



American National Standard/American Dental Association
Specification No. 119

Manual Toothbrushes

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

ADA American
Dental
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Council on
Scientific Affairs

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TOOTHBRUSHES

The Council on Scientific Affairs of the American Dental Association has approved American Dental Association Specification No. 119 for Manual Toothbrushes. This and other specifications for dental materials, instruments and equipment are being formulated by working groups of the ADA Standards Committee on Dental Products (formerly Accredited Standards Committee MD156 for Dental Materials, Instruments and Equipment). 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 specifications, showing professional recognition of their usefulness in dentistry, and has forwarded them to the American National Standards Institute with a recommendation that the specifications be approved as American National Standards. The American National Standards Institute granted approval of ADA Specification No. 119 as an American National Standard on November 20, 2008.

The Council thanks the working group members and the organizations with which they were affiliated at the time the specification was developed:

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FOREWORD

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

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

The content of this specification is identical to the content of ISO 20126:2005 and ISO 22254:2005. Modifications consist of changes to the order and numbering of the sections in combining the two standards.

ANSI/ADA Specification No. 119 for Manual Toothbrushes replaces Proposed ANSI/ADA Specification No. 77 for Stiffness of Tufted Area of Toothbrushes. ANSI/ADA Specification No. 77 was based on ISO 8627:1987 Dentistry -- Stiffness of the tufted area of tooth-brushes, which was withdrawn by ISO in August 2005. ISO 8627:1987 was revised by ISO 20126:2005 Dentistry -- Manual toothbrushes -- General requirements and test methods and ISO 22254:2005 Dentistry -- Manual toothbrushes -- Resistance of tufted portion to deflection.

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

The stiffness of the tufted area of a manual toothbrush has been of great concern for both consumers and manufacturers. This specification 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 specification 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 Specification No. 119 does not address manual interdental brushes and powered oral hygiene devices.

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1 SCOPE

This specification 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 specification are manual interdental brushes and powered oral hygiene devices as these instruments are covered by separate specifications.

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 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
- 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