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Dentistry — Oral hygiene products — Manual interdental brushes

Art dentaire — Produits d'hygiène bucco-dentaire — Brosses interdentaires manuelles

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Foreword

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ISO 16409 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 7, *Oral care products*.

Introduction

Manual interdental brushes are used for oral hygiene purposes intended to provide health benefits. Their main application purpose is mechanical plaque removal, primarily from the interdental region.

Dentistry — Oral hygiene products — Manual interdental brushes

1 Scope

This International Standard specifies requirements and test methods for performance criteria for manual interdental brushes with a round cross-section of the brush head.

It also specifies the accompanying information, such as the manufacturer's instructions for use and labelling of the packaging.

This International Standard is not applicable to powered interdental brushes, manual toothbrushes, dental floss, tapes, and strings, nor is it applicable to interdental cleaners that do not include filaments.

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*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 and the following apply.

3.1
manual interdental brush
hand-powered device composed of filaments emanating radially from a stem, intended for cleaning of interdental surfaces

3.2
interdental brush head
portion of manual interdental brush, which passes in and out of spaces between the teeth to clean the exposed surfaces

NOTE The brush head can be fixed or removable, but is fixed during use.

3.3
interdental brush handle
portion of manual interdental brush which holds the stem of the manual interdental brush

3.4
stem
central support structure of the manual interdental brush head, usually composed of twisted wire, which secures the filaments

NOTE The stem is secured in the handle or in a connector, or fulfils the function of a handle itself.

3.5
filament
single strand attached to the stem

3.6
stem retention force
force required to remove the stem from the interdental brush handle holding it

3.7
passage hole diameter
minimum diameter of a hole through which a manual interdental brush head can pass without stem deformation

3.8
brush size
index of brush sizes determined by the passage hole diameter

4 Classification

Manual interdental brushes shall be classified as follows:

— Type 1: replacement heads may be mounted into a handle;

— Type 2: the brush head is permanently affixed into the handle;

— Type 3: the stem fulfils the function of a handle.

5 Requirements

5.1 Defects or contamination

Manual interdental brushes, including all supplied parts, shall be free of apparent defects or contamination.

Testing shall be done in accordance with 7.3.

5.2 Brush size

The brush size of manual interdental brushes shall be in accordance with Table 1.

Table 1 — Brush size of interdental brushes

Dimensions in millimetres

Brush size	Passage hole diameter
1	⩽ 0,8
2	0,9 to 1,0
3	1,1 to 1,2
4	1,3 to 1,5
5	1,6 to 1,8
6	⩾ 1,9

Determine the brush size of a manual interdental brush by using the passage hole diameter in accordance with 7.4

5.3 Filament retention

The filaments of manual interdental brushes shall not be removed when tested in accordance with 7.5.

5.4 Stem retention

The stem of manual interdental brushes of Type 1 and Type 2 shall withstand a removal force not less than 15 N.

Testing shall be done in accordance with 7.6.

5.5 Stem durability

The stem of manual interdental brushes shall withstand repeated bending for 20 cycles.

Testing shall be done in accordance with 7.7.

6 Sampling

The manual interdental brushes used for testing shall be representative of manufactured manual interdental brushes, and shall not be altered or adjusted in any way, except as needed to perform the tests.

A minimum of eight manual interdental brushes of each type shall be tested.

7 Test methods

7.1 General

All tests shall be conducted using dry interdental brushes at a temperature of (23 ± 5) °C and (50 ± 10) % relative humidity.

7.2 Pass/fail criteria

For the filament retention, stem retention and stem durability tests, if no product fails, the product set passes. If one manual interdental brush does not meet the minimum requirement, test another eight interdental brushes. If no more manual interdental brushes fail, the product passes. If a total of two or more manual interdental brushes of the sixteen fail, the product fails.

For the determination of the passage hole diameter, see 7.4.

7.3 Visual inspection

Visual inspection shall be performed with normal visual acuity, without magnification.

