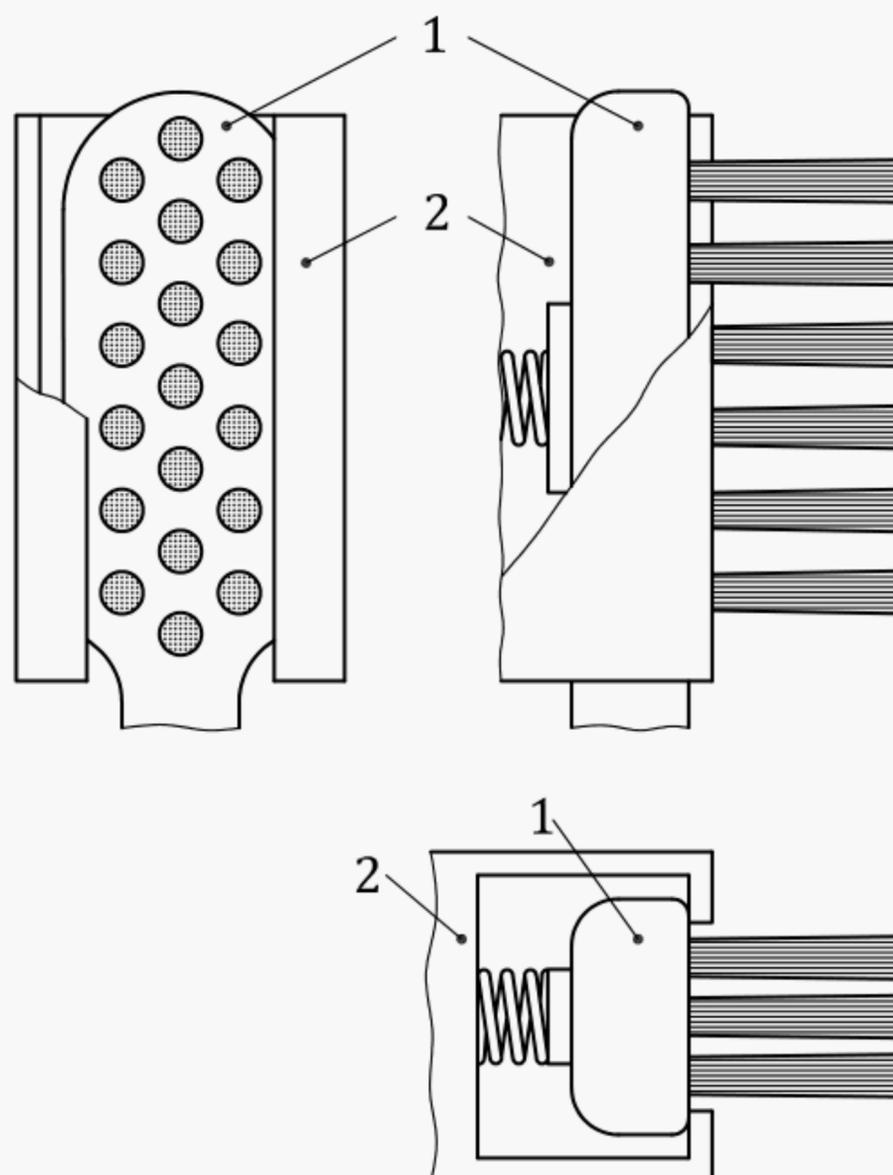
5.4.1.3 Apparatus for applying, measuring and indicating the removal force, for example, digital force gauge or universal testing machine (force range: 5 N to 50 N, accuracy: 0,1 N, range of pulling speed: 20 mm/min to 100 mm/min).

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).



