



Revised American National Standard/
American Dental Association
Standard No. 119

Manual Toothbrushes

Modified adoption of ISO 20126:2012, *Dentistry — Manual toothbrushes— General requirements and test methods*; and ISO 22254:2005, *Dentistry – Manual toothbrushes — Resistance of tufted portion to deflection*.

ADA American
Dental
Association®
Council on
Scientific Affairs

2015

These materials are subject to copyright claims of ISO and ADA. No part of this publication may be reproduced in any form, including electronic retrieval system, without the prior permission of ADA. All requests pertaining to ANSI/ADA Standard No. 119 should be submitted to ADA.

REVISED AMERICAN NATIONAL STANDARD/AMERICAN DENTAL STANDARD NO. 119 FOR MANUAL TOOTHBRUSHES

The Council on Scientific Affairs of the American Dental Association has approved revised American Dental Association Standard No. 119 for Manual Toothbrushes. This and other standards for dental materials, instruments and equipment are being formulated by working groups of the ADA Standards Committee on Dental Products. The Committee has representation from all interests in the United States in the standardization of materials, instruments and equipment in dentistry. The Council has adopted the standards, showing professional recognition of their usefulness in dentistry, and has forwarded them to the American National Standards Institute with a recommendation that the standards be approved as American National Standards. The American National Standards Institute granted approval of revised ADA Standard No. 119 as an American National Standard on January 29, 2015.

The ADA Standards Committee on Dental Products thanks the members of Working Group 7.45 and the organizations with which they were affiliated at the time the specification was developed:

Chi Shing Wong, (chairman), Colgate-Palmolive, Co., Piscataway, NJ;

Clifton M. Carey, University of Colorado, Aurora, CO;

P.L. Fan, Santa Fe, NM;

Arthur J. Ferrara, Ferrara & Co., LLC, Princeton, NJ;

Spiro Megremis, American Dental Association, Chicago, IL;

Zaker Sabri, Sabri Dental Enterprises, Downers Grove, IL;

Bruce Schemehorn, Therametric Technologies, Inc., Noblesville, IN;

Stephen H. Thong, Church & Dwight, Princeton, NJ; and

Kevin Yost, Ranir Global, Grand Rapids, MI.

REVISED AMERICAN NATIONAL STANDARD/AMERICAN DENTAL STANDARD NO. 119 FOR MANUAL TOOTHBRUSHES

FOREWORD

(This foreword is not a part of revised ANSI/ADA Standard No. 119 for Manual Toothbrushes).

ANSI/ADA Standard No. 119: 2015 is a revision of ANSI/ADA Standard No. 119: 2008. This standard is a modified adoption of ISO 20126:2012, Dentistry – Manual toothbrushes – General requirements and test methods and ISO 22254:2005, Dentistry – Manual toothbrushes – Resistance of tufted portion to deflection. ISO 20126: 2012 is a revision of ISO 20126:2005. ADA SCDP Working Group No. 7.45 on Manual Toothbrushes examined the international standards and found them acceptable for adoption as ANSI/ADA Standard No. 119. This standard revises and replaces ANSI/ADA Standard No. 119: 2008.

The major changes to this version of ANSI/ADA Standard No. 119 are the additions of requirements for handle impact strength and the handle impact test method.

Manual toothbrushes are used for the removal of dental plaque and oral debris in order to facilitate oral hygiene. This standard is intended for the evaluation of the physical properties of manual toothbrushes.

The stiffness of the tufted area of a manual toothbrush has been of great concern for both consumers and manufacturers. This standard provides a test method for determining the resistance of the tufted portion to deflection, described in Annex A, which could be used to derive a stiffness as described in Annex B. However, this standard does not contain requirements for stiffness of manual toothbrushes and its classification. For stiffness determination, the measurement of the tufted area is required, but the result of the measurement varies over a wide range depending on the method of the measurement and the shape of the tuft holes. Therefore, the resistance of the tufted area and stiffness determinations are described only in Annexes A and B.

ANSI/ADA Standard No. 119 does not address manual interdental brushes and powered oral hygiene devices.

REVISED AMERICAN NATIONAL STANDARD/AMERICAN DENTAL STANDARD NO. 119 FOR MANUAL TOOTHBRUSHES

1 SCOPE

This standard describes requirements and test methods for the physical properties of manual toothbrushes in order to promote the safety of these products for their intended use.

Also specified is a test method for determining the resistance of the tufted portion of manual toothbrushes to deflection. This test method is applicable to toothbrushes having a conventional, flat trim design and may not be applicable to toothbrushes with other designs.

Specifically excluded from this standard are manual interdental brushes and powered oral hygiene devices as these instruments are covered by separate 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 — standard and test methods

(ISO standards for dentistry are available from the American Dental Association, Department of Standards, 211 E. Chicago Ave., Chicago, IL 60611 or www.adacatalog.org. Other ISO standards are available from the American National Standards Institute, 25 W. 43rd St., New York, NY 10036 or www.ansi.org).

3 TERMS AND DEFINITIONS

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

- 3.1 **Brush head** – working end of a manual toothbrush to which the filaments are attached
- 3.2 **Brush neck** – part of the toothbrush which joins the brush head to the handle
- 3.3 **Filament** – single strand within the brush head
- 3.4 **Manual toothbrush** – hand-powered device, the working end of which carries filaments, for primarily cleaning surfaces within the oral cavity
- 3.5 **Resistance to deflection** – resisting force of the tufts to deflection under a force of 5 N, applied at right angles to the tuft hole plane
- 3.6 **Tuft** – group of filaments gathered together and attached to the brush head
- 3.7 **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.
- 3.8 **Tuft hole surface** – surface of the tuft holes, which can be convex, triangular or plane and which is limited by a peripheral tangent line to the outer tuft holes

3.9 Tuft removal force – force required to remove one tuft from the brush head

3.10 Tufted area – linear projection of the tuft hole surface on to the tuft hole plane

NOTE: An alternative definition is: area surrounded by a peripheral tangent line to the outer tufts where they meet the tuft hole plane.

3.11

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]

3.12

center 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]

3.13

pendulum length – L_p , distance, expressed in metres, between the axis of rotation of the pendulum and the center 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.

3.14

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

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.

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 METHODS