7.4 Passage hole diameter

7.4.1 Apparatus

7.4.1.1 Measuring plate, made of stainless steel or hardened steel, with a thickness of (2,0 ± 0,1) mm. The measuring plate has a total of 30 holes without sharp edges, with diameters ranging from 0,6 mm up to 3,5 mm in 0,1 mm increments (see Figure 1). The tolerance of hole diameter shall be from −0,02 mm to +0,02 mm.

7.4.2 Procedure

7.4.2.1 Step 1

Select a hole on the measuring plate (7.4.1.1), such that the manual interdental brush head may pass unobstructed through the hole.

7.4.2.2 Step 2

Insert the manual interdental brush into the hole, by hand, until the entire manual interdental brush head passes through the hole, and then pull out the manual interdental brush head from the hole. Repeat with all eight brush samples.

7.4.2.3 Step 3

If all eight samples can be inserted and removed from the hole without stem deformation, the sample set is judged to have passed that hole. Otherwise, the sample set is judged not to have passed that hole.

7.4.2.4 Step 4

If the sample set is judged to have passed the hole in step 3, repeat step 2 using the hole smaller by one increment. If the sample set does not pass the hole in step 3, repeat step 2 using the hole larger by one increment.

7.4.2.5 Step 5

Stop the test when the smallest hole has been determined that allows passage without deformation of all samples in the set.

7.4.2.6 Step 6

Record the size of the smallest hole.

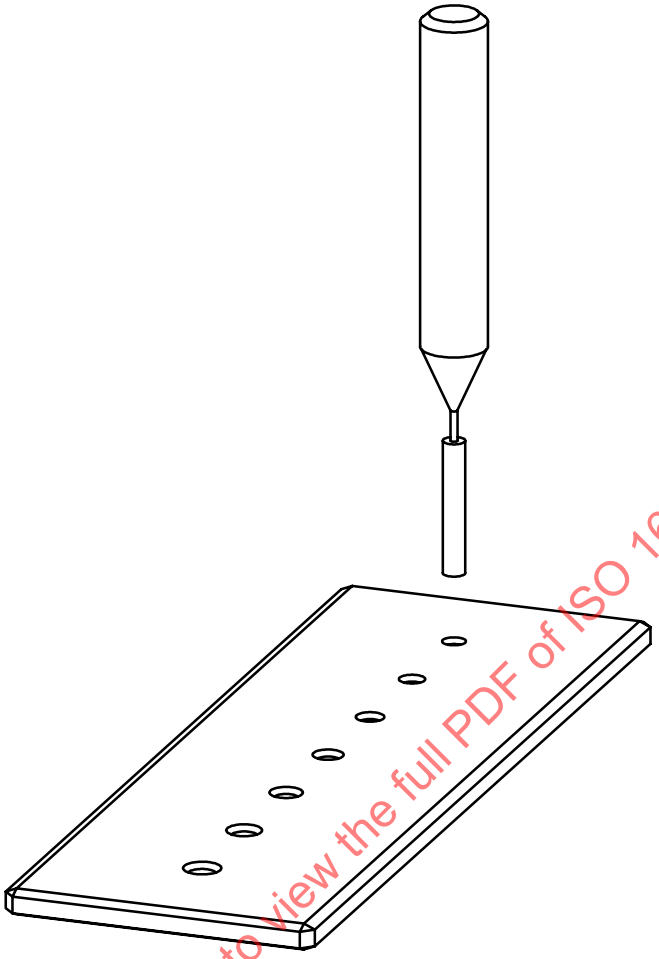
7.4.2.7 Step 7 (optional)

For non-cylindrical trims, i.e. those that are tapered, repeat from step 2 with the following modification to step 2.

Insert the manual interdental brush into the hole, by hand, until the manual interdental brush head passes the hole 3 mm further than the thickness of the plate, and then pull out the manual interdental brush head from the hole. Repeat with all eight brush samples.

7.4.3 Evaluation

The diameter of the smallest hole is the passage hole diameter. For non-cylindrical brushes, the brush size determined in accordance with 7.4.2.7 may additionally be identified.



NOTE The design of the manual interdental brush head is given as an example, but other designs are also used.

Figure 1 — Measuring plate for the determination of passage hole diameter showing seven holes of the indicated 30 holes

7.5 Filament retention

7.5.1 Apparatus

7.5.1.1 **Measuring plate**, as described in 7.4.1.1.