Key

- 1 brush head
- 2 brush head gripping device

Figure 2 — Example of gripping unit for tuft retention test

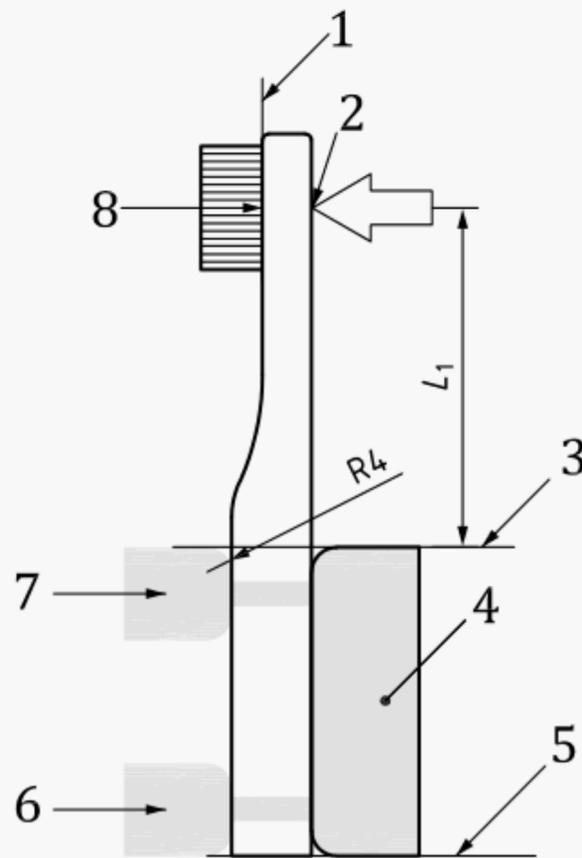
5.5 Handle impact test

5.5.1 Apparatus

5.5.1.1 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 shall be $(4,0 \pm 0,1)$ mm.

5.5.1.2 Impact tester, with the striker for pendulum.

5.5.1.3 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.



Key

- 1 tuft hole plane
- 2 hitting point for the striker edge
- 3 top plane of the clamping unit
- 4 main block
- 5 bottom plane of the clamping unit
- 6 lower holding block
- 7 upper holding block
- 8 centre of the tuft hole area
- L_1 length

NOTE The open arrow in the figure shows the striker direction.

Figure 3 — Clamping unit to hold toothbrush

5.5.2 Procedure

Hold the toothbrush handle using the clamping unit (5.5.1.1) with clamping torque $(0,70 \pm 0,03)$ N·m. Ensure that the tuft hole plane (see Figure 3, key item 1) is perpendicular to the bottom plane of the clamping unit (see Figure 3, 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 (see Figure 3, key item 8) from the opposite side of the tuft hole surface (see Figure 3, key item 2).

The length, L_1 , between the top plane of the clamping unit (see Figure 3, key item 3) and the centre of tuft hole area (see Figure 3, key item 8) is 55 mm. Any curvature of the corners (R4) 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 formula:

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

where

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

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

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

NOTE 2 ASTM D256-10 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.

ISO 13802 states that the impact length shall be within 1 % of the pendulum length. Since the pendulum length can vary with machines, the ASTM D256-10 tolerance 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 in metres, from the period of the oscillation, T_p , in seconds, using the following formula:

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

where $4\pi^2$ 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 formula:

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

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.

5.6 Fatigue resistance test

5.6.1 Apparatus

5.6.1.1 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.

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

5.6.1.3 Apparatus for counting the number of cycles completed.

5.6.1.4 Apparatus for stopping the application of force.

- a) Completion of the required number of cycles.
- b) Handle breakage.

5.6.2 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.

5.7 Fatigue resistance test after chemical challenge

5.7.1 Apparatus and chemicals

5.7.1.1 Apparatus for mixing the chemical challenge solution, for example, stirring bar or mixer.

5.7.1.2 Container, that can be sealed and is chemically inert, for example, a glass bottle.

5.7.1.3 Chemical components, of purity and of the amounts listed in [Table 1](#).

Table 1 — Quantity and purity of products used

Component	Purity %	Amount g	CAS number	Synonyms
Ethanol	96	100	64-17-5	Ethyl alcohol
<i>L</i> -carvone	98	1,5	6485-40-1	—
<i>L</i> -menthol	98	1,5	2216-51-5	—
Sodium lauryl sulfate	95	15,0	151-21-3	—
Glycerine	98	200	56-81-5	—
Water	ISO 3696:1987, Grade 3	682	7732-18-5	—

5.7.2 Procedure

Add 1,5 g of *L*-carvone, 1,5 g of *L*-menthol and 15,0 g of sodium lauryl sulfate to 100 g of ethanol in the container ([5.7.1.2](#)) and stir well using the mixing apparatus ([5.7.1.1](#)). Add 250 ml of Grade 3 water in accordance with ISO 3696:1987 and stir well to obtain a clear solution. Add 200 g of glycerine and 432 ml of Grade 3 water in accordance with ISO 3896:1987 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 Grade 3 water in accordance with ISO 3696:1987 and shake off excess water. Perform the test as required in [5.6](#) (fatigue resistance test).

5.8 Visual inspection for filament end-rounding

5.8.1 General

[Subclause 5.8](#) sets out the procedure for examining the free end of the filament of a toothbrush. The filament ends are evaluated by visual inspection under appropriate magnification.

5.8.2 Apparatus

Optical viewing system, capable of differentiating between acceptable and unacceptable shape of filament tips (e.g. 20× to 90× magnification).

