ANSI/ADA Standard No. 47-2006
Reaffirmed by ANSI: January 17, 2017

American National Standard/American Dental Association

Standard No. 47

Dental Units

Modified adoption of *ISO 7494-1:2004, Dentistry — Dental units — Part 1: General requirements and test methods*; and *ISO 7494-2:2003, Dentistry — Dental units — Part 2: Water and air supply.*

ADA American Dental Association®
Council on Scientific Affairs

2006

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AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION **STANDARD** NO. 47 FOR DENTAL UNITS

The Council on Scientific Affairs of the American Dental Association has approved American Dental Association Standard No. 47 for Dental Units. This and other standards 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 standards be approved as American National Standards. The American National Standards Institute granted approval of ADA Standard No. 47 as an American National Standard on November 29, 2006.

The Council thanks the working group members and the organizations with which they were affiliated at the time the standard was developed: William E. Strampe (chairman), USAF Dental Evaluation and Consultation Service, Great Lakes, IL; Ed Holland, DentalEZ, Malvern, PA; Joe LaForge, USAF Dental Evaluation and Consultation Service, Great Lakes, IL; Howard Roberts, USAF Dental Evaluation and Consultation Service, Great Lakes, IL; George Szalony, Pelton and Crane, Charlotte, NC; Jeff Zawada, A-dec, Inc., Newberg, OR; and Bill Zulauf, Midmark Corp., Versailles, OH.

AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION **STANDARD** NO. 47 FOR DENTAL UNITS

FOREWORD

(This Foreword does not form a part of ANSI/ADA Standard No. 47 for Dental Units).

This revised standard is a modified adoption of ISO 7494-1:2004, Dentistry — Dental units –- Part 1: General requirements and test methods; and ISO 7494-2:2003, Dentistry — Dental units –- Part 2: Water and air supply. The ADA SCDP working group examined the two ISO standards and found them acceptable for adoption as revised ANSI/ADA Standard No. 47. The two standards have been combined and the paragraphs re-numbered.

The working group made the following modifications (cited by original paragraph number):

ISO 7494-1

A Deleted: 5.1.1.6 (*Disconnectable Hoses)*.
Rationale: Disconnectable hoses do not need to be a requirement.

ISO 7494-2

A Deleted: 4.3 (*Backflow prevention devices)*.
Deleted: 4.7 (*Bottled water/backflow prevention*).
Deleted: 4.9 *(Water-disinfection system backflow prevention devices)*.
Deleted: 6.3 *(Systems using municipal water – test for backflow prevention device).*
Deleted: 6.4 *(Bottled water supply system supplying procedural water or solution – test for backflow prevention device).*
Rationale: The Uniform Plumbing Code (UPC), which is widely adopted by governing bodies in the U.S., specifies backflow prevention requirements to protect the domestic water supply against contamination from connected equipment, including dental units. Because backflow prevention measures established by the UPC include devices outside the scope of this document, these requirements from ISO 7494-2 are not adopted.

B Deleted: 4.5 (*Water venturi).*
Deleted: 6.2 *(Water venturi — test for backflow prevention device).*
Rationale: Use of water venturi systems is restricted by U.S. UPC.

C Changed: 4.4 (*Cuspidor/air gap*). Changed “20 mm” to “25.4 mm (1 inch).”
Rationale: U.S. UPC specifies 1 inch.

D 5.5.2 (*Particle filters – for air*) – Changed “not exceeding 25 µm” to “not exceeding 90 µm”.
Rationale: Criteria for determining pore size is not specified in the ISO standard; the trend in U.S. manufacturing is to utilize a wider range of pore sizes.

AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION **STANDARD NO**. 47 FOR DENTAL UNITS

1 SCOPE

ANSI/ADA Standard No. 47 specifies requirements and test methods for dental units, regardless of whether or not they are electrically powered. Requirements and test methods for the materials, design and construction of the water and air supply within dental units are also included in order to ensure that the pressurized water and air supplied via the dental unit are of appropriate quality. Provisions for the prevention of retraction of oral fluids into the water supply of the dental unit are included as well. This specification does not address prevention of contamination and/or proliferation of hazardous micro-organisms (for example bacteria, viruses) in the dental unit.

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.

ANSI/ADA Specification No. 33, *Dental Terminology;*

ISO 1942, *Dental Terminology;*

ISO 6875, *Dental patient chair;*

ISO 9687, *Dental equipment — Graphical symbols;*

ISO 11144, *Dental equipment — Connections for supply and waste lines;*

IEC 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety and essential performance.*

(ANSI/ADA and ISO dental standards may be purchased from the American Dental Association, Department of Standards Administration, 211 E. Chicago Ave., Chicago, IL 60611. IEC standards may be purchased from the American National Standards Institute, 25 W. 43rd St., New York, NY 10036).

3 TERMS AND DEFINITIONS

For the purposes of this document, the terms and definitions given in ANSI/ADA 33, IEC 60601-1 and ISO 1942 (some of which are repeated below for convenience) apply.

3.1 Antibacterial filter – filter intended to trap and reduce bacteria in the procedural water or in the compressed air.

3.2 Backflow – flow of water, air and/or another medium back into the municipal water supply via the dental unit

3.3 Backflow-prevention device – device to prevent backflow.
EXAMPLE: Pipe disconnector or air gap.

3.4 Bottled water system – water supply system that is based on a reservoir supplying procedural water or solution separately from the incoming water from the municipal water supplier.

3.5 Cleaning system for suction or wastewater lines – system for cleaning the suction or wastewater lines configured in such a way that the suction or wastewater tubes are connected to the procedural water supply for flushing.

3.6 Dental air – common ambient air available in the dental office, used for dental procedures in the oral cavity of the patient.
NOTE: This air is different from medical air used for anaesthetic purposes or for surgical purposes (e.g. during endoscopy).

3.7 Dental equipment – furniture, machines, apparatus and accessories thereto, specially manufactured and/or presented