7.5.1.2 **Gripping unit**, for securely holding the measuring plate stationary during the procedure (see Figure 2).

7.5.2 Procedure

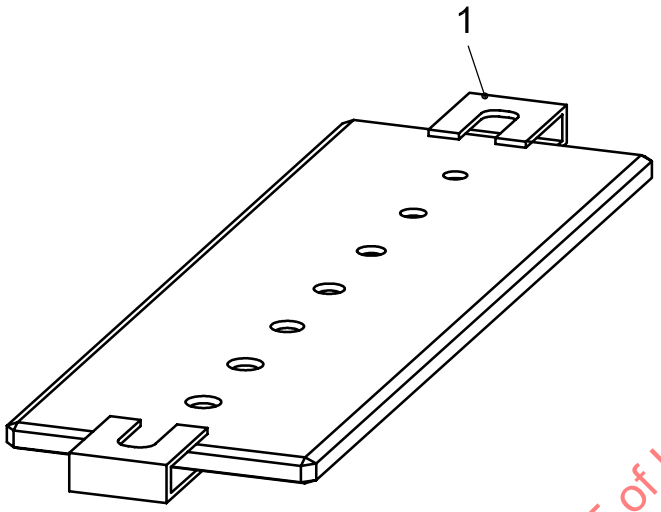
Place the measuring plate (7.5.1.1) in the gripping unit (7.5.1.2), such that its position remains fixed during the procedure.

Based on the results of 7.4, select the hole that is 0,2 mm larger than the determined passage hole diameter (e.g. when the passage hole diameter is 1,0 mm, the 1,2 mm hole is used).

Using the selected hole, repeatedly let the manual interdental brush head pass in and out of the hole in the measuring plate 80 times. If a filament falls out before the end of the 80 cycles, terminate the test.

7.5.3 Evaluation

Inspect the interdental brush head visually to evaluate the integrity of the filaments and the stem. If the result complies with requirement of 5.3, the manual interdental brush has passed the test.



Key

1 gripping unit

Figure 2 — Measuring plate with gripping unit

7.6 Stem retention

7.6.1 Apparatus

7.6.1.1 **Measuring plate**, as described in 7.4.1.1.

7.6.1.2 **Gripping unit**, for securely holding the measuring plate stationary during the procedure (see Figure 3).

7.6.1.3 **Clamp**, for securely holding the stem at the middle of the manual interdental brush head.

NOTE This can be, for example, a Collet Chuck used to grip the stem, consisting of an outer shell that slips over the stem and a probe that screws into the shell, pinching the stem between itself and the shell.

7.6.1.4 **Apparatus**, for applying, measuring and indicating the stem retention force.

NOTE This can be, for example, a digital force gauge or a universal force testing machine.

The assembly of the apparatus for the stem retention test is shown in Figure 3.

7.6.2 Procedure

Place the measuring plate (7.6.1.1) in the gripping unit (7.6.1.2) and lock into place, such that the clamp (7.6.1.3) can pull the stem along its longitudinal axis.

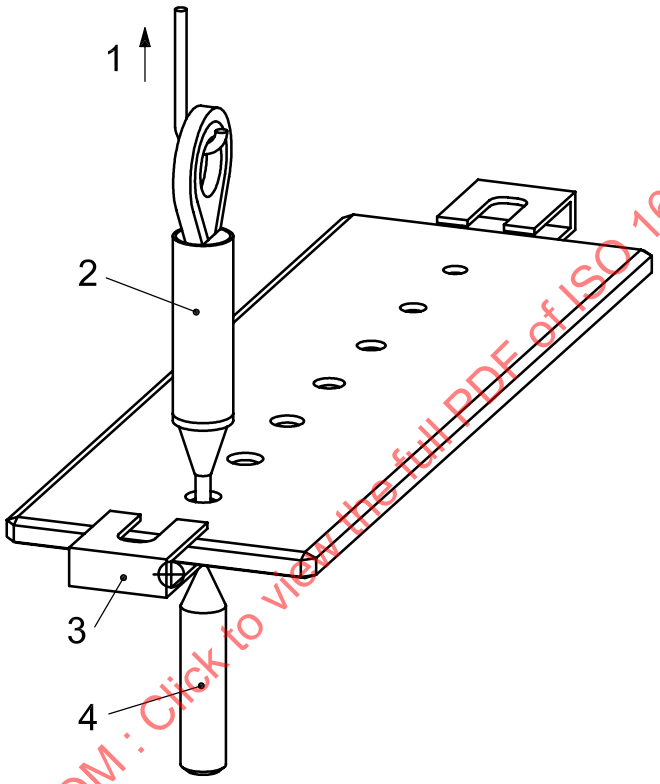
Based on the results of 7.4, select the hole that is 0,2 mm larger than the determined passage hole diameter (e.g. when the passage hole diameter is 1,0 mm, the 1,2 mm hole is used).