5.8.3 Procedure

All the filaments of three tufts, with one tuft from each of the three areas of toe, centre and heel on the brush head shall be used for this test. Position a brush under the microscope to allow clear visualization of the filament end shapes, scoring the tuft for overall end-rounding. Score and record the proportion of filaments meeting the “Pass” criteria (see [Figure 4](#)) and not having a sharp edge considered to damage the soft tissue in 10 % increments (e.g. 70 %, 80 %). Note the scoring for the tuft as a “Pass” when the requirement of [4.7](#) is met. For reference, some examples of bristles that do not meet the “Pass” criteria are shown in [Figure 5](#).

Alternatively, entire tufts may be cut from the head to be examined separately with a judgement as to the proportion meeting the “Pass” criterion, or individual counting and recording of the number of filaments both examined and meeting the “Pass” criterion.

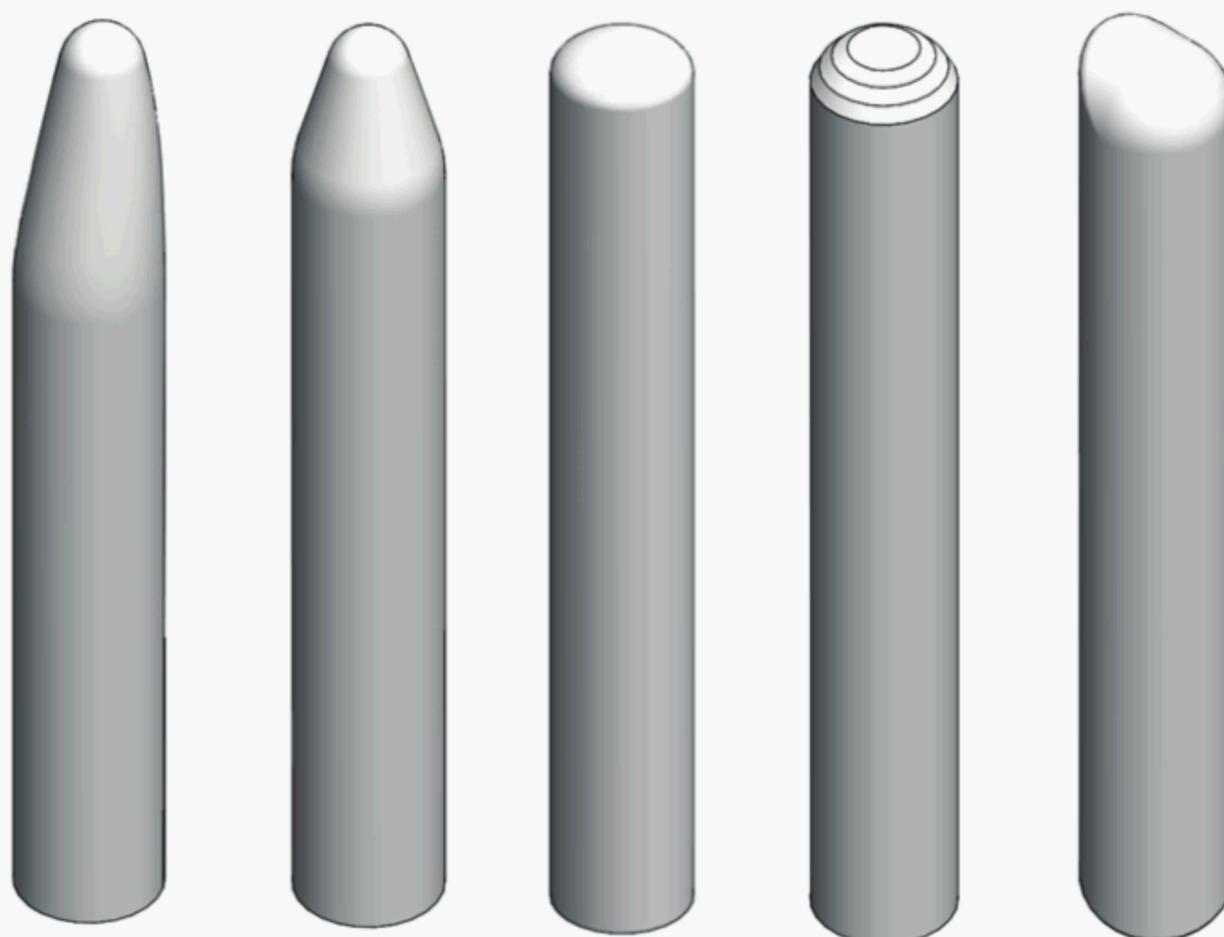


Figure 4 — Examples of acceptable (passing) filament end-rounding bristle shapes under magnification

