



American National Standard/
American Dental Association
Standard No. 167

Test Methods for Dental Unit Waterline Biofilm Treatment

Identical adoption of ISO 16954:2015, *Dentistry — Test methods for dental unit waterline biofilm treatment*

ADA American
Dental
Association®

Standards Committee on Dental Products

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**AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION
STANDARD NO. 167 FOR TEST METHODS FOR DENTAL UNIT WATERLINE
BIOFILM TREATMENT**

The ADA Standards Committee on Dental Products (SCDP) has approved ANSI/ADA Standard No. 167 for Test Methods for Dental Unit Waterline Biofilm Treatment. This and other standards for dental materials, instruments and equipment are being formulated by working groups of the ADA SCDP. The Committee has representation from all interests in the United States in the standardization of materials, instruments and equipment in dentistry. The Committee 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 ADA Standard No. 167 as an American National Standard on May 18, 2018.

The ADA Standards Committee on Dental Products thanks the members of Working Group 6.48 on Air and Water Treatment Systems, and the organizations with which they were affiliated at the time the standard was developed:

Shannon Mills (chairman), Previser Corp., Concord, NH;
Satish Alapati, University of Illinois at Chicago;
Joel Anderson, Food and Drug Administration, Battle Ground, WA;
Kristy Azzolin, American Dental Association, Chicago, IL;
Donald Cohen, Health Compliance Team, Little Silver, NJ;
Rodney Donlan, Center for Disease Control and Prevention, Atlanta, GA;
Brad Downs, Sterisil, Inc., Palmer Lake, CO;
Scott Erickson, 3M Corp., St. Paul, MN;
P.L., Fan, Individual Representative, Santa Fe, NM;
Jerry Hall, 3M Corp., St. Paul, MN;
Gregory Kobussen, 3M Corp., St. Paul, MN;
Shira Kramer, Sterilex Corporation, Owings Mills, MD;
Nancy Lin, National Institute of Standards and Technology, Gaithersburg, MD;
Robert Meyer, Foxhammer, Inc., Spearfish, SD;
Thad Overmyer, Anodia Systems, Danville, KY;
Nuala Porteous, University of Texas, San Antonio, TX;
Douglas Risk, U.S. Air Force Dental Corps, Nanjemoy, MD;
Gary Schumacher, Individual Representative, Gaithersburg, MD;
Robert Staat, University of Louisville, KY;
Margaret Williams, Center for Disease Control and Prevention, Atlanta, GA;
Jeff Zawada, A-dec, Inc., Newberg, OR; and
Wu Zhang, Loma Linda University, CA.

AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION STANDARD NO. 167 FOR TEST METHODS FOR DENTAL UNIT WATERLINE BIOFILM TREATMENT

FOREWORD

(This Foreword does not form a part of ANSI/ADA Standard No. 167 for Test Methods for Dental Unit Waterline Biofilm Treatment).

This standard is an identical adoption of ISO 16954:2015, Dentistry – Test method for dental unit waterline biofilm treatment. ADA SCDP Working Group 6.48 on Air and Water Treatment Systems examined the international standard and found it acceptable for identical adoption as ANSI/ADA Standard No. 167. This standard cancels and replaces ANSI/ADA Standard No. 137:2014 for Essential Characteristics of Test Methods for the Evaluation of Treatment Methods Intended to Improve or Maintain the Microbiological Quality of Dental Unit Procedural Water.

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1 Scope

This standard provides type test methods for evaluating the effectiveness of treatment methods intended to prevent or inhibit the formation of biofilm or to remove biofilm present in dental unit procedural water delivery systems under laboratory conditions.

This standard does not apply to devices intended to deliver sterile procedural water or sterile solution. It also does not apply to lines, tubing, or hoses that deliver compressed air within the dental unit.

This standard does not establish specific upper limits for bacterial contamination or describe test methods to be used in clinical situations. It also does not establish test methods for evaluating any deleterious side effects potentially caused by treatment methods.

The test methods provided in this standard can be used to test other dental equipment that delivers non-sterile water to the oral cavity.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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 7494-1, *Dentistry — Dental units — Part 1: General requirements and test methods*

ISO 7494-2, *Dentistry — Dental units — Part 2: Water and air supply*

ISO 10523, *Water quality — Determination of pH*

ISO 19458, *Water quality — Sampling for microbiological analysis*

IEC 60601-1, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

ISO and IEC 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 IEC 60601-1, ISO 1942, ISO 7494-1, and ISO 7494-2 and the following apply.