Insert the manual interdental brush head through the selected hole. Place the clamp on the stem. The stem should be secured at approximately the midpoint of the interdental brush head. Pull the clamp at a pulling speed of (20 ± 2) mm/min to remove the stem from the interdental brush handle.

Record the removal force.

7.6.3 Evaluation

If the removal force is higher than the value stated in 5.4, the manual interdental brush has passed the test.



Key

1 pull force
2 clamp
3 gripping unit
4 manual interdental brush handle

Figure 3 — Example of an assembled apparatus for stem retention test

7.7 Stem durability

7.7.1 Apparatus

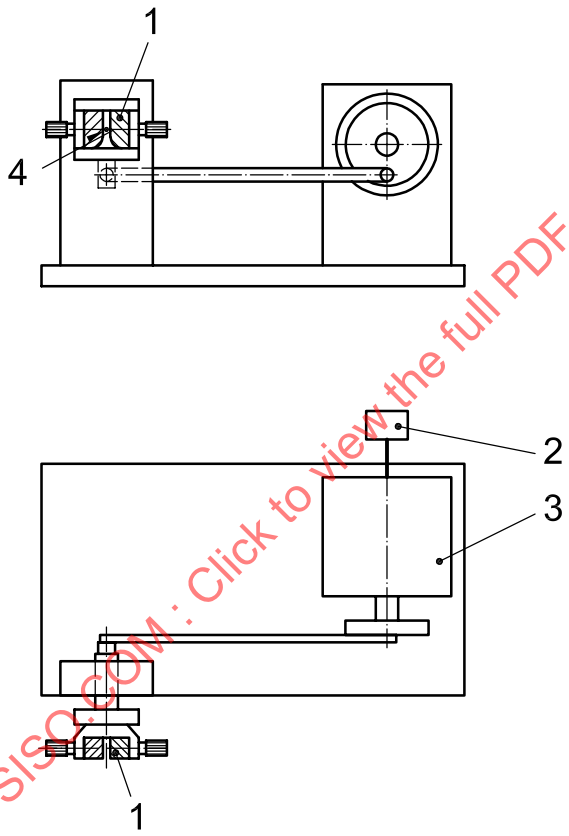
7.7.1.1 Equipment, to flex the stem of a manual interdental brush repeatedly at (30 ± 3) cycles/min (see Figures 4 to 8).

7.7.2 Procedure

Place the manual interdental brush in the gripping unit, such that the longitudinal axis of the stem is in the vertical position (0 degree) and the top of the interdental brush head points downwards. Close the gripping unit to fix the position of the interdental brush handle, as shown in Figures 7 and 8. Attach the (500 ± 5) g mass at the end of the interdental brush head, e.g. with a piece of string. Using the equipment, flex the manual interdental brush [(45 ± 3) degrees to left and (45 ± 3) degrees to right]. Repeat a maximum of 20 cycles at (30 ± 3) cycles per minute or until the stem breaks. Record the breakage if breakage occurs at less than 20 cycles.

7.7.3 Evaluation

If breakage occurs at less than 20 cycles, the manual interdental brush has failed the test.



Key

1 gripping unit
2 speed controller
3 motor
4 pivotal centre

Figure 4 — Structure of the equipment for stem durability test (front view and top view)