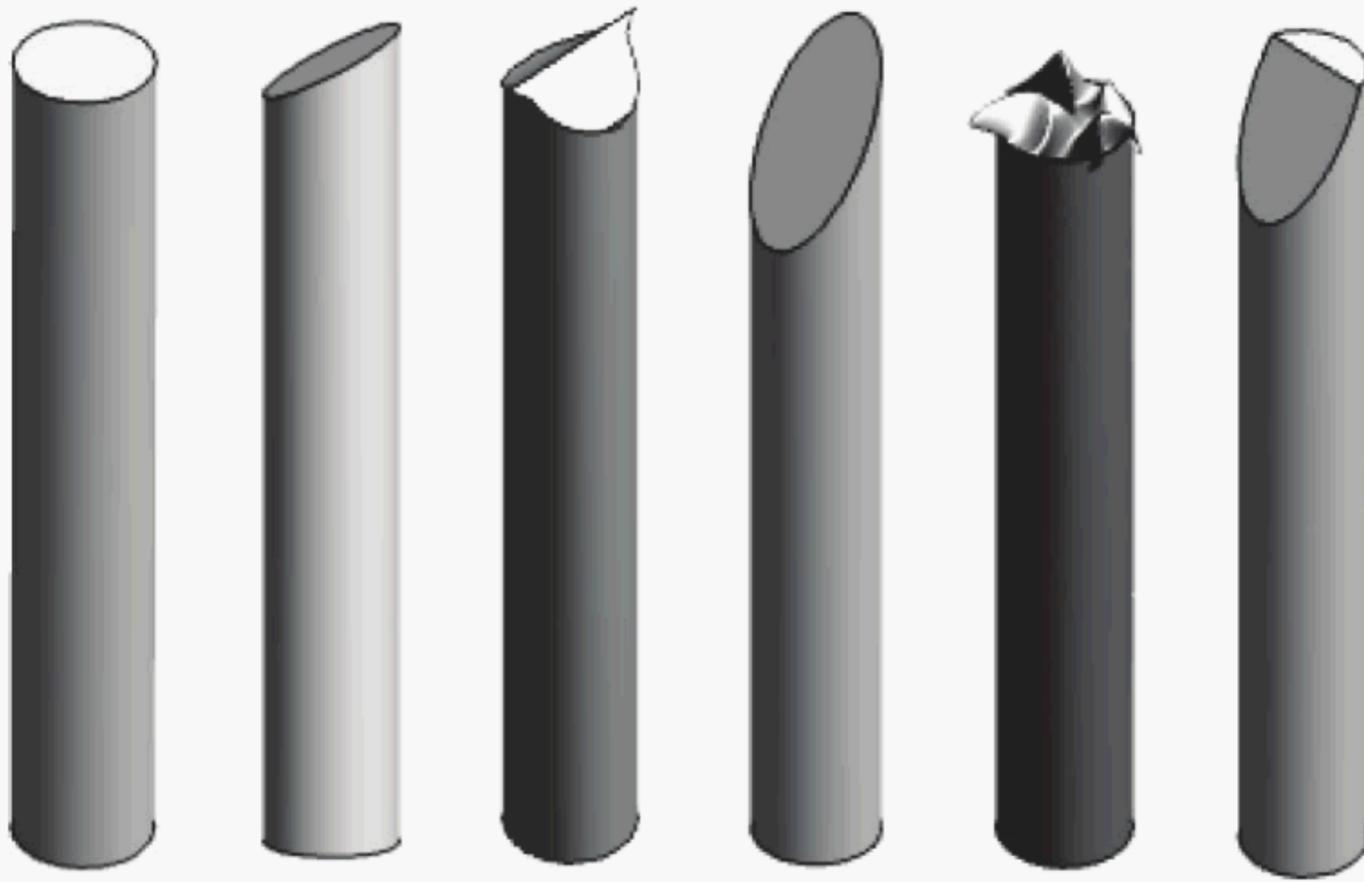


Figure 5 — Examples of unacceptable (failing) filament end-rounding bristle shapes under magnification

6 Test report

The test report shall include the following information:

- a) the number of this International Standard, i.e. ISO 20126:2022;
- b) an identification of the toothbrush e.g. photograph, manufacturer's model number;
- c) the test method used;
- d) the results;
- e) any deviations from the procedure;
- f) any unusual features noted during the test;
- g) the date of the test.

7 Marking and labelling

7.1 The toothbrush shall be marked with a manufacturer's tracking code.

7.2 The packaging shall be marked with the following information:

- a) name and, either the address of the manufacturer or the responsible distributor, or both;
- b) trade name.

8 Packaging

The packaging shall neither contaminate nor permit contamination of the toothbrush.

Bibliography

- [1] ISO 7405, *Dentistry — Evaluation of biocompatibility of medical devices used in dentistry*
- [2] ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*
- [3] ISO 13802:2015, *Plastics — Verification of pendulum impact-testing machines — Charpy, Izod and tensile impact-testing*
- [4] ASTM D256-10, *Standard test Methods for Determining the Izod Pendulum Impact Resistance of Plastics*