3.1

biofilm

structured community of microorganisms inhabiting a self-developed extracellular biopolymeric matrix attached to a surface

3.2

dental unit

combination of interconnected dental equipment and dental instruments constituting a functional assembly for use in the provision of dental treatment

[SOURCE: ISO 1942:2009, 2.86]

3.3

dental unit procedural water delivery system

system of components of a dental unit which convey water from a supply source to one or more outlets used for dental treatment

3.4

procedural water

water supplied by the dental unit for use in the oral cavity

EXAMPLE Handpiece procedural water, multifunctional syringe water, scaler procedural water, or rinse cup water.

[SOURCE: ISO 7494-2:2003, 3.1]

3.5

surrogate dental unit water system

test apparatus which accurately recreates the procedural water delivery system of a dental unit, including design, construction, configuration, and operation of all water-bearing elements of the procedural water delivery system, but not necessarily including other dental unit components which do not directly come in contact with or control the flow of procedural water

3.6

test water

water having specified chemical and physical characteristics used for testing prior to the addition of the specified bacterial challenge suspension

3.7

bacterial challenge suspension

consortium of specified bacteria suspended in a nutrient growth medium or buffered solution used to inoculate test water

3.8

inoculated test water

prepared aqueous suspension used in testing, containing specified amounts of sterilized test water and one or more bacterial challenge suspension(s)

3.9

test apparatus for the control group

apparatus used in testing in which no treatment method is applied and no antimicrobial material is present in the waterline components

3.10

test apparatus for the test group

apparatus used in testing in which a treatment specified by the dental unit manufacturer is applied and any antimicrobial materials specified by the manufacturer are present in the waterline components, unless otherwise specified in the test requirements

4 Treatment methods

Depending upon the specific technical approach of a treatment method and its intended benefits, the performance objectives of a dental unit procedural water delivery system treatment method can include one or both of the following:

- prevention or inhibition of biofilm formation on surfaces within the dental unit procedural water delivery system;
- removal of biofilm from surfaces within the dental unit procedural water delivery system.

This standard specifies separate test methods for each of the above performance objectives. These requirements can be expanded upon, for example to include additional replicates or test scenarios. Additions to the test method shall follow the general principles of this standard and be fully described in the test report.

5 Test water and bacterial challenge suspensions

5.1 Test water

This subclause specifies the preparation of test water prior to inoculation.

5.1.1 Reagents

5.1.1.1 Water, in accordance with ISO 3696:1987, grade 3.

5.1.1.2 Calcium chloride (CaCl_2), or an equivalent molar quantity of a calcium chloride hydrate.

5.1.1.3 Magnesium chloride (MgCl_2), or an equivalent molar quantity of a magnesium chloride hydrate.

5.1.1.4 Sodium bicarbonate (NaHCO_3).

5.1.1.5 Tryptic soy broth (TSB), 1/3-strength, 10.0 g tryptic soy medium per liter broth.

5.1.1.6 Sodium hydroxide (NaOH), 1 mol/l.

5.1.1.7 Hydrochloric acid (HCl), 1 mol/l.

5.1.2 Preparation of hardness stock solution 1

Dissolve 74.0 g of calcium chloride (5.1.1.2) and 31.7 g of magnesium chloride (5.1.1.3) in 1.00 l water (5.1.1.1). Hardness stock solution 1 shall be sterilized by heat or filter-sterilized using a 0.2 μm microfilter and used within 24 h or stored at $(5 \pm 3)^\circ\text{C}$ for up to 6 months.

5.1.3 Preparation of hardness stock solution 2

Dissolve 56.0 g of sodium bicarbonate (5.1.1.4) in 1.00 l water (5.1.1.1). Hardness stock solution 2 shall be filter-sterilized using 0.2 μm microfilter and used within 24 h or stored at $(5 \pm 3)^\circ\text{C}$ for up to 6 months. Hardness stock solution 2 is not to be heat sterilized.

5.1.4 Preparation of test water prior to inoculation

For each liter of test water to be prepared, add 1.00 ml of 1/3-strength TSB (5.1.1.5) and 1.80 ml of hardness stock solution 1 (5.1.2) to 1.00 l water (5.1.1.1) and steam sterilize. After the sterilized solution has cooled, for each liter of test water add 4.00 ml of hardness stock solution 2 